

Korean Statutes related to COVID-19





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Korean Statutes related to COVID-19

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**Korean Statutes related to
COVID-19**

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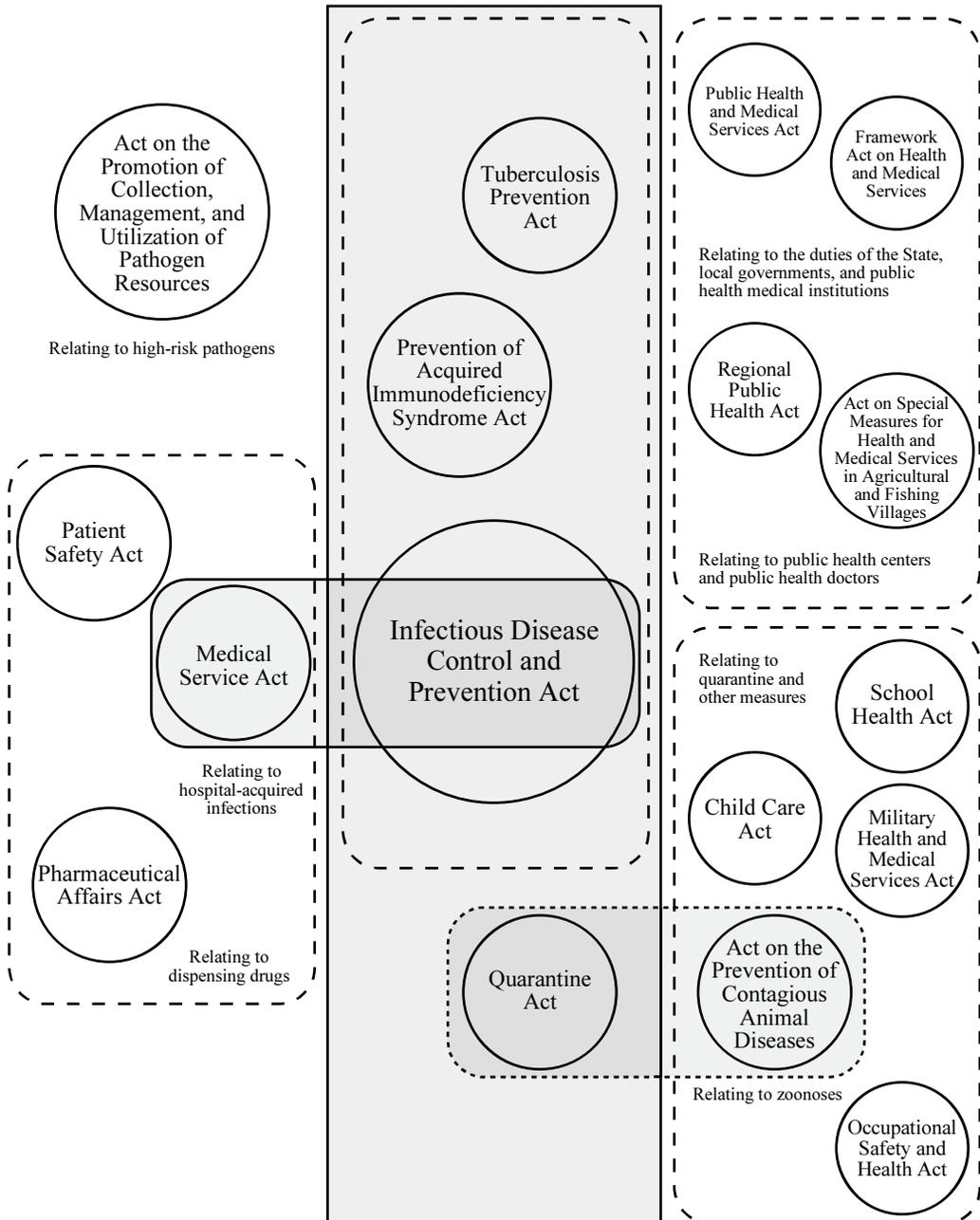
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Legislative Frameworks for Responding to Infectious Diseases

1.1 Legislative Frameworks for Responding to Infectious Diseases



1.2 The Infectious Disease Control and Prevention Act and Other Statutes

One of the most representative statutes providing for a series of administrative actions designed to prevent and control the occurrence and spread of infectious diseases is the Infectious Disease Control and Prevention Act. The 2015 and 2018 outbreaks of the Middle East Respiratory Syndrome (MERS) triggered the amendment of said Act, which features a battery of infectious disease management schemes encompassing the following elements: the operation of systems to manage patients from the preparatory stage, such as research on new strains of infectious diseases; changes to the categorization of the diseases; responses to and management of them; and the payment of compensation for loss. The Act provides a legal basis to give priorities to managing communicable diseases with a high fatality rate or the probability of massive outbreak, which thus necessitates a high-level quarantine measures such as negative-pressure isolation wards; and enables the designation and operation of the Emergency Operation Center, which takes the first action and provides command in case an infectious disease breaks out or spreads, as well as of quarantine facilities for those who come in contact with infected cases.

The Act has also enabled the following: enhancing the disclosure of information people should know to prevent infectious diseases; reinforcing on-site measures required to be taken in areas where an infectious disease outbreak occurs; recruiting epidemiological investigators; establishing the immunization registry integration system; collecting, managing, and retaining necessary data; establishing, designating, and operating research-driven hospitals or other hospitals specialized in contagious diseases in order to strengthen expertise in managing such diseases; and providing financial support not only to hospitalized patients and isolated persons but also to medical personnel or founders of medical institutions who work to help monitoring, preventing, and managing the diseases and conducting epidemiological investigations, within the budget.

Other than the aforementioned Act, the Quarantine Act also provides a legal basis for the Government to take quarantine and control measures for purposes of preventing communicable diseases and responding to such diseases in case of an outbreak.

The Quarantine Act further stipulates procedures for quarantining all means of transport, persons, and cargo which enter or depart from Korea and measures for preventing infectious diseases. The Act provides in subparagraph 1 of Article 2 that the quarantinable infectious diseases shall include severe acute respiratory syndrome (SARS), novel influenza, MERS, and the like; and that the Minister of Health and Welfare may publicly notify contagious diseases that are likely to be transmitted from foreign countries to Korea or vice versa.

Under the Act, the Minister of Health and Welfare may as well designate and manage as a quarantine inspection required area, in the manner prescribed in Article 5, an area reporting outbreaks of an infectious disease subject to a health care crisis management resulting from an infectious disease. The Act also provides quarantine inspections in Article 12, quarantine measures in Article 15, the isolation of patients of a quarantinable infectious disease in Article 16, the monitoring of contacts of a patient of a quarantinable infectious disease in Article 17, and preventive measures against non-quarantinable infectious diseases in Article 20.

1.3 The Framework Act on Health and Medical Services, the Public Health and Medical Services Act, and Other Statutes

Provisions relating to contagious diseases are also interlinked with health and medical services: The Framework Act on Health and Medical Services prescribes the rights and duties of the people, the duties of the State and local governments, and basic matters for health and medical services; whereas the Public Health and Medical Services Act stipulates that the public health and medical institutions are obligated to promptly respond to infectious diseases, as prescribed in Article 7, to comply with the purpose of the Act regarding the effective provision of high-quality public health and medical services to the people.

Among other related statutes, the Regional Public Health Act sets out in Article 11 (1) 5 the functions and duties of public health centers to prevent and manage communicable diseases; and the Act on Special Measures for Health and Medical Services in Agricultural and Fishing Villages provides in Article 6-2 (1) the dispatch of public health doctors to other regions, institutions, or facilities if it is deemed urgently required due to an outbreak of a contagious disease or the like.

1.4 The Medical Service Act, the Pharmaceutical Affairs Act, and Other Statutes

Medical institutions and medicines, among other things, related to treating infectious disease cases are covered by The Medical Service Act and the Pharmaceutical Affairs Act: The Medical Services Act obligates the head of a medical institution to (i) submit a patient's records where it is necessary to conduct an epidemiological investigation on an infectious disease or on vaccination under Article 21 (3); and (ii) comply with the medical treatment standards for infectious disease cases under subparagraph 9 of Article 36. The Act also has separate provisions on medical care-associated infections: Article 47 (1) requires the head of a hospital-level medical institution over a certain size to take measures necessary for preventing medical care-associated infections including the establishment and operation of an infection control committee and infection control rooms and the placement of personnel dedicated to infection control.

The Pharmaceutical Affairs Act allows in Article 23 (3) pharmacists to dispense prescription drugs and over-the-counter drugs even without prescriptions issued by a physician or dentist if they sell oral vaccines to prevent spread of an infectious disease after the Minister of Health and Welfare recognizes such infectious disease has broken out or is likely to break out widely. Further, Article 23 (4) of the Act provides an exception to the principle barring persons other than pharmacists and oriental medicine pharmacists from dispensing drugs, thereby allowing physicians and dentists to directly dispense drugs to patients suffering from cholera, typhoid, paratyphoid, shigellosis, colon bacillus infection with enterorrhagia, or hepatitis A or to persons admitted to a social welfare facility.

1.5 The Child Care Act, the School Health Act, and Other Statutes

The Child Care Act requires in Article 23 (4) 3 that the continuing education for principals of child care centers shall include education on the prevention of infectious diseases. With respect to infants and young children infected or likely to be infected with a disease, Article 32 (1) of the Act requires the principals of child care centers to take measures necessary to treat and prevent diseases; and Article 32 (2) thereof allows the principals to segregate such infants and young children from the child care centers or take other necessary measures.

Article 14-3 (1) of the School Health Act and Article 22-2 (1) of the Enforcement Decree of said Act requires the Minister of Education to formulate, in consultation with the Minister of the Interior and Safety and the Minister of Health and Welfare, measures addressing the following: the prevention and control of infectious diseases and follow-up measures; manual on response to infectious diseases; school health and hygiene relating to infectious diseases; education necessary for the prevention and control of infectious diseases; training for real-life situations such as map exercise to enhance the ability to respond to infectious diseases; and storing articles and preparing facilities necessary for the prevention of infectious diseases. The Act also provides in Article 14-4 (1) that the Minister of Education shall distribute a response manual to address an outbreak of a communicable disease.

The School Health Act asks the head of a school to (i) record the certificates of vaccination provided in the Infectious Disease Control and Prevention Act in Article 10 (1); and (ii) take measures necessary for the medical treatment and prevention of diseases among students who have been infected or are likely to be infected with diseases in Article 11 (1). Article 8 of the Act enables the head of a school to suspend students and school personnel who are infected or suspected to have been infected, or are likely to be infected with a communicable disease (referring to a contagious disease or highly infectious disease stipulated in the Infectious Disease Control and Prevention Act), as prescribed by Presidential Decree thereof.

Written by Joon-seo Lee(Senior Research Fellow of KLRI)

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Related Statutes

2.1 Infectious Disease Control and Prevention Act

Act No. 17067, Mar. 4, 2020

CHAPTER I General Provisions

Article 1 (Purpose)

The purpose of this Act is to contribute to improving and maintaining citizens' health by preventing the occurrence and epidemic of infectious diseases hazardous to citizens' health, and prescribing necessary matters for the prevention and control thereof.

Article 2 (Definitions)

The terms used in this Act are defined as follows: <Amended by Act No. 9932, Jan. 18, 2010; Act No. 11645, Mar. 22, 2013; Act No. 12444, Mar. 18, 2014; Act No. 13392, Jul. 6, 2015; Act No. 14316, Dec. 2, 2016; Act No. 15534, Mar. 27, 2018; Act No. 16725, Dec. 3, 2019; Act No. 17067, Mar. 4, 2020>

1. The term "infectious disease" means any infectious disease classified in Class 1 infectious diseases, Class 2 infectious diseases, Class 3 infectious diseases, Class 4 infectious diseases, parasitic diseases, infectious diseases under surveillance by the World Health Organization, infectious diseases spread through bioterrorism, sexually transmitted infectious diseases, zoonoses, and nosocomial infectious diseases;
2. The term "Class 1 infectious disease" means any of the following infectious diseases spread through bioterrorism or infectious diseases with a high mortality rate or a high risk of mass outbreak, requiring immediate reporting on the outbreak or epidemic thereof as well as high-level isolation, such as negative pressure isolation: *Provided*, That Class 1 infectious diseases shall include infectious diseases designated by the Minister of Health and Welfare as they are predicted to be suddenly transmitted into or epidemic in the Republic of Korea and require urgent prevention and control:
 - (a) Ebola virus disease;
 - (b) Marburg hemorrhagic fever;
 - (c) Lassa fever;
 - (d) Crimean-Congo hemorrhagic fever;
 - (e) South American hemorrhagic fever;
 - (f) Rift Valley fever;
 - (g) Smallpox;
 - (h) Pest;
 - (i) Anthrax;
 - (j) Botulism;
 - (k) Tularemia;
 - (l) Emerging infectious disease syndrome;
 - (m) Severe Acute Respiratory Syndrome (SARS);
 - (n) Middle East Respiratory Syndrome (MERS);
 - (o) Animal influenza infection in humans;
 - (p) Novel influenza;
 - (q) Diphtheria;
3. The term "Class 2 infectious disease" means any of the following infectious diseases that shall be reported within 24 hours of outbreak or epidemic in consideration of the possibility of transmission and require isolation: *Provided*, That Class 2 infectious diseases shall include infectious diseases designated by the Minister of Health and Welfare as they are predicted to be suddenly transmitted into

or epidemic in the Republic of Korea and require urgent prevention and control:

- (a) Tuberculosis;
 - (b) Varicella;
 - (c) Measles;
 - (d) Cholera;
 - (e) Typhoid;
 - (f) Paratyphoid;
 - (g) Shigellosis;
 - (h) Colon bacillus infection with enterorrhagia;
 - (i) Hepatitis A;
 - (j) Pertussis;
 - (k) Mumps;
 - (l) Rubella;
 - (m) Poliomyelitis;
 - (n) Meningococcal meningitis;
 - (o) Haemophilus influenzae type B;
 - (p) Streptococcus pneumoniae infection;
 - (q) Hansen's disease (Leprosy);
 - (r) Scarlet fever;
 - (s) Vancomycin Resistant Staphylococcus Aureus (VRSA);
 - (t) Carbapenem-resistant Enterobacteriaceae (CRE);
 - (u) Hepatitis E;
4. The term "Class 3 infectious disease" means any of the following infectious diseases that shall be reported within 24 hours of outbreak or epidemic as the outbreak thereof requires continuous surveillance: *Provided*, That Class 3 infectious diseases shall include infectious diseases designated by the Minister of Health and Welfare as they are predicted to be suddenly transmitted into or epidemic in the Republic of Korea and require urgent prevention and control:
- (a) Tetanus;
 - (b) Hepatitis B;
 - (c) Japanese encephalitis;
 - (d) Hepatitis C;
 - (e) Malaria;
 - (f) Legionellosis;
 - (g) Vibrio vulnificus sepsis;
 - (h) Epidemic typhus;
 - (i) Murine typhus;
 - (j) Scrub typhus;
 - (k) Leptospirosis;
 - (l) Brucellosis;
 - (m) Rabies;
 - (n) Hemorrhagic fever with renal syndrome;
 - (o) Acquired immunodeficiency syndrome (AIDS);
 - (p) Creutzfeldt-Jakob disease (CJD) and variant Creutzfeldt-Jakob disease (vCJD);
 - (q) Yellow fever;
 - (r) Dengue fever;
 - (s) Q fever;
 - (t) West Nile fever;
 - (u) Lyme disease (Lyme borreliosis);
 - (v) Tick-borne encephalitis;

- (w) Melioidosis;
 - (x) Chikungunya fever;
 - (y) Severe fever with thrombocytopenia syndrome (SFTS);
 - (z) Zika virus infection;
5. The term "Class 4 infectious disease" means any of the following infectious diseases that require sentinel surveillance to investigate whether they are epidemic, other than Classes 1 through 3 infectious diseases:
- (a) Influenza;
 - (b) Syphilis;
 - (c) Ascariasis;
 - (d) Trichuriasis;
 - (e) Enterobiasis;
 - (f) Clonorchiasis;
 - (g) Paragonimiasis;
 - (h) Fasciolopsis buski;
 - (i) Hand, foot and mouth disease;
 - (j) Gonorrhea;
 - (k) Chlamydia infection;
 - (l) Chancroid;
 - (m) Genital herpes;
 - (n) Condyloma acuminata;
 - (o) Vancomycin-resistant Enterococci (VRE) infection;
 - (p) Methicillin-resistant Staphylococcus aureus (MRSA) infection;
 - (q) Multidrug-resistant Pseudomonas aeruginosa (MRPA) infection;
 - (r) Multidrug-resistant Acinetobacter baumannii (MRAB) infection;
 - (s) Norovirus infection;
 - (t) Acute respiratory infection;
 - (u) Imported parasite disease;
 - (v) Enterovirus infection;
 - (w) Human papilloma virus infection;
6. The term "parasitic disease" means any infectious disease publicly notified by the Minister of Health and Welfare, among those spread by parasite infection;
7. Deleted; <by Act No. 15534, Mar. 27, 2018>
8. The term "infectious disease under surveillance by the World Health Organization" means any infectious disease designated to be subject to surveillance by the World Health Organization to prepare for international public health emergencies, as publicly notified by the Minister of Health and Welfare;
9. The term "infectious disease spread through bioterrorism" means any infectious disease publicly notified by the Minister of Health and Welfare, among those spread by pathogens either deliberately used or for terrorism, etc.;
10. The term "sexually transmitted infectious disease" means any infectious disease publicly notified by the Minister of Health and Welfare, among those transmitted by sexual contact;
11. The term "zoonosis" means any infectious disease publicly notified by the Minister of Health and Welfare, among those spread by pathogens transmittable from animals to humans and vice-versa;
12. The term "nosocomial infectious disease" means any infectious disease that occurs to patients, expecting mothers, etc. in the course of undergoing medical activities, which is publicly notified by the Minister of Health and Welfare as it requires surveillance;
13. The term "patient of an infectious disease" means a person whose body has been affected by the pathogen of an infectious disease to indicate relevant symptoms and whose case has been confirmed

- through a diagnosis by a physician, dentist, or oriental medical doctor according to the diagnosis standards referred to in Article 11 (6), or through a laboratory test by an institution for confirming pathogens of infectious diseases referred to in Article 16-2;
14. The term "probable patient of an infectious disease" means a person suspected of being affected by the pathogen of an infectious disease who has yet to be confirmed as a patient of an infectious disease;
 15. The term "pathogen carrier" means a person who has no clinical symptoms but carries the pathogen of an infectious disease;
 - 15-2. The term "person suspected of contracting an infectious disease" means any of the following persons:
 - (a) A person (hereinafter referred to as "contact") who comes into contact with or is suspected of coming into contact with a patient or probable patient of an infectious disease or pathogen carrier (hereinafter referred to as "patient of an infectious disease, etc.");
 - (b) A person who has stayed in, or passed through, a quarantine inspection required area or strict quarantine inspection required area defined in subparagraph 7 or 8 of Article 2 of the Quarantine Act, and may have contracted an infectious disease;
 - (c) A person who has been exposed to risk factors, such as infectious pathogens, and may have contracted an infectious disease;
 16. The term "surveillance" means the complete processes of systematically and continuously collecting, analyzing, and interpreting data on the outbreak of infectious diseases, and the pathogens and vectors thereof, of timely distributing the findings thereof to those who need such findings, and of using such findings for the prevention and control of infectious diseases;
 - 16-2. The term "sentinel surveillance" means conducting regular and continuous medical monitoring by designating a surveillance agency for the outbreak of infectious diseases of relatively low disease severity, for which conducting a total inspection is difficult due to high incidence rates;
 17. The term "epidemiological investigation" means the activities of investigating the number of cases involving patients of an infectious disease, etc. and of tracing the sources of their infection, etc., if such cases occur, in order to contain such infectious diseases and to prevent their spread, and the activities of examining the causes of adverse reactions, if such cases occur after vaccinations have been taken against infectious diseases or if it is unclear whether a disease is infectious but it is necessary to investigate the cause thereof;
 18. The term "adverse reaction to a vaccination" means any symptom or disease that may be caused by a vaccination, which is related to such vaccination in terms of time;
 19. The term "high-risk pathogen" means the pathogen of an infectious disease determined by Ordinance of the Ministry of Health and Welfare, which could cause a serious threat to citizens' health if used for biological terrorism or leaked to the outside due to accidents, etc.;
 20. The term "overseas emerging infectious disease subject to control" means any infectious disease designated by the Minister of Health and Welfare, which is caused by a variant or coproma of an existing pathogen, or a new pathogen, unknown to science, giving rise to a new health problem internationally, and which requires countermeasures against transmission into the Republic of Korea.

Article 3 (Relationship to Other Statutes)

Except as otherwise provided in other statutes, this Act shall apply to the prevention and control of infectious diseases.

Article 4 (Responsibilities of the State and Local Governments)

- (1) The State and local governments shall respect the dignity and values of patients of an infectious disease, etc. as human beings, protect their fundamental rights, and shall not impose on them any

disadvantage, such as restrictions on employment, except by statutes.

- (2) The State and local governments shall perform the following projects for preventing and controlling infectious diseases: *<Amended by Act No. 12444, Mar. 18, 2014; Act No. 13392, Jul. 6, 2015; Act No. 17067, Mar. 4, 2020>*
1. Preventive and control measures against infectious diseases;
 2. Medical treatment and protection of patients of an infectious disease, etc.;
 3. Formulation and implementation of plans for vaccination for the prevention of infectious diseases;
 4. Education and publicity concerning infectious diseases;
 5. Collection, analysis, and provision of information on infectious diseases;
 6. Investigation and research on infectious diseases;
 7. Collection, testing, preservation, and control of infectious pathogens (including specimens, such as blood, body fluids, and tissues, for identifying infectious pathogens), and the surveillance of drug resistance thereof;
 8. Nurturing specialists for the prevention of infectious diseases;
 9. International cooperation for the exchange, etc. of infectious disease control information;
 10. Stockpiling of medicines, etc. for the treatment and prevention of infectious diseases;
 11. Evaluation of infectious disease control projects;
 12. Investigation and research on the occurrence of infectious diseases caused by factors affecting demographic changes, such as climate change, low birth rate, and aging population, and the formulation of preventive measures;
 13. Support for corporations or associations which perform duties for prevention and treatment of Hansen's disease;
 14. Establishment and operation of an information system for the prevention and control of infectious diseases;
 15. Formulation of a plan, education, and training for preparing against the transmission of overseas emerging infectious diseases into the Republic of Korea;
 16. Continuous monitoring of the trends of outbreaks of overseas emerging infectious diseases, and the risk evaluation thereof, and the designation of overseas emerging infectious diseases subject to control;
 17. Preparation of a system for prevention from and countermeasures against overseas emerging infectious diseases subject to control, and the publication of reports and the public notice of the relevant guidelines (including manuals) on such overseas emerging infectious diseases, through the collection of information on pathogens, etc. thereof, the analysis of characteristics thereof, and research thereon.
- (3) The State and local governments (including superintendents of education) shall share information on infectious diseases and information on situations of the outbreak and prevalence thereof and mutually cooperate in order to efficiently treat such diseases and prevent the spread thereof. *<Newly Inserted by Act No. 13392, Jul. 6, 2015>*
- (4) The State and local governments shall share the relevant information with medical institutions and medical personnel's associations prescribed in the Medical Service Act in order to surveil and prevent the outbreak of infectious diseases. *<Newly Inserted by Act No. 13392, Jul. 6, 2015>*

Article 5 (Responsibilities and Rights of Medical Personnel)

- (1) Medical personnel, the heads of medical institutions, etc. prescribed in the Medical Service Act shall have the right to be provided information on the medical treatment of patients of infectious diseases, and may be compensated for any loss caused by the diagnosis, treatment, etc., of patients of infectious diseases.
- (2) Medical personnel, the heads of medical institutions, etc. prescribed in the Medical Service Act shall

make utmost effort for the diagnosis, management, treatment, etc., of patients of infectious diseases, and shall actively cooperate to comply with administrative orders issued by the Minister of Health and Welfare or the heads of local governments.

- (3) Medical personnel, the heads of medical institutions, etc. prescribed in the Medical Service Act shall actively cooperate with the State and local governments that perform the affairs of the surveillance of outbreak, prevention, and control of infectious diseases, and epidemiological investigations.

[This Article Wholly Amended by Act No. 13392, Jul. 6, 2015]

Article 6 (Duties and Rights of Citizens)

- (1) Where each citizen is isolated or quarantined and medically treated due to an infectious disease, he/she may be compensated for any loss caused by such isolation and medical treatment. <Amended by Act No. 13392, Jul. 6, 2015>
- (2) Each citizen shall have the right to know information on the situation of the outbreak of infectious diseases and the prevention and control of infectious diseases and how to cope therewith, and the State and local governments shall promptly disclose the relevant information. <Amended by Act No. 13392, Jul. 6, 2015>
- (3) Each citizen shall have the right to receive the diagnosis and medical treatment of any infectious disease under this Act at a medical institution, and the State and local governments shall bear expenses incurred therein. <Newly Inserted by Act No. 13392, Jul. 6, 2015>
- (4) Each citizen shall actively cooperate with the State and local governments that perform activities for the prevention and control of infectious diseases, such as treatment and isolation or quarantine measures. <Newly Inserted by Act No. 13392, Jul. 6, 2015>

CHAPTER II Master Plans and Projects

Article 7 (Formulation of Plans for Prevention and Control of Infectious Diseases)

- (1) The Minister of Health and Welfare shall formulate and implement a master plan for preventing and controlling infectious diseases (hereinafter referred to as "master plan") for every five years. <Amended by Act No. 9932, Jan. 18, 2010>
- (2) A master plan shall include the following: <Amended by Act No. 13392, Jul. 6, 2015; Act No. 17067, Mar. 4, 2020>
1. Basic objectives of and direction-setting for implementing the prevention and control of infectious diseases;
 2. Plans for projects for preventing and controlling major infectious diseases, and methods of implementation;
 - 2-2. Matters regarding stockpiling and managing medicines, equipment, etc. in preparation for an infection disease outbreak;
 3. Schemes for nurturing infectious disease specialists;
 - 3-2. Schemes for strengthening the capabilities of each medical institution by type, prescribed in each subparagraph of Article 3 (2) of the Medical Service Act, to respond to emergencies with respect to infectious diseases;
 4. Schemes for managing statistics and information on infectious diseases;
 5. Schemes for sharing information related to infectious diseases among medical institutions;
 6. Other matters necessary for preventing and controlling infectious diseases.
- (3) A Special Metropolitan City Mayor, a Metropolitan City Mayor, a *Do* Governor, the Special Self-Governing Province Governor (hereinafter referred to as "Mayor/*Do* Governor"), and the head of a *Si/Gun/Gu* (referring to the head of an autonomous *Gu*; hereinafter the same shall apply) shall

formulate and implement an implementation plan, based on a master plan.

- (4) The Minister of Health and Welfare, a Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* may request relevant administrative agencies or associations to provide data necessary for formulating and implementing master plans or implementation plans under paragraph (3). *<Amended by Act No. 9932, Jan. 18, 2010>*
- (5) The head of a relevant administrative agency or association in receipt of a request under paragraph (4) shall comply therewith unless there is a compelling reason not to do so.

Article 8 (Operation of Organizations Supporting Infectious Disease Control Projects)

- (1) The Minister of Health and Welfare and a Mayor/*Do* Governor may establish an organization supporting infectious disease control projects which consists of private professionals, in order to support the implementation of mater plans and implementation plans under Article 7 and international cooperation affairs, etc. *<Amended by Act No. 9932, Jan. 18, 2010>*
- (2) The State and a local government may subsidize a necessary budget for the operation, etc. of an organization supporting infectious disease control projects.
- (3) Matters necessary for the establishment, operation, support, etc. of an organization supporting infectious disease control projects under paragraphs (1) and (2) shall be prescribed by Presidential Decree.

Article 8-2 (Infectious Disease Hospitals)

- (1) The State shall establish, or operate by designation, an infectious disease specialty hospital or infectious disease research hospital equipped with adequate facilities, personnel, and research capabilities to pursue research and prevention of infectious diseases, to nurture and train infectious disease specialists, and to diagnose and treat patients of infectious diseases.
- (2) To diagnose and treat patients of infectious diseases, the State shall establish, or operate by designation, an infectious disease specialty hospital equipped with at least the number of sickbeds (including negative pressure isolation rooms and isolation beds) prescribed by Ordinance of the Ministry of Health and Welfare, by region.
- (3) The State may provide budget support for establishing, or operating by designation, an infectious disease specialty hospital or infectious disease research hospital under paragraph (1) or (2), within budgetary limits.
- (4) Procedures necessary for and methods of establishing, or operating by designation, an infectious disease specialty hospital or infectious disease research hospital under paragraph (1) or (2), and details of support therefor shall be prescribed by Presidential Decree.

[This Article Newly Inserted by Act No. 13639, Dec. 29, 2015]

Article 8-3 (Measures for Controlling Resistant Bacteria)

- (1) For the prevention of breakout, spread, etc. of resistant bacteria, the Minister of Health and Welfare shall formulate and promote measures for controlling resistant bacteria through deliberations by the Infectious Disease Control Committee prescribed in Article 9 every five years.
- (2) The measures for controlling resistant bacteria shall include objectives and directions of policy, matters to prevent the spread of resistant bacteria, such as the improvement of medical environment, matters concerning the reinforcement of monitoring system, and other matters recognized to be necessary for measures for controlling resistant bacteria.
- (3) Matters necessary for procedures for formulating measures for controlling resistant bacteria, etc. shall be prescribed by Presidential Decree.

[This Article Newly Inserted by Act No. 14316, Dec. 2, 2016]

Article 8-4 (Cooperation in Business)

- (1) For the formulation and implementation of measures for controlling resistant bacteria, the Minister of Health and Welfare may listen to the opinions of the relevant public officials or relevant experts or request the relevant institutions, organizations, etc. to render cooperation, such as submission of necessary materials.
- (2) To prepare measures for controlling resistant bacteria, the Minister of Health and Welfare may request the heads of the relevant central administrative agencies to render necessary cooperation, such as submitting materials or opinions on the objectives and directions of the measures for controlling resistant bacteria.
- (3) Any person who receives a request for cooperation prescribed in paragraphs (1) and (2) shall comply therewith unless he/she has any justifiable ground to the contrary.

[This Article Newly Inserted by Act No. 14316, Dec. 2, 2016]

Article 8-5 (Emergency Operations Center)

- (1) The Director of the Korea Centers for Disease Control and Prevention shall establish and operate a standing(24/7) Emergency Operations Center to collect and disseminate information on infectious diseases, manage the situation, and take initial measures and command in emergencies where infectious diseases are transmitted into or epidemic in the Republic of Korea.
- (2) Matters necessary for the establishment and operation of the Emergency Operations Center under paragraph (1) shall be prescribed by Presidential Decree.

[This Article Newly Inserted by Act No. 15534, Mar. 27, 2018]

Article 9 (The Infectious Disease Control Committee)

- (1) An Infectious Disease Control Committee (hereinafter referred to as the "Committee") shall be established under the Ministry of Health and Welfare to deliberate on major policies on the prevention and control of infectious diseases. *<Amended by Act No. 9932, Jan. 18, 2010>*
- (2) The Committee shall deliberate on the following: *<Amended by Act No. 12444, Mar. 18, 2014; Act No. 14316, Dec. 2, 2016; Act No. 16725, Dec. 3, 2019>*
 1. Formulation of master plans;
 2. Provision of medical services related to infectious diseases;
 3. Investigation and research on infectious diseases;
 4. Dissemination of knowledge concerning the prevention, control, etc. of infectious diseases, and the enhancement of the human rights of patients of an infectious disease, etc.;
 5. Matters concerning autopsy orders issued under Article 20;
 6. Matters concerning standards for and methods of conducting vaccinations under Article 32 (2);
 - 6-2. Matters concerning the preemptive stockpiling and long-term purchase of vaccines used for mandatory vaccination services referred to in Article 24 and special vaccination services referred to in Article 25 (hereinafter referred to as "mandatory vaccines, etc.") pursuant to Article 33-2 (1);
 - 6-3. Determining the distribution criteria, such as the priority of supplying mandatory vaccines, etc. prescribed in Article 33-2 (2), and other necessary matters;
 7. Formulation and implementation of crisis control measures against infectious diseases under Article 34;
 8. Matters concerning the preemptive stockpiling, long-term purchase, and production of preventive and therapeutic medicines, equipment, etc. under Article 40 (1) and (2);
 - 8-2. Determination of criteria for distribution, including priorities on supplying medicines under Article 40-2, and other necessary matters;
 9. Matters concerning compensation by the State for injury caused by vaccination, etc. under Article 71;

10. Matters concerning measures for controlling resistant bacteria;
11. Other matters concerning the prevention and control of infectious diseases, which are referred by the Chairperson of the Committee to its meeting.

Article 10 (Composition of the Committee)

- (1) The Committee shall be comprised of not more than 30 members, including one Chairperson and one Vice-Chairperson. <Amended by Act No. 15534, Mar. 27, 2018>
- (2) The Director of the Korea Centers for Disease Control and Prevention shall be the Chairperson; the Vice-Chairperson shall be appointed by the Chairperson, from among its members; and its members shall be appointed or commissioned by the Minister of Health and Welfare, from among the following persons. In such cases, non-public official members shall constitute a majority of all members: <Amended by Act No. 9932, Jan. 18, 2010; Act No. 13639, Dec. 29, 2015; Act No. 15534, Mar. 27, 2018; Act No. 16725, Dec. 3, 2019>
 1. Public officials in charge of duties of preventing and controlling infectious diseases;
 2. Medical personnel specializing in infectious diseases or infectious disease control;
 3. Persons with expertise related to infectious diseases;
 4. Persons recommended by a consultative council of Mayors/Do Governors prescribed in Article 165 of the Local Autonomy Act;
 5. Persons recommended by a non-profit, non-governmental organization defined in Article 2 of the Assistance for Non-Profit, Non-Governmental Organizations Act;
 6. Persons with considerable knowledge and experience in infectious diseases.
- (3) Advisory committees by field, comprised of the members of the Committee and external experts, may be established to efficiently perform the duties of the Committee.
- (4) Except as provided in paragraphs (1) through (3), matters necessary for the composition, operation, etc. of the Committee and advisory committees shall be prescribed by Presidential Decree.

CHAPTER III Reporting

Article 11 (Reporting by Physicians)

- (1) Where any of the following cases (excluding cases caused by a Class 4 infectious disease subject to sentinel surveillance under Article 16 (6)) occurs, a physician, dentist, or oriental medical doctor shall report such fact to the head of the medical institution to which he/she belongs, and shall instruct the relevant patient and his/her cohabitants how to prevent infection determined by the Minister of Health and Welfare: *Provided*, That a physician, dentist, or oriental medical doctor who does not belong to a medical institution shall report such fact to the director of the competent public health center: <Amended by Act No. 9932, Jan. 18, 2010; Act No. 13639, Dec. 29, 2015; Act No. 15534, Mar. 27, 2018; Act No. 17067, Mar. 4, 2020>
 1. Where he/she diagnoses a patient of an infectious disease, etc. or examines the corpse of such patient, etc.;
 2. Where he/she diagnoses a person indicating an adverse reaction to a vaccination, or examines the corpse of such person;
 3. Where a patient of an infectious disease, etc. dies of any infectious disease falling under Classes 1 through 3 infectious diseases;
 4. Where a person suspected as a patient of an infectious disease refuses infectious pathogen testing.
- (2) Where a staff member of an institution for confirming pathogens of infectious diseases referred to in Article 16-2 discovers a patient of an infectious disease, etc. prescribed by Ordinance of the Ministry of Health and Welfare through a laboratory test, etc., he/she shall report such fact to the head of the

relevant institution. <Amended by Act No. 13392, Jul. 6, 2015; Act No. 15534, Mar. 27, 2018; Act No. 17067, Mar. 4, 2020>

- (3) Upon receipt of a report under paragraph (1) or (2), the head of a medical institution and the head of an institution for confirming pathogens of infectious diseases referred to in Article 16-2 shall report thereon to the Minister of Health and Welfare or the director of the competent public health center, immediately in cases of Class 1 infectious diseases, within 24 hours in cases of Classes 2 and 3 infectious diseases, and within seven days in cases of Class 4 infectious diseases, respectively. <Newly Inserted by Act No. 13392, Jul. 6, 2015; Act No. 15534, Mar. 27, 2018; Act No. 17067, Mar. 4, 2020>
- (4) Where any case falling under any subparagraph of paragraph (1) (excluding any case caused by a Class 4 infectious disease subject to sentinel surveillance under Article 16 (6)) occurs, a military doctor serving in the Army, Navy, Air Force, or a unit under the direct control of the Ministry of Defense, shall report such fact to the commander of the unit to which he/she belongs, and the commander of the unit in receipt of such report shall report thereon to the director of the competent public health center, immediately in cases of Class 1 infectious diseases, and within 24 hours in cases of Classes 2 and 3 infectious diseases. <Amended by Act No. 13639, Dec. 29, 2015; Act No. 15534, Mar. 27, 2018>
- (5) Where any case falling under paragraph (1) 1 or 3 occurs due to a Class 4 infectious disease subject to sentinel surveillance under Article 16 (6), an institution of sentinel surveillance of infectious diseases referred to in Article 16 (1) shall report thereon to the Minister of Health and Welfare or the director of the competent public health center, as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010; Act No. 13639, Dec. 29, 2015; Act No. 15534, Mar. 27, 2018>
- (6) Matters necessary for standards for diagnosing patients of infectious diseases, etc. methods and procedures for reporting, etc. under paragraphs (1) through (5) shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010; Act No. 13392, Jul. 6, 2015>

Article 12 (Other Persons Obligated to Report)

- (1) Upon the outbreak of an infectious disease determined by Ordinance of the Ministry of Health and Welfare that is among Classes 1 through 3 infectious diseases, any of the following persons shall request a physician, dentist, or oriental medical doctor to perform a diagnosis or an autopsy, or report it to the director of a public health center having jurisdiction over the relevant location: <Amended by Act No. 9932, Jan. 18, 2010; Act No. 13392, Jul. 6, 2015; Act No. 15534, Mar. 27, 2018>
 1. In an ordinary family, the cohabiting householder: *Provided*, That where the householder is absent, a member of the household;
 2. In a school, hospital, government office, company, entertainment place, chapel, means of transportation, such as vessel, aircraft, and train, business office or place of business, restaurant, accommodation, or any other place determined by Ordinance of the Ministry of Health and Welfare where many people gather, its manager, executive, or representative.
- (2) If a person detects a patient of an infectious disease, etc. or a person suspected of having died of any infectious disease, regardless of whether the person is obligated to report under paragraph (1), the person shall notify the director of the competent public health center thereof.
- (3) Matters necessary for the methods and period of reporting as prescribed in paragraph (1), methods and procedures for notification as prescribed in paragraph (2), and other relevant matters shall be determined by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010; Act No. 13392, Jul. 6, 2015>

Article 13 (Reporting by Directors of Public Health Centers)

- (1) The director of a public health center in receipt of a report made under Articles 11 and 12 shall report the details thereof to the competent Special Self-Governing Province Governor or the head of the competent *Si/Gun/Gu*, who shall, in turn, report the same to the Minister of Health and Welfare and the competent Mayor/*Do* Governor, respectively. *<Amended by Act No. 9932, Jan. 18, 2010>*
- (2) Upon receipt of a report referred to in paragraph (1), the Minister of Health and Welfare, the competent Mayor/*Do* Governor, or the head of the competent *Si/Gun/Gu* may require a person falling under Article 11 (1) 4 (limited to persons suspected of contracting any Class 1 infectious disease) to undergo infectious pathogen testing. *<Newly Inserted by Act No. 17067, Mar. 4, 2020>*
- (3) Matters necessary for methods and procedures to report pursuant to paragraph (1), and other relevant matters shall be determined by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 9932, Jan. 18, 2010>*

Article 14 (Notification of Zoonoses)

- (1) Upon receipt of a report referred to in Article 11 (1) 2 of the Act on the Prevention of Contagious Animal Diseases, the head of the national animal disease control agency, the head of a *Si/Gun/Gu* having jurisdiction over the place where animals subject to reporting are located, or the head of a *City/Do* animal disease control agency shall immediately notify the Director of the Korea Centers for Disease Control and Prevention of contagious animal diseases prescribed in the same Act, if they fall under any of the following: *<Amended by Act No. 16725, Dec. 3, 2019>*
 1. Anthracnose;
 2. Highly pathogenic avian influenza;
 3. Rabies;
 4. Other zoonoses prescribed by Presidential Decree.
- (2) The Director of the Korea Centers for Disease Control and Prevention notified under paragraph (1) shall take appropriate measures under this Act to prevent infectious diseases and the spread thereof. *<Newly Inserted by Act No. 13392, Jul. 6, 2015>*
- (3) No head of an administrative agency in receipt of a report or notification made under paragraph (1) shall disclose the identity of the reporting person externally if such person asks him/her not to do so.
- (4) Necessary matters concerning methods and procedures for notification prescribed in paragraph (1), and other relevant matters shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 9932, Jan. 18, 2010>*

Article 15 (Detection and Management of Patients of Infectious Disease)

Where the director of a public health center receives a report under Articles 11 and 12 on any patient of an infectious disease, etc. who lives in his/her jurisdiction, he/she shall record such patient, etc. in a register and maintain the register (including electronic documents), as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 9932, Jan. 18, 2010>*

CHAPTER IV Surveillance of Infectious Diseases, Epidemiological Investigation, Etc.

Article 16 (Sentinel Surveillance of Infectious Diseases)

- (1) The Minister of Health and Welfare may designate a health and medical service institution or any other institution or organization under the Framework Act on Health and Medical Services, as an institution of sentinel surveillance of infectious diseases, in consideration of the characteristics of a disease and the region of the outbreak thereof in order to ensure sentinel surveillance on the outbreak

- of infectious diseases. <Amended by Act No. 9932, Jan. 18, 2010; Act No. 16725, Dec. 3, 2019>
- (2) The Minister of Health and Welfare, a Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* may request the head of an institution of sentinel surveillance of infectious diseases designated under paragraph (1) (hereinafter referred to as "sentinel surveillance institution") to submit necessary data in connection with the sentinel surveillance of infectious diseases, or to provide necessary cooperation for the prevention and control of infectious diseases. In such cases, a sentinel surveillance institution shall comply therewith unless there is a compelling reason not to do so. <Amended by Act No. 9932, Jan. 18, 2010>
 - (3) The Minister of Health and Welfare, a Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* shall provide relevant institutions, organizations, establishments, or citizens with important information on national health collected under paragraph (2). <Amended by Act No. 9932, Jan. 18, 2010>
 - (4) The Minister of Health and Welfare, a Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* may subsidize sentinel surveillance institutions for expenses incurred in sentinel surveillance activities. <Amended by Act No. 9932, Jan. 18, 2010>
 - (5) The Minister of Health and Welfare may revoke the designation of a sentinel surveillance institution, where it falls under any of the following subparagraphs: <Amended by Act No. 13392, Jul. 6, 2015; Act No. 16725, Dec. 3, 2019>
 1. Where it fails to comply with a request to submit data or provide cooperation referred to in paragraph (2);
 2. Where it is unable to conduct sentinel surveillance affairs on infectious diseases due to business closure, etc.;
 3. In other cases prescribed by Ordinance of the Ministry of Health and Welfare, including where it is negligent in performing sentinel surveillance affairs on infectious diseases.
 - (6) Infectious diseases subject to sentinel surveillance under paragraph (1) shall be Class 4 infectious diseases, and matters necessary for the designation of sentinel surveillance institutions and causes for revoking such designation shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Newly Inserted by Act No. 13392, Jul. 6, 2015; Act No. 15534, Mar. 27, 2018>
 - (7) If deemed urgently necessary to obtain information related to the likelihood of the outbreak or epidemic of any infectious disease, the Director of the Korea Centers for Disease Control and Prevention may request the head of a public institution prescribed by Presidential Decree among public institutions under the Act on the Management of Public Institutions, to provide such information. In such cases, the head of the public institution requested to provide such information shall comply with such request unless there is a compelling reason not to do so. <Amended by Act No. 13392, Jul. 6, 2015>
 - (8) Matters necessary for the details of, procedures for, and treatment of information to be provided pursuant to paragraph (7) shall be prescribed by Presidential Decree. <Amended by Act No. 13392, Jul. 6, 2015>

Article 16-2 (Institutions for Confirming Pathogens of Infectious Diseases)

- (1) Any of the following institutions (hereinafter referred to as "institution for confirming pathogens of infectious diseases") may confirm infectious pathogens through laboratory testing, etc.:
 1. The Korea Centers for Disease Control and Prevention;
 2. The National Quarantine Station;
 3. Public health and environment research institutes defined in Article 2 of the Public Health and Environment Research Institute Act;
 4. Public health centers prescribed in Article 10 of the Regional Public Health Act;
 5. Medical institutions having a full-time medical specialist in diagnostic laboratory medicine, among the medical institutions prescribed in Article 3 of the Medical Service Act;
 6. Medical schools having a diagnostic laboratory medicine department, among the medical schools

- established under Article 4 of the Higher Education Act;
7. The Korean National Tuberculosis Association (limited to cases of testing the pathogens of tuberculosis patients) established under Article 21 of the Tuberculosis Prevention Act;
 8. Institutions (limited to cases of testing the pathogens of Hansen's disease patients) established for the purpose of supporting treatment and rehabilitation of Hansen's disease patients, etc. under Article 32 of the Civil Act;
 9. Institutions having a full-time medical specialist in diagnostic laboratory medicine, among the institutions entrusted by the State, local governments, medical institutions, etc. with the duties of examining specimens taken from the human body.
- (2) The Minister of Health and Welfare may evaluate and manage the laboratory testing capability of institutions for confirming pathogens of infectious diseases to ensure the accuracy and reliability of their testing results of infectious pathogens.
 - (3) Matters necessary for the methods and procedures for evaluating and managing the laboratory testing capability of institutions for confirming pathogens of infectious diseases referred to in paragraph (2), and other relevant matters shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 17067, Mar. 4, 2020]

Article 17 (Fact-Finding Surveys)

- (1) The Minister of Health and Welfare and Mayors/*Do* Governors shall conduct fact-finding surveys to understand the actual conditions of management of and infection by infectious diseases and the actual conditions of resistant bacteria, and publicize the outcomes of such surveys. <Amended by Act No. 9932, Jan. 18, 2010; Act No. 13392, Jul. 6, 2015; Act No. 14316, Dec. 2, 2016; Act No. 17067, Mar. 4, 2020>
- (2) With respect to surveys referred to in paragraph (1), the Minister of Health and Welfare or a Mayor/*Do* Governor may request the heads of relevant institutions, corporations, or organizations, including medical institutions, to submit necessary data or statement of opinions. In such cases, any person in receipt of such request shall comply therewith unless there is good cause. <Newly Inserted by Act No. 17067, Mar. 4, 2020>
- (3) Matters necessary for specifics included in fact-finding surveys under paragraph (1); the timing, methods, and procedures for conducting fact-finding surveys and the publication of the outcomes thereof; and other relevant matters shall be determined by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010; Act No. 17067, Mar. 4, 2020>

Article 18 (Epidemiological Investigations)

- (1) Where the Director of the Korea Centers for Disease Control and Prevention, a Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* deems that an infectious disease breaks out and is likely to be epidemic subsequently or that it is unclear whether a disease is infectious but it is necessary to investigate the cause thereof, he/she shall, without delay, conduct an epidemiological investigation and then provide information concerning the findings thereof to the relevant medical institutions to a necessary extent: *Provided*, That if necessary for preventing the prevalence of the infectious disease in other areas, such information shall be provided to other medical institutions. <Amended by Act No. 13392, Jul. 6, 2015; Act No. 16725, Dec. 3, 2019>
- (2) The Director of the Korea Centers for Disease Control and Prevention, a Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* shall establish an epidemiological investigation team to conduct an epidemiological investigation, respectively.
- (3) No one shall commit any of the following acts in the course of an epidemiological investigation conducted by the Director of the Korea Centers for Disease Control and Prevention, a Mayor/*Do* Governor, or the head of a *Si/Gun/Gu*: <Amended by Act No. 13392, Jul. 6, 2015>

1. Refusing, obstructing, or evading the epidemiological investigation without good cause;
 2. Making a false statement or presenting false materials;
 3. Intentionally omitting or concealing any fact.
- (4) Matters necessary for the details and timing and methods of conducting epidemiological investigations prescribed in paragraph (1), and the composition, duties, etc. of epidemiological investigation teams prescribed in paragraph (2) shall be prescribed by Presidential Decree.

Article 18-2 (Request for Epidemiological Investigations)

- (1) Where an infectious disease or any disease unknown for its cause has broken out or is likely to break out, medical personnel or the head of a medical institution prescribed in the Medical Service Act may request the Minister of Health and Welfare or a Mayor/*Do* Governor to conduct an epidemiological investigation under Article 18.
- (2) The Minister of Health and Welfare or a Mayor/*Do* Governor in receipt of a request prescribed in paragraph (1) shall notify, without delay, the relevant medical personnel or the founder of the relevant medical institution of whether to conduct an epidemiological investigation, the ground therefor, and other relevant matters.
- (3) Necessary matters concerning requests for conducting an epidemiological investigation under paragraph (1), and the methods, procedures, etc. for notification made under paragraph (2) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 13392, Jul. 6, 2015]

Article 18-3 (Fosterage of Personnel for Epidemiological Investigations)

- (1) The Minister of Health and Welfare may regularly provide education and training on epidemiological investigations to those falling under any subparagraph of Article 60-2 (3).
<Amended by Act No. 17067, Mar. 4, 2020>
- (2) The courses of education and training prescribed in paragraph (1) and other necessary matters shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 13392, Jul. 6, 2015]

Article 18-4 (Requirement for Presentation of Materials and Other Relevant Matters)

- (1) To efficiently conduct epidemiological investigations, etc. under Article 18, the Minister of Health and Welfare may require the head of a relevant central administrative agency and an institution or organization, etc. prescribed by Presidential Decree to present materials necessary for epidemiological investigations.
- (2) Where the Minister of Health and Welfare conducts epidemiological investigations under Article 18, he/she may, if necessary, request the head of a relevant central administrative agency to provide necessary assistance, such as dispatch of the personnel belonging to such agency.
- (3) A person in receipt of a requirement for the presentation of materials as prescribed in paragraph (1) and a request for assistance as prescribed in paragraph (2) shall comply therewith, except in extenuating circumstances.
- (4) Necessary matters concerning the extent and methods of requirements for the presentation of materials as prescribed in paragraph (1) and requests for assistance as prescribed in paragraph (2), shall be prescribed by Presidential Decree.

[This Article Newly Inserted by Act No. 13392, Jul. 6, 2015]

Article 19 (Medical Examinations)

A person engaged in any occupation prescribed by Ordinance of the Ministry of Health and Welfare that requires a medical examination to prevent sexually transmitted infectious diseases, and a person infected by a sexually transmitted infectious disease and deemed by the head of a *Si/Gun/Gu* as highly likely to

transmit the infection thereof, shall undergo a medical examination for sexually transmitted infectious diseases, as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010>

Article 20 (Autopsy Orders)

- (1) Where the Director of the Korea Centers for Disease Control and Prevention deems impracticable to identify whether a person suspected of having died of an infectious disease posing a potentially serious threat to national health has actually been died of the infectious disease, and to ascertain the cause of his/her death without conducting an autopsy, he/she may order an autopsy.
- (2) An autopsy under paragraph (1) shall be conducted with consent from a relative defined in subparagraph 16 of Article 2 of the Act on Funeral Services (where a person with priority entitlement stipulated under each item of the same subparagraph does not exist, a relative refers to a person with subordinate entitlement; hereinafter referred to as "relative"): *Provided*, That an autopsy order may be issued without consent from a relative, under extenuating circumstances that make it impracticable to obtain prior consent from a relative, such as unknown whereabouts and no contact details, and delay in the autopsy is deemed likely to make it impossible to achieve the purposes of the autopsy, which is preventing infectious diseases and protecting national health.
- (3) The Director of the Korea Centers for Disease Control and Prevention shall designate an infectious disease specialist, or a person specializing in anatomy, pathology, or forensic medicine, as a physician in charge of an autopsy to require him/her to conduct the autopsy.
- (4) Autopsies under paragraph (3) shall be conducted at facilities satisfying the biological safety level determined and publicly notified by the Minister of Health and Welfare for each group of infectious disease, with which the deceased is suspected of being infected. <Amended by Act No. 9932, Jan. 18, 2010>
- (5) Matters necessary for the designation of physicians in charge of autopsies, standards for facilities to be equipped for each type of infectious disease, management of relevant corpses under paragraph (3), and other relevant matters shall be determined by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010>

Article 20-2 (Methods of Conducting Funeral for the Deceased)

- (1) In cases of death of a patient of an infectious disease, etc. (including a person confirmed after his/her death to have contained pathogens of an infectious disease), the Minister of Health and Welfare may restrict the methods of conducting funeral, etc. for the deceased, within necessary limits, for quarantining and preventing the spread of the infectious disease.
- (2) Where the Minister of Health and Welfare intends to impose restrictions under paragraph (1), he/she shall provide explanations to the bereaved of the deceased on the necessity of the relevant measures and the detailed methods, process, etc. thereof.
- (3) The Minister of Health and Welfare may request the installer or manager of a crematory facility to cooperate in taking measures under paragraph (1), and the installer or manager of the crematory facility in receipt of such request shall fully cooperate therein.
- (4) The targets, methods, and process for restrictions imposed under paragraph (1), and other necessary matters, shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 13639, Dec. 29, 2015]

CHAPTER V High-Risk Pathogens

Article 21 (Reporting on Extraction, Distribution and Transfer, or Transfer of High-Risk Pathogens)

- (1) A person who has extracted a high-risk pathogen from a patient of an infectious disease, food, animal/plant, or any other environment shall, without delay, report to the Minister of Health and Welfare on the name of the high-risk pathogen, the name of the object from which the pathogen has been extracted, the date and time of extraction, etc. <Amended by Act No. 9932, Jan. 18, 2010; Act No. 16725, Dec. 3, 2019>
- (2) A person who intends to have a high-risk pathogen distributed and transferred shall report to the Minister of Health and Welfare on the name of the high-risk pathogen, its distribution and transfer plan, etc. in advance. <Newly Inserted by Act No. 16725, Dec. 3, 2019>
- (3) A person who intends to have a high-risk pathogen transferred shall report to the Minister of Health and Welfare on the name of the high-risk pathogen, its transfer plan, etc. in advance. <Newly Inserted by Act No. 16725, Dec. 3, 2019>
- (4) Upon receipt of any report prescribed in paragraphs (1) through (3), the Minister of Health and Welfare shall review the report, and accept it if it is in compliance with this Act. <Newly Inserted by Act No. 17067, Mar. 4, 2020>
- (5) Upon receipt of a report on the extraction of a high-risk pathogen pursuant to paragraph (1), the Minister of Health and Welfare may conduct an on-site inspection. <Newly Inserted by Act No. 16725, Dec. 3, 2019>
- (6) A person who possesses or controls high-risk pathogens shall prepare records on the current status of possession of such high-risk pathogens on an annual basis and submit them to the Director of the Korea Centers for Disease Control and Prevention. <Newly Inserted by Act No. 15534, Mar. 27, 2018; Act No. 16725, Dec. 3, 2019>
- (7) Matters necessary for methods and procedures for reporting prescribed in paragraphs (1) through (3) and the preparation and submission of records prescribed in paragraph (6), and other relevant matters shall be determined by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010; Act No. 15534, Mar. 27, 2018; Act No. 16725, Dec. 3, 2019; Act No. 17067, Mar. 4, 2020>

Article 22 (Permission for Introduction of High-Risk Pathogens)

- (1) A person who intends to introduce high-risk pathogens into the domestic environment for the purposes of diagnosis, academic research, etc. of infectious diseases shall obtain permission therefor from the Minister of Health and Welfare by satisfying the following requirements: <Amended by Act No. 9932, Jan. 18, 2010; Act No. 16725, Dec. 3, 2019>
 1. Installing and operating a facility handling high-risk pathogens referred to in Article 23 (1);
 2. Formulating a plan for safely transporting high-risk pathogens and emergency measures;
 3. Designating a manager in exclusive charge of high-risk pathogens, satisfying the requirements prescribed by Ordinance of the Ministry of Health and Welfare.
- (2) A person who intends to modify any of the matters permitted under paragraph (1) shall obtain permission therefor from the Minister of Health and Welfare: *Provided*, That where intending to modify any minor matter prescribed by Presidential Decree, he/she shall report such modification to the Minister of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010>
- (3) Where a person who has obtained permission for introducing high-risk pathogens into the domestic environment under paragraph (1) intends to transfer the relevant high-risk pathogens after acquiring them, he/she shall designate a place to acquire them, as prescribed by Presidential Decree, and report, in advance, a transfer plan to the Minister of Health and Welfare pursuant to Article 21 (1). In such cases, the Minister of Health and Welfare shall review the details of the plan, and accept it if it

is in compliance with this Act. <Amended by Act No. 9932, Jan. 18, 2010; Act No. 17067, Mar. 4, 2020>

- (4) Matters necessary for methods and procedures for granting permission or reporting under paragraphs (1) through (3), and other relevant matters shall be determined by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010>

Article 23 (Safety Control of High-Risk Pathogens)

- (1) A person who intends to examine, possess, control, and transfer high-risk pathogens shall establish and operate a facility necessary for the examination, possession, control, and transfer thereof (hereinafter referred to as “facility handling high-risk pathogens”).
- (2) A person who intends to establish and operate any facility handling high-risk pathogens shall obtain permission therefor from the Minister of Health and Welfare or file a report thereon with the Minister of Health and Welfare according to the safety control level of the facility handling high-risk pathogens.
- (3) Where a person who has obtained permission pursuant to paragraph (2) intends to modify any of the matters permitted, he/she shall obtain permission for such modification: *Provided*, That where he/she intends to modify any minor matter prescribed by Presidential Decree, he/she shall file a report on such modification.
- (4) Where a person who has filed a report pursuant to paragraph (2) intends to modify any of the matters reported, he/she shall file a report on such modification.
- (5) Where a person who has obtained permission or filed a report pursuant to paragraph (2) closes any facility handling high-risk pathogens, he/she shall file a report thereon with the Minister of Health and Welfare.
- (6) Upon receipt of any report prescribed in paragraphs (2), (4), and (5), the Minister of Health and Welfare shall review the details of the report, and accept it if it is in compliance with this Act.
- (7) A person who has obtained permission or filed a report pursuant to paragraph (2) shall comply with the safety control guidelines prescribed by Presidential Decree according to the safety control levels of facilities handling high-risk pathogens.
- (8) The Minister of Health and Welfare may inspect whether a person who examines, possesses, controls, and transfers high-risk pathogens complies with the safety control guidelines referred to in paragraph (7), the standards for permission and reporting referred to in paragraph (9), etc.
- (9) Matters necessary for the safety control levels of facilities handling high-risk pathogens, the standards and procedures for permission for and reporting on establishment and operation thereof, the standards and procedures for reporting on closure, etc. under paragraphs (1) through (5) shall be prescribed by Presidential Decree.

[This Article Wholly Amended by Act No. 17067, Mar. 4, 2020]

Article 23-2 (Revocation of Permission for Facilities Handling High-Risk Pathogens)

Where a person who has obtained permission for or filed a report on establishment and operation of a facility handling high-risk pathogens pursuant to Article 23 (2) falls under any of the following subparagraphs, the Minister of Health and Welfare may revoke such permission or order the closure or suspension of operation of the facility handling high-risk pathogens for a specified period not exceeding one year: *Provided*, That in cases falling under subparagraph 1, the Minister of Health and Welfare shall revoke the permission or order the closure of the facility handling high-risk pathogens: <Amended by Act No. 17067, Mar. 4, 2020>

1. Where he/she has obtained the permission or filed the report by fraud or other improper means;
2. Where he/she modifies any of the matters permitted or reported without obtaining permission therefor or without filing a report thereon under Article 23 (3) or (4);
3. Where he/she fails to observe the safety control guidelines under Article 23 (7);

4. Where he/she fails to meet the standards for permission or reporting under Article 23 (9).
[This Article Newly Inserted by Act No. 15183, Dec. 12, 2017]

Article 23-3 (Permission for Possessing Pathogens of Infectious Disease Spread through Bioterrorism)

- (1) A person intending to possess any pathogen prescribed by Ordinance of the Ministry of Health and Welfare (hereinafter referred to as “pathogens of infectious diseases spread through bioterrorism”), among the pathogens causing an infectious disease spread through bioterrorism, for the purposes of diagnosis, academic research, etc. of infectious diseases, shall obtain permission therefor from the Minister of Health and Welfare in advance: *Provided*, That where it is impracticable to obtain permission in advance due to unavoidable cause prescribed by Presidential Decree, including cases of possessing a pathogen of an infectious disease spread through bioterrorism after extracting it from a probable patient of an infectious disease, permission shall be obtained immediately after possessing such pathogen.
- (2) A person who obtains permission for introducing high-risk pathogens into the domestic environment under Article 22 (1) shall be deemed to have obtained permission prescribed in paragraph (1).
- (3) Any person intending to modify any of the matters permitted under paragraph (1) shall obtain permission for modification from the Minister of Health and Welfare: *Provided*, That in cases of modifying any minor matter prescribed by Presidential Decree, such as replacing a person handling high-risk pathogens, a report on such modification shall be submitted to the Minister of Health and Welfare.
- (4) Necessary matters for the methods and procedures for permission, permission for modification, or reporting on modification prescribed in paragraphs (1) through (3), and other relevant matters shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 16725, Dec. 3, 2019]

Article 23-4 (Standards for Handling High-Risk Pathogens)

- (1) High-risk pathogens can only be handled by any of the following persons:
 1. A person who has graduated from a university or college of a level at least equivalent to a junior college referred to in subparagraph 4 of Article 2 of the Higher Education Act, majoring in a field related to health and medical services or biology, or a person having an academic background equivalent thereto;
 2. A person who has at least two years of working experience in a field related to health and medical services or biology, among those who have graduated from a university or college of a level at least equivalent to a junior college referred to in subparagraph 4 of Article 2 of the Higher Education Act or who have an academic background at least equivalent thereto, majoring in a field other than health and medical services or biology;
 3. A person who has at least four years of working experience in a field related to health and medical services or biology, among those who have graduated from a high school or high technical school referred to in subparagraph 3 of Article 2 of the Elementary and Secondary Education Act or who have an academic background at least equivalent thereto.
- (2) No one shall permit any person not falling under any subparagraph of paragraph (1) to handle high-risk pathogens.
- (3) Detailed matters for the academic background and working experience prescribed in the subparagraphs of paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 16725, Dec. 3, 2019]

Article 23-5 (Education on Handling High-Risk Pathogens)

- (1) A person who handles high-risk pathogens shall receive necessary education for the safe handling of high-risk pathogens each year.
- (2) The Minister of Health and Welfare may entrust the conduct of education prescribed in paragraph (1) to a specialized institution or organization prescribed by Ordinance of the Ministry of Health and Welfare.
- (3) Matters necessary for education and the entrustment thereof prescribed in paragraphs (1) and (2) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 16725, Dec. 3, 2019]

CHAPTER VI Vaccination**Article 24 (Mandatory Vaccination)**

- (1) The Special Self-Governing Province Governor or the head of a *Si/Gun/Gu* shall provide mandatory vaccination services (hereinafter referred to as "mandatory vaccination") at public health centers under his/her jurisdiction for the following: *<Amended by Act No. 9932, Jan. 18, 2010; Act No. 11645, Mar. 22, 2013; Act No. 12444, Mar. 18, 2014; Act No. 14316, Dec. 2, 2016; Act No. 15534, Mar. 27, 2018>*
 1. Diphtheria;
 2. Poliomyelitis;
 3. Pertussis;
 4. Measles;
 5. Tetanus;
 6. Tuberculosis;
 7. Hepatitis B;
 8. Mumps;
 9. Rubella;
 10. Varicella;
 11. Japanese encephalitis;
 12. Haemophilus influenzae type B;
 13. Pneumococcus;
 14. Influenza;
 15. Hepatitis A;
 16. Human papilloma virus infection;
 17. Other infectious diseases designated by the Minister of Health and Welfare as deemed necessary for preventing infectious diseases.
- (2) The Special Self-Governing Province Governor or the head of a *Si/Gun/Gu* may entrust medical institutions prescribed in the Medical Service Act within his/her jurisdiction with the affairs of mandatory vaccination under paragraph (1), as prescribed by Presidential Decree. *<Amended by Act No. 15534, Mar. 27, 2018>*
- (3) The Special Self-Governing Province Governor or the head of a *Si/Gun/Gu* shall pre-notify the parents of children subject to mandatory vaccination, of such mandatory vaccination, as prescribed by Ordinance of the Ministry of Health and Welfare. In such cases, he/she may process personally identifiable information referred to in Article 24 of the Personal Information Protection Act. *<Newly Inserted by Act No. 11439, May 23, 2012; Act No. 15534, Mar. 27, 2018>*

Article 25 (Special Vaccination)

- (1) The Special Self-Governing Province Governor or the head of a *Si/Gun/Gu* shall provide special vaccination services (hereinafter referred to as "special vaccination") at public health centers under his/her jurisdiction in any of the following cases: <Amended by Act No. 9932, Jan. 18, 2010>
1. Where the Minister of Health and Welfare requests the Special Self-Governing Province Governor or the head of a *Si/Gun/Gu* to provide vaccination services for preventing infectious diseases;
 2. Where the Special Self-Governing Province Governor or the head of a *Si/Gun/Gu* deems vaccinations necessary for preventing infectious diseases.
- (2) Article 24 (2) shall apply *mutatis mutandis* to the entrustment of special vaccination specified in paragraph (1).

Article 26 (Public Announcement of Vaccination)

Where the Special Self-Governing Province Governor or the head of a *Si/Gun/Gu* is to provide special vaccination services, he/she shall determine the date, time, place, type of vaccination, and scope of persons subject to vaccination, and shall make prior public announcement thereof: *Provided*, That in cases of any changes in standards, etc. for providing vaccination services under Article 32 (2), prior public announcement on such changes shall be made.

Article 26-2 (Pre-Checking of Vaccination Records)

- (1) The director of each public health center and the head of each medical institution entrusted with vaccination services under Article 24 (2) (including where the same is applied *mutatis mutandis* in Article 25 (2)), before providing vaccination services, shall check on the vaccination record of a person who intends to be vaccinated, with consent from the relevant person him/herself or his/her legal representative, as prescribed by Presidential Decree: *Provided*, That this shall not apply where consent is not obtained from such person or his/her legal representative.
- (2) The pre-checking of a vaccination record referred to in the main clause of paragraph (1) may be made through the integrated vaccination management system specified in Article 33-4. <Amended by Act No. 16725, Dec. 3, 2019>

[This Article Newly Inserted by Act No. 13639, Dec. 29, 2015]

Article 27 (Certificates of Vaccination)

- (1) The Minister of Health and Welfare, the Special Self-Governing Province Governor, or the head of a *Si/Gun/Gu* shall issue a certificate of vaccination to those who have undergone mandatory vaccination or special vaccination or their legal representatives, as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010; Act No. 13639, Dec. 29, 2015; Act No. 15534, Mar. 27, 2018>
- (2) Where a person, other than the Special Self-Governing Province Governor or the head of a *Si/Gun/Gu*, provides vaccination services under this Act, the Minister of Health and Welfare, the Special Self-Governing Province Governor, or the head of a *Si/Gun/Gu* may authorize the person who has provided vaccination services to issue a certificate of vaccination, as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010; Act No. 13639, Dec. 29, 2015>
- (3) Certificates of vaccination referred to in paragraphs (1) and (2) may be issued in electronic form.

Article 28 (Keeping and Reporting of Vaccination Records)

- (1) Where the Special Self-Governing Province Governor or the head of a *Si/Gun/Gu* provides mandatory or special vaccination, or receives a report under paragraph (2), he/she shall prepare and keep records on vaccinations, as prescribed by Ordinance of the Ministry of Health and Welfare, and

report the details thereof to the competent Mayor/*Do* Governor and the Minister of Health and Welfare, respectively. <Amended by Act No. 9932, Jan. 18, 2010; Act No. 15534, Mar. 27, 2018>

- (2) Where a person, other than the Special Self-Governing Province Governor or the head of a *Si/Gun/Gu*, provides vaccination services under this Act, he/she shall report to the Special Self-Governing Province Governor or the head of the competent *Si/Gun/Gu*, as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010>

Article 29 (Epidemiological Investigations on Vaccination)

The Director of the Korea Centers for Disease Control and Prevention, a Mayor/*Do* Governor or the head of a *Si/Gun/Gu* shall conduct an investigation, based on the following classifications, and if any case of an adverse reaction to vaccinations occurs, he/she shall conduct an epidemiological investigation pursuant to Article 18 to establish its cause:

1. The Director of the Korea Centers for Disease Control and Prevention: An investigation into the effects of vaccinations, and adverse reactions to vaccinations;
2. A Mayor/*Do* Governor or the head of a *Si/Gun/Gu*: An investigation into adverse reactions to vaccinations.

Article 30 (Vaccination Injury Investigation Teams)

- (1) A vaccination injury investigation team shall be established under the Korea Centers for Disease Control and Prevention to investigate the causes of diseases, disabilities, and death resulting from vaccinations referred to in Article 71 (1) and (2), and compensation, etc. for injury therefrom, and to investigate a third party's intention or negligence under Article 72 (1).
- (2) Matters necessary for the establishment, operation, etc. of a vaccination injury investigation team prescribed in paragraph (1) shall be prescribed by Presidential Decree.

Article 31 (Ascertainment as to Completion of Vaccination)

- (1) The Special Self-Governing Province Governor or the head of a *Si/Gun/Gu* may request the principal of an elementary school and the principal of a middle school to submit inspection records on whether vaccination has been completed under Article 10 of the School Health Act.
- (2) The Special Self-Governing Province Governor or the head of a *Si/Gun/Gu* may request the head of a kindergarten defined under the Early Childhood Education Act and the head of a day care center defined under the Child Care Act to ascertain whether infants and young children have been vaccinated, as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010; Act No. 10789, Jun. 7, 2011>
- (3) If the Special Self-Governing Province Governor or the head of a *Si/Gun/Gu* finds that some infants, young children, students, etc. have not been vaccinated after verifying records submitted under paragraph (1) and results of ascertainment under paragraph (2), he/she shall vaccinate such infants, young children, students, etc.

Article 32 (Vaccination Week and Standards for Vaccination)

- (1) The Minister of Health and Welfare may promulgate Vaccination Week to promote vaccination against infectious diseases by raising citizens' interest to get vaccinated. <Amended by Act No. 9932, Jan. 18, 2010>
- (2) Matters necessary for standards for and methods of conducting vaccination and other relevant matters shall be determined by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010>

Article 33 (Planned Production of Vaccines)

- (1) Where the Minister of Health and Welfare determines that the domestic supply of vaccines is

insufficient or in other cases prescribed by Ordinance of the Ministry of Health and Welfare, he/she may pre-compute the number of vaccines necessary for vaccination against infectious diseases and require a medicine manufacturer under Article 31 of the Pharmaceutical Affairs Act (hereinafter referred to as "medicine manufacturer") to produce them, and subsidize researchers, etc. of vaccines within budgetary limits. <Amended by Act No. 9932, Jan. 18, 2010; Act No. 16725, Dec. 3, 2019>

- (2) The Minister of Health and Welfare may fully or partially prepay expenses incurred in producing vaccines under paragraph (1) to the relevant medicine manufacturer, as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010>

Article 33-2 (Stockpiling Mandatory Vaccines)

- (1) In order to facilitate mandatory vaccination services referred to in Article 24 and special vaccination services referred to in Article 25, the Minister of Health and Welfare may take preemptive measures for stockpiling necessary mandatory vaccines, etc. or concluding a contract for long-term purchases thereof, after undergoing deliberation by the Committee.
- (2) The Minister of Health and Welfare may determine the distribution criteria, such as the priority of supplying mandatory vaccines, etc. stockpiled pursuant to paragraph (1), and other necessary matters, after undergoing deliberation by the Committee.

[This Article Newly Inserted by Act No. 16725, Dec. 3, 2019]

Article 33-3 (Reporting Plans for Producing Mandatory Vaccines)

A person intending to produce or import mandatory vaccines, etc., from among those who have obtained permission or filed a notification by item pursuant to Article 31 or 42 of the Pharmaceutical Affairs Act, shall submit a plan for producing or importing mandatory vaccines, etc. (including any modification thereof) and the implementation results thereof to the Minister of Health and Welfare, as prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 16725, Dec. 3, 2019]

Article 33-4 (Establishment and Operation of Integrated Vaccination Management System)

- (1) To efficiently process various data or information required for providing vaccination services and computerize the recording and management affairs, the Minister of Health and Welfare shall establish and operate an integrated vaccination management system (hereinafter referred to as the "Integrated Management System").
- (2) The Minister of Health and Welfare may collect, manage, and maintain the following data for establishing and operating the Integrated Management System, and request related agencies and organizations to provide necessary data. In such cases, the agencies and organizations in receipt of such request shall comply therewith unless there is good cause:
 1. Personal information of persons who should be vaccinated (including personally identifiable information referred to in Article 24 of the Personal Information Protection Act and other personal information prescribed in Presidential Decree);
 2. Details of vaccinations, including the names of persons vaccinated, vaccine names, and dates of vaccinations;
 3. Other data prescribed by Presidential Decree as required to provide vaccination services, including information on the medical institutions entrusted with vaccination services and the details of applications for compensation for injury suffered from vaccination.
- (3) The director of each public health center and the head of each medical institution entrusted with vaccination services under Article 24 (2) (including where the same is applied *mutatis mutandis* in Article 25 (2)), after providing vaccination services under this Act, shall enter information specified in paragraph (2) 2 in the Integrated Management System, as prescribed by Presidential Decree.
- (4) The Minister of Health and Welfare may provide the parents of children who should be vaccinated

with the details of vaccinations of their children or may support the issuance of certificates of vaccination, by utilizing the Integrated Management System, as prescribed by Presidential Decree. In such cases, to verify suitability for providing the details of vaccinations or issuing a certificate of vaccination, he/she may request the Minister of National Court Administration to furnish computerized registration data referred to in Article 11 of the Act on the Registration of Family Relations; and the Minister of National Court Administration shall comply therewith unless there is good cause.

- (5) The Integrated Management System may be utilized with a link to the following information systems related to vaccination services:
1. The education information system referred to in Article 30-4 of the Elementary and Secondary Education Act;
 2. The early childhood education information system referred to in Article 19-2 of the Early Childhood Education Act;
 3. Other information systems prescribed by Ordinance of the Ministry of Health and Welfare, including the integrated electronic civil petition window referred to in Article 9 of the Electronic Government Act.
- (6) Except as provided in this Act, matters concerning the protection and management of information referred to in paragraphs (1) through (5) shall be governed by the Personal Information Protection Act.

[This Article Newly Inserted by Act No. 13639, Dec. 29, 2015]

CHAPTER VII Measures to Prevent Spread of Infectious Diseases

Article 34 (Formulation and Implementation of Crisis Control Measures against Infectious Diseases)

- (1) The Minister of Health and Welfare shall formulate and implement crisis control measures against infectious diseases (hereinafter referred to as "crisis control measures against infectious diseases") after deliberation by the Committee in order to respond to an emergency resulting from the spread of infectious diseases or the transmission of new overseas infectious diseases into the Republic of Korea. *<Amended by Act No. 9932, Jan. 18, 2010; Act No. 13392, Jul. 6, 2015>*
- (2) Crisis control measures against infectious diseases shall include the following: *<Amended by Act No. 9932, Jan. 18, 2010; Act No. 13392, Jul. 6, 2015>*
1. Systems for responding to the occurrence of a disaster and the transmission of overseas emerging infectious diseases, and roles therein by agency;
 2. Judgment on a disaster or emergency, decision on emergency warning, and disaster and emergency management systems;
 3. Preparation of the lists of experts, such as medical personnel, facilities, and medical institutions to be mobilized during an infectious disease emergency;
 4. Schemes of stockpiling and securing medical supplies;
 5. Training for actual situations, such as citizens' codes of conduct and education and map exercise for the personnel, facilities, and institutions to be mobilized, by a disaster or emergency;
 6. Other matters deemed necessary by the Minister of Health and Welfare for coping with disasters or emergencies.
- (3) The Minister of Health and Welfare shall regularly conduct training, based on crisis control measures against infectious diseases. *<Newly Inserted by Act No. 13392, Jul. 6, 2015>*
- (4) Matters necessary for the formulation, implementation, etc. of crisis control measures against infectious diseases shall be prescribed by Presidential Decree. *<Amended by Act No. 13392, Jul. 6, 2015>*

Article 34-2 (Disclosure of Information during Infectious Disease Emergency)

- (1) Where the spread of an infectious disease harmful to citizens' health results in the issuance of a crisis alert of the caution level or higher prescribed in Article 38 (2) of the Framework Act on the Management of Disasters and Safety, the Minister of Health and Welfare shall promptly disclose information with which citizens are required to be acquainted for preventing the infectious disease, such as the movement paths, transportation means, medical treatment institutions, and contacts of patients of the infectious disease, by posting such information on the information and communications network, distributing a press release, etc. *<Amended by Act No. 17067, Mar. 4, 2020>*
- (2) Where any information disclosed under paragraph (1) falls under any of the following subparagraphs, the relevant person may file an objection with the Minister of Health and Welfare, in writing, orally, or using the information and communications network: *<Newly Inserted by Act No. 17067, Mar. 4, 2020>*
 1. Where any disclosed information is different from the actual fact;
 2. Where he/she has any opinion on any disclosed information.
- (3) Where the Minister of Health and Welfare deems that the objection raised under paragraph (2) is well-grounded, he/she shall take necessary measures, such as correcting the relevant disclosed information. *<Newly Inserted by Act No. 17067, Mar. 4, 2020>*
- (4) Matters necessary for the scope of, procedures, methods, etc. for disclosing information and raising objections prescribed in paragraphs (1) and (2) shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 17067, Mar. 4, 2020>*

[This Article Newly Inserted by Act No. 13392, Jul. 6, 2015]

Article 35 (Formulation of Crisis Control Measures against Infectious Diseases by City/Do)

- (1) The Minister of Health and Welfare shall notify Mayors/*Do* Governors of crisis control measures against infectious diseases formulated under Article 34 (1). *<Amended by Act No. 9932, Jan. 18, 2010>*
- (2) Each Mayor/*Do* Governor shall formulate and implement crisis control measures against infectious diseases by each Special Metropolitan City, Metropolitan City, *Do*, or Special Self-Governing Province (hereinafter referred to as "City/*Do*"), based on the crisis control measures against infectious diseases notified under paragraph (1).

Article 35-2 (Prohibition of Presentation of False Statement to Medical Personnel during Disaster)

No one shall make a false statement, present false materials, or intentionally omit or conceal any fact to medical personnel with respect to facts necessary for confirming whether the relevant party is infected, including records of visits to medical institutions and of medical treatment, after a forecast or alert is issued to indicate the level of caution or higher under Article 38 (2) of the Framework Act on the Management of Disasters and Safety. *<Amended by Act No. 15183, Dec. 12, 2017>*

[This Article Newly Inserted by Act No. 13392, Jul. 6, 2015]

Article 36 (Designation of Infectious Disease Control Institutions)

- (1) The Minister of Health and Welfare or a Mayor/*Do* Governor shall designate a medical institution referred to in Article 3 of the Medical Service Act as an infectious disease control institution, as prescribed by Ordinance of the Ministry of Health and Welfare. *<Newly Inserted by Act No. 17067, Mar. 4, 2020>*
- (2) The head of a *Si/Gun/Gu* may designate a medical institution prescribed in the Medical Service Act as an infectious disease control institution, as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 9932, Jan. 18, 2010; Act No. 17067, Mar. 4, 2020>*
- (3) The head of a medical institution designated under paragraphs (1) and (2) (hereinafter referred to as

"infectious disease control institution") shall establish facilities for preventing infectious diseases and for treating patients of an infectious disease, etc. (hereinafter referred to as "infectious disease control facilities"). In such cases, an infectious disease control institution that exceeds the scale prescribed by Ordinance of the Ministry of Health and Welfare, shall establish single-occupancy hospital rooms with anterooms, negative pressure facilities, etc. in accordance with the standards prescribed by Ordinance of the Ministry of Health and Welfare, in order to prevent the spread of an infectious disease. <Amended by Act No. 9932, Jan. 18, 2010; Act No. 13639, Dec. 29, 2015; Act No. 17067, Mar. 4, 2020>

- (4) The Minister of Health and Welfare, a Mayor/Do Governor, or the head of a *Si/Gun/Gu* shall subsidize expenses incurred in establishing and operating infectious disease control facilities, to infectious disease control institutions. <Amended by Act No. 17067, Mar. 4, 2020>
- (5) Where a medical institution, other than an infectious disease control institution, intends to establish and operate infectious disease control facilities, it shall report such fact to the Special Self-Governing Province Governor or the head of the relevant *Si/Gun/Gu*, as prescribed by Ordinance of the Ministry of Health and Welfare. In such cases, the Special Self-Governing Province Governor or the head of the relevant *Si/Gun/Gu* shall review the details of such report, and accept it if it is in compliance with this Act. <Amended by Act No. 9932, Jan. 18, 2010; Act No. 17067, Mar. 4, 2020>
- (6) When an emergency occurs, including the outbreak of an infectious disease, the Minister of Health and Welfare, a Mayor/Do Governor, or the head of a *Si/Gun/Gu* may instruct infectious disease control institutions to conduct any necessary affairs, such as commencing medical treatment. <Newly Inserted by Act No. 13392, Jul. 6, 2015; Act No. 17067, Mar. 4, 2020>

Article 37 (Establishment of Infectious Disease Control Institutions during Infectious Disease Emergencies)

- (1) Where patients of an infectious disease occur in mass or infectious disease control institutions designated under Article 36 are insufficient to accommodate all patients of an infectious disease, etc., the Minister of Health and Welfare, a Mayor/Do Governor, or the head of a *Si/Gun/Gu* may take the following measures: <Amended by Act No. 9932, Jan. 18, 2010>
 1. Designating any medical institution, other than infectious disease control institutions designated under Article 36, as an infectious disease control institution for a certain period;
 2. Establishing and operating isolation wards, sanatoriums, or clinics.
- (2) The head of an infectious disease control institution designated under paragraph (1) 1 shall establish infectious disease control facilities, as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010>
- (3) The Minister of Health and Welfare, a Mayor/Do Governor, or the head of a *Si/Gun/Gu* shall subsidize expenses incurred in establishing and operating facilities under paragraph (2), to infectious disease control institutions. <Amended by Act No. 9932, Jan. 18, 2010>
- (4) No head of an infectious disease control institution designated under paragraph (1) 1 may refuse any order issued under paragraph (2) without good cause.
- (5) When an emergency occurs, including the outbreak of an infectious disease, the Minister of Health and Welfare, a Mayor/Do Governor, or the head of a *Si/Gun/Gu* may order infectious disease control institutions to conduct any necessary affairs, such as the beginning of medical treatment. <Newly Inserted by Act No. 13392, Jul. 6, 2015; Act No. 15534, Mar. 27, 2018>

Article 38 (Prohibition of Refusal to Hospitalize Patients of Infectious Disease)

No infectious disease control institution may refuse to hospitalize patients of an infectious disease, etc. without justifiable grounds.

Article 39 (Methods of Establishing and Managing Infectious Disease Control Facilities, etc.)

Matters necessary for methods, etc. of establishing and operating infectious disease control institutions, and isolation wards, sanatoriums, or clinics under Article 37 shall be determined by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010>

Article 39-2 (Evaluation of Infectious Disease Control Facilities)

The Minister of Health and Welfare, a Mayor/Do Governor, or the head of a *Si/Gun/Gu* may conduct evaluations of infectious disease control institutions regularly, and reflect the findings thereof in the supervision, support, etc. of said institutions. In such cases, methods, process, and time-frame of such evaluations, details of the supervision and support, and other related matters, shall be determined by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 13639, Dec. 29, 2015]

Article 39-3 (Designation of Facilities for Quarantining Contacts)

- (1) A Mayor/Do Governor shall designate a facility for quarantining contacts of patients of an infectious disease, etc. (hereinafter referred to as “facility for quarantining contacts”) upon the outbreak or epidemic of such disease: *Provided*, That a medical institution under Article 3 of the Medical Service Act shall not be designated as a facility for quarantining contacts.
- (2) Where contacts of patients of an infectious disease, etc. occur in mass or facilities for quarantining contacts designated under paragraph (1) are insufficient to accommodate all contacts, the Minister of Health and Welfare or a Mayor/Do Governor may designate a facility, other than facilities for quarantining contacts designated under paragraph (1), as a facility for quarantining contacts for a certain period.
- (3) Matters necessary for methods for designating and managing facilities for quarantining contacts under paragraphs (1) and (2) and other matters shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 15534, Mar. 27, 2018]

Article 40 (Stockpiling Medicines and Equipment for Infectious Diseases Spread through Bioterrorism)

- (1) When there is a likelihood of a pandemic of an infectious disease spread through bioterrorism or any other infectious disease, the Minister of Health and Welfare may determine preventive and therapeutic medicines, equipment, etc., after undergoing deliberation by the Committee, and stockpile them or concluding a contract for long-term purchase, in advance. <Amended by Act No. 9932, Jan. 18, 2010>
- (2) When there is a likelihood of a pandemic of an infectious disease spread through bioterrorism and any other infectious disease, the Minister of Health and Welfare may determine preventive and therapeutic medicines and require medicine manufacturers to produce them, notwithstanding Article 31 (2) of the Pharmaceutical Affairs Act. <Amended by Act No. 9932, Jan. 18, 2010; Act No. 16725, Dec. 3, 2019>
- (3) The Minister of Health and Welfare shall investigate the efficacy and adverse reactions of preventive and therapeutic medicines under paragraph (2), and conduct epidemiological investigations pursuant to Article 18 if any case of adverse reactions occurs. <Amended by Act No. 9932, Jan. 18, 2010>

Article 40-2 (Distribution Standards including Priorities in Supplying Medicines for Infectious Diseases)

The Minister of Health and Welfare may determine distribution standards, including priorities in supplying medicines stockpiled or produced under Article 40 (1) and (2) in preparation for a pandemic

of infectious diseases spread by biological terrorism or any other infectious disease, and other necessary matters after deliberation by the Committee.

[This Article Newly Inserted by Act No. 12444, Mar. 18, 2014]

Article 40-3 (Export Embargoes)

- (1) Where any Class 1 infectious disease breaks out and the public health is likely to be harmed significantly due to a sudden price increase or lack of supply of products prescribed by Ordinance of the Ministry of Health and Welfare, including quasi-drugs and drugs (hereinafter referred to as "quasi-drugs, etc."), necessary for disease prevention, quarantine, and treatment, the Minister of Health and Welfare may prohibit the relevant quasi-drugs, etc. from being exported or shipped out of the Republic of Korea.
- (2) Where the Minister of Health and Welfare intends to impose an embargo prescribed in paragraph (1), he/she shall have a prior consultation with the heads of the relevant central administrative agencies, and determine and publicize an embargo period in advance.

[This Article Newly Inserted by Act No. 17067, Mar. 4, 2020]

Article 41 (Management of Patients of Infectious Disease)

- (1) Patients of an infectious disease, etc. with a particularly high risk of transmission, which falls under Class 1 infectious diseases or is an infectious disease publicly notified by the Minister of Health and Welfare, shall receive inpatient treatment at an infectious disease control institution. *<Amended by Act No. 9932, Jan. 18, 2010; Act No. 15534, Mar. 27, 2018>*
- (2) Where sickbeds at an infectious disease control institution are fully occupied, and thus the infectious disease control institution is unable to accommodate patients of an infectious disease, etc., the Minister of Health and Welfare, a Mayor/Do Governor, or the head of a *Si/Gun/Gu* may permit such patients, etc. to receive inpatient treatment at medical institutions, other than infectious disease control institutions. *<Amended by Act No. 9932, Jan. 18, 2010>*
- (3) The Minister of Health and Welfare, a Mayor/Do Governor, or the head of a *Si/Gun/Gu* may permit any of the following persons to undergo treatment at his/her home or infectious disease control facilities: *<Amended by Act No. 9932, Jan. 18, 2010>*
 1. A person, other than those subject to inpatient treatment under paragraphs (1) and (2);
 2. A person at the risk of infection or transmission of an infectious disease through contact with a patient of an infectious disease, etc.
- (4) Matters necessary for methods and procedures for undergoing home-care and inpatient treatment under paragraphs (1) through (3), and other relevant matters, shall be prescribed by Presidential Decree.

Article 41-2 (Employer's Obligation to Cooperate)

- (1) Where an employee is hospitalized, quarantine, or isolated under this Act, the relevant employer may grant a paid leave during the period of such hospitalization, quarantine, or isolation, in addition to the paid leave provided for in Article 60 of the Labor Standards Act. In such cases, if the cost of granting a paid leave is subsidized by the State, the employer shall provide the paid leave.
- (2) No employer shall dismiss, or otherwise treat unfavorably, an employee on the reason of a paid leave granted under paragraph (1) and shall dismiss such employee during the period of the paid leave: *Provided*, That this shall not apply where the employer is unable to continue his/her business.
- (3) The State may subsidize the cost of granting a paid leave under paragraph (1).
- (4) The scope of subsidization granted under paragraph (3), procedures for application therefor, and other necessary matters, shall be prescribed by Presidential Decree.

[This Article Newly Inserted by Act No. 13639, Dec. 29, 2015]

Article 42 (Compulsory Dispositions with respect to Infectious Diseases)

- (1) The Minister of Health and Welfare, a Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* may assign the relevant public official to conduct a necessary investigation or medical diagnosis by entering the residence, means of transportation, such as a ship, aircraft, or train, or any other place where a patient of any of the following infectious diseases, etc. is deemed present, and where such medical diagnosis deems that the relevant person is a patient of an infectious disease, etc., the relevant public official may escort and compel such person to undergo medical treatment or be hospitalized: *<Amended by Act No. 9932, Jan. 18, 2010; Act No. 15534, Mar. 27, 2018>*
1. Class 1 infectious diseases;
 2. Tuberculosis, measles, cholera, typhoid, paratyphoid, shigellosis, colon bacillus infection with enterorrhagia, hepatitis A, meningococcal meningitis, poliomyelitis, scarlet fever, and other infectious diseases determined by the Minister of Health and Welfare, among Class 2 infectious diseases;
 3. Deleted; *<by Act No. 15534, Mar. 27, 2018>*
 4. Infectious diseases determined by the Minister of Health and Welfare, among Class 3 infectious diseases;
 5. Infectious diseases under surveillance by the World Health Organization;
 6. Deleted. *<by Act No. 15534, Mar. 27, 2018>*
- (2) Where any Class 1 infectious disease breaks out, the Minister of Health and Welfare, a Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* may have the relevant public official take any of the following measures for persons suspected of contracting the infectious disease. In such cases, the relevant public official may conduct a necessary investigation or medical diagnosis to confirm the presence or absence of infectious disease symptoms: *<Newly Inserted by Act No. 17067, Mar. 4, 2020>*
1. Quarantine at home or in a facility;
 2. Checking the presence or absence of symptoms of an infectious disease based on the wired or wireless communications, or using devices based on the information and communications technology, etc.
- (3) With respect to persons deemed patients of an infectious disease, etc. as a result of investigations or medical diagnosis referred to in paragraph (2), the Minister of Health and Welfare, a Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* may assign the relevant public official to escort and compel such persons to undergo medical treatment or be hospitalized. *<Newly Inserted by Act No. 17067, Mar. 4, 2020>*
- (4) Where a person refuses an investigation or medical diagnosis referred to in paragraphs (1) and (2) or a test referred to in Article 13 (2) (hereafter in this Article referred to as “investigation refuser”), the Minister of Health and Welfare, a Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* shall assign the relevant public official to escort such person to an infectious disease control institution and compel such person to undergo necessary investigation or diagnosis. *<Amended by Act No. 13639, Dec. 29, 2015; Act No. 17067, Mar. 4, 2020>*
- (5) A public official who takes measures for investigation, medical diagnosis, quarantine or isolation, treatment, hospitalization, or escort pursuant to paragraphs (1) through (4) shall carry an identification indicating his/her authority and produce it to relevant persons. *<Newly Inserted by Act No. 13639, Dec. 29, 2015; Act No. 17067, Mar. 4, 2020>*
- (6) Where necessary for taking any measure for investigation, medical diagnosis, quarantine or isolation, treatment, or hospitalization prescribed in paragraphs (2) through (4) and (7), the Minister of Health and Welfare, a Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* may request cooperation from the chief of the competent police station. In such cases, the chief of the competent police station in receipt of such request shall comply therewith unless there is a compelling reason not to do so. *<Newly Inserted by Act No. 13639, Dec. 29, 2015; Act No. 17067, Mar. 4, 2020>*

- (7) The Minister of Health and Welfare, a Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* may quarantine or isolate any investigation refuser at such refuser's home or in an infectious disease control facility; and if the investigation refuser is deemed a patient of an infectious disease, etc. according to the results of an investigation or medical diagnosis conducted under paragraph (4), he/she shall compel such patient to undergo medical treatment or to be hospitalized in an infectious disease control facility. <Newly Inserted by Act No. 13639, Dec. 29, 2015; Act No. 17067, Mar. 4, 2020>
- (8) Where any person suspected of contracting an infectious disease or investigation refuser is found not to be a patient of an infectious disease, etc., the Minister of Health and Welfare, a Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* shall immediately release the investigator refuser from quarantine or isolation referred to in paragraph (2) or (7). <Newly Inserted by Act No. 13639, Dec. 29, 2015; Act No. 17067, Mar. 4, 2020>
- (9) Where the Minister of Health and Welfare, a Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* gives medical treatment to, or hospitalizes, any investigation refuser pursuant to paragraph (7), he/she shall notify the guardian of the investigation refuser thereof. In such cases, Article 43 shall apply *mutatis mutandis* to matters necessary for the methods of, procedures, etc. for notification. <Newly Inserted by Act No. 13639, Dec. 29, 2015; Act No. 17067, Mar. 4, 2020>
- (10) Notwithstanding paragraph (8), if a disposition of quarantine or isolation is not released without good cause, the relevant persons suspected of contracting an infectious disease or investigation refuser may make a rescue claim seeking the release; and in regards to the process, methods, etc. of such rescue claim, the Habeas Corpus Act shall apply *mutatis mutandis*. In such cases, "person suspected of contracting an infectious disease or investigation refuser" shall be construed as "inmate"; and "Minister of Health and Welfare, a Mayor/*Do* Governor, or the head of a *Si/Gun/Gu*" who has ordered the disposition of quarantine or isolation shall be construed as "custodian" (for the purposes of this paragraph, the application of Article 6 (1) 3 of the Habeas Corpus Act shall be excluded). <Newly Inserted by Act No. 13639, Dec. 29, 2015; Act No. 17067, Mar. 4, 2020>
- (11) Matters necessary for the criteria for designating institutions to conduct investigations, medical diagnosis, quarantine or isolation, or treatment under paragraphs (1) through (4) and (7), the methods for quarantine and for checking the presence or absence of symptoms with regard to persons suspected of contracting an infectious disease under paragraph (2), and other relevant matters shall be prescribed by Presidential Decree. <Newly Inserted by Act No. 13639, Dec. 29, 2015; Act No. 17067, Mar. 4, 2020>

Article 43 (Hospitalization Notice to Patients of Infectious Disease)

- (1) Where a patient of an infectious disease, etc. needs to receive inpatient treatment under Article 41, the Minister of Health and Welfare, a Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* shall notify the person subject to inpatient treatment and his/her guardian thereof. <Amended by Act No. 9932, Jan. 18, 2010>
- (2) Matters necessary for methods of and procedures for notification under paragraph (1), and other relevant matters, shall be determined by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010>

Article 43-2 (Notification to Persons Subject to Quarantine or Isolation)

- (1) Where the Minister of Health and Welfare, a Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* takes any measure for hospitalization, quarantine, or isolation prescribed in Article 42 (2), (3), and (7), subparagraph 3 of Article 47, or Article 49 (1) 14, he/she shall notify such fact to persons subject to hospitalization, quarantine, or isolation and his/her guardian.
- (2) Matters necessary for the methods of, procedures, etc. for notification referred to in paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 17067, Mar. 4, 2020]

Article 44 (Management of Imprisoned Patients)

The head of a correctional institution shall provide inmates infected with infectious diseases with measures to prevent the spread of the infectious disease and appropriate medical services.

Article 45 (Temporary Restrictions on Work)

- (1) No patients of an infectious disease, etc. may be engaged in any occupation involving frequent contact with the general public by its nature, and no one may hire patients of an infectious disease, etc. for such occupation, as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 9932, Jan. 18, 2010>*
- (2) If a person required to undergo a medical examination for a sexually transmitted infectious disease under Article 19 fails to undergo the medical examination, he/she shall not be engaged in any occupation provided for in the same Article, and the person who operates the relevant business shall not permit any person who fails to undergo medical examination to be engaged in the business.

Article 46 (Measures for Medical Examination and Vaccination, etc.)

The Minister of Health and Welfare, a Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* may take measures for requiring any of the following persons to undergo a medical examination, or to receive a vaccination necessary for preventing an infectious disease, etc., as prescribed by Ordinance of the Ministry of Health and Welfare: *<Amended by Act No. 9932, Jan. 18, 2010; Act No. 13392, Jul. 6, 2015>*

1. Family members of a patient of an infectious disease, etc. or his/her cohabitants;
2. A person suspected of being infected by an infectious disease, who resides in or enters an area where the infectious disease breaks out;
3. A person suspected of being infected with an infectious disease through contact with patients of an infectious disease, etc.

Article 47 (Control Measures against Epidemic of Infectious Diseases)

In order to prevent the further spread of an infectious disease upon the epidemic of the infectious disease, the Minister of Health and Welfare, Mayors/*Do* Governors, or heads of *Sis/Guns/Gus* shall take all or some of the following measures: *<Amended by Act No. 13392, Jul. 6, 2015; Act No. 17067, Mar. 4, 2020>*

1. The following measures for places where patients of an infectious disease, etc. are present or places deemed contaminated with the pathogen of an infectious disease:
 - (a) Temporary closure;
 - (b) Prohibition of entry of the general public;
 - (c) Restriction on movement into the relevant places;
 - (d) Other measures for passage blocking;
2. Suspending the business of a medical institution;
3. Hospitalizing or quarantining persons suspected of contracting an infectious disease at an appropriate place for a certain period;
4. Prohibiting the acts of using, receiving, moving, discarding, or cleaning things infected or suspected of being infected by the pathogen of an infectious disease, or burning up or disposing of such things;
5. Issuing an order to disinfect or take other necessary measures for, places infected by the pathogen of an infectious disease;
6. Issuing an order to prevent laundering at a specified place or to dispose of wastes at a specified place.

Article 48 (Disinfection Measures for Infected Places, etc.)

- (1) The commander of a unit belonging to the Army, Navy, or Air Force, the commander of a unit under direct control of the Ministry of National Defense, and a person falling under any subparagraph of Article 12 (1), shall disinfect or take other necessary measures for, places where patients of an infectious disease, etc. occurred, or places suspected of being contaminated with the pathogen of an infectious disease, in accordance with the direction of a physician, oriental medical doctor, or relevant public official.
- (2) Matters necessary for taking measures, including disinfection, under paragraph (1), shall be determined by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 9932, Jan. 18, 2010>*

CHAPTER VIII Preventive Measures**Article 49 (Preventive Measures against Infectious Diseases)**

- (1) In order to prevent infectious diseases, the Minister of Health and Welfare, Mayors/*Do* Governors, or heads of *Sis/Guns/Gus* shall take all or some of the following measures: *<Amended by Act No. 13392, Jul. 6, 2015; Act No. 13639, Dec. 29, 2015; Act No. 17067, Mar. 4, 2020>*
1. Completely or partially holding up traffic in jurisdiction;
 2. Restricting or prohibiting performances, assemblies, religious ceremonies, or any other large gathering of people;
 3. Conducting medical examinations or performing autopsies or dissection of corpses;
 4. Issuing an order to prohibit the sale or receipt of food that exposes the risk of transmitting infectious diseases, to discard of such food, or to take other necessary disposal;
 5. Issuing an order to take preventive measures for persons who have involved in slaughter for the prevention of zoonoses, or for persons, etc. exposed to zoonoses;
 6. Issuing an order to restrict or prohibit the possession and transfer of things which may transmit infectious diseases, to destruct or incinerate such things, or to take other necessary disposal;
 7. Issuing an order to assign physicians at any means of transportation, such as ships, aircraft, and trains, places of business, or other public places, or to install facilities necessary for the prevention of infectious diseases at such places;
 8. Issuing an order to disinfect or take other necessary measures for, facilities or places related to public sanitation, or to prohibit the installation, remodeling, alteration, disuse, or use of waterworks, sewers, wells, garbage dumps, and lavatories;
 9. Issuing an order to exterminate rodents, vermin, or other animals transmitting infectious diseases or to install facilities for exterminating such;
 10. Restricting or prohibiting fishing or swimming at a specified place of water, or the use of a specified well;
 11. Prohibiting capturing animals which are intermediate hosts transmitting infectious diseases, or prohibiting eating such animals in the raw state;
 12. Mobilizing medical persons, medical practitioners, and other necessary medical personnel during an epidemic period of an infectious disease;
 13. Issuing an order to disinfect or take other necessary measures for, buildings infected by the pathogens of infectious diseases;
 14. Hospitalizing or quarantining persons suspected of contracting an infectious disease at an appropriate place for a certain period.
- (2) Where a Mayor/*Do* Governor or the head of a *Si/Gun/Gu* intends to prohibit the use of drinking

water pursuant to paragraph (1) 8 and 10, he/she shall separately supply drinking water during a period of such prohibition, and where a Mayor/*Do* Governor or the head of a *Si/Gun/Gu* intends to take measures under paragraph (1) 1, 2, 6, 8, 10, and 11, he/she shall preinform the relevant residents thereof.

Article 49-2 (Protection Measures for Persons Vulnerable to Infection)

- (1) Where a crisis alert of the caution level or higher prescribed in Article 38 (2) of the Framework Act on the Management of Disasters and Safety is issued, in order to protect children, senior citizens, etc. (hereinafter referred to as “persons vulnerable to infection”) using social welfare facilities from respiratory infectious diseases, the Minister of Health and Welfare, a Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* may take necessary measures, such as providing face masks to persons vulnerable to infection.
- (2) Matters necessary for the types of infectious diseases, the scope of persons vulnerable to infection, the procedures for provision, and other relevant matters under paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 17067, Mar. 4, 2020]

Article 50 (Other Preventive Measures against Infectious Diseases)

- (1) Where patients of an infectious disease, etc. occur or are likely to occur, the commander of a unit belonging to the Army, Navy, or Air Force, the commander of a unit under direct control of the Ministry of National Defense, and a person falling under Article 12 (1) 2, shall take a disinfection measure or other necessary measures, and shall take additional measures necessary for preventing infectious diseases, consulting with the Special Self-Governing Province Governor or the head of the relevant *Si/Gun/Gu*. <Amended by Act No. 13392, Jul. 6, 2015>
- (2) The Minister of Education or a superintendent of education shall consult with the Minister of Health and Welfare where he/she issues, on grounds of the outbreak of an infectious disease, an order for business suspension or temporary school closure prescribed in Article 64 of the Elementary and Secondary Education Act or an order for business suspension or temporary kindergarten closure prescribed in Article 31 of the Early Childhood Education Act, to schools defined in subparagraph 2 of Article 2 of the School Health Act. <Newly Inserted by Act No. 13392, Jul. 6, 2015>

Article 51 (Disinfection Duty)

- (1) The Special Self-Governing Province Governor or the head of a *Si/Gun/Gu* shall conduct the cleaning or disinfection, and take measures to exterminate rodents, vermin, etc. (hereinafter referred to as "disinfection") in order to prevent infectious diseases. In such cases, disinfection shall be conducted safely by minimizing their harmful effects on human health and nature. <Amended by Act No. 9932, Jan. 18, 2010; Act No. 17067, Mar. 4, 2020>
- (2) The standards and methods for disinfection referred to in paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Newly Inserted by Act No. 17067, Mar. 4, 2020>
- (3) A person who manages or operates facilities prescribed by Presidential Decree, among those resided or used by a multiple number of persons, such as multi-family housing and accommodations, shall conduct disinfection necessary for the prevention of infectious diseases, as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010; Act No. 17067, Mar. 4, 2020>
- (4) A facility manager or operator who is required to conduct disinfection under paragraph (3) shall authorize a person who has filed a report on his/her disinfection services pursuant to Article 52 (1) to conduct disinfection: *Provided*, That where a housing management service provider defined in Article 2 (1) 15 of the Multi-Family Housing Management Act is equipped with disinfection equipment stipulated in Article 52 (1), he/she may directly disinfect multi-family housing under

his/her management. *<Amended by Act No. 13474, Aug. 11, 2015; Act No. 17067, Mar. 4, 2020>*

Article 52 (Reporting on Business of Disinfection Services)

- (1) A person who intends to provide disinfection services as business (excluding housing management service providers referred to in the proviso of Article 51 (4)) shall be equipped with facilities, equipment, and human resources determined by Ordinance of the Ministry of Health and Welfare and file a reporting on disinfection services with the Special Self-Governing Province Governor or the head of the competent *Si/Gun/Gu*. The same shall also apply to the modification of matters already reported. *<Amended by Act No. 9932, Jan. 18, 2010; Act No. 17067, Mar. 4, 2020>*
- (2) Upon receiving a report referred to in paragraph (1), the Special Self-Governing Province Governor or the head of the competent *Si/Gun/Gu* shall review the details of the report, and accept it if it is in compliance with this Act. *<Newly Inserted by Act No. 17067, Mar. 4, 2020>*
- (3) Where a person who has filed a report on disinfection services pursuant to paragraph (1) (hereinafter referred to as "disinfection service provider") falls under any of the following cases, the Special Self-Governing Province Governor or the head of the competent *Si/Gun/Gu* shall deem such report of disinfection services revoked: *<Amended by Act No. 15183, Dec. 12, 2017; Act No. 16101, Dec. 31, 2018; Act No. 17067, Mar. 4, 2020>*
 1. Where he/she files a report on the closure of his/her business with the head of the competent tax office pursuant to Article 8 (7) of the Value-Added Tax Act;
 2. Where the head of the competent tax office revokes the relevant business registration pursuant to Article 8 (8) of the Value-Added Tax Act;
 3. Where facilities, etc. necessary for disinfection services have continued to be absent for at least six months without filing a report on suspension or closure of business under Article 53 (1).
- (4) If necessary to deem a report on disinfection services revoked pursuant to paragraph (3), the Special Self-Governing Province Governor or the head of a *Si/Gun/Gu* may request the head of the competent tax office to provide information about whether the disinfection service provider has closed his/her business. In such cases, the head of the competent tax office so requested shall provide information about whether the disinfection service provider has closed his/her business pursuant to Article 36 (1) of the Electronic Government Act. *<Newly Inserted by Act No. 15183, Dec. 12, 2017; Act No. 17067, Mar. 4, 2020>*

Article 53 (Reporting on Suspension of Disinfection Services)

- (1) Where a disinfection service provider intends to suspend his/her business for at least 30 days or to permanently close it, he/she shall file a report thereon with the Special Self-Governing Province Governor or the head of the competent *Si/Gun/Gu*, as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 9932, Jan. 18, 2010; Act No. 17067, Mar. 4, 2020>*
- (2) Where a disinfection service provider intends to reopen his/her business after suspending business, he/she shall file a report thereon with the Special Self-Governing Province Governor or the head of the competent *Si/Gun/Gu*, as prescribed by Ordinance of the Ministry of Health and Welfare. In such cases, the Special Self-Governing Province Governor or the head of the competent *Si/Gun/Gu* shall review the details of the report, and accept it if it is in compliance with this Act. *<Newly Inserted by Act No. 17067, Mar. 4, 2020>*

Article 54 (Conducting Disinfections)

- (1) A disinfection service provider shall conduct disinfection according to standards and methods determined by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 9932, Jan. 18, 2010>*
- (2) Where a disinfection service provider has conducted disinfection, he/she shall record and keep matters concerning such disinfection, as prescribed by Ordinance of the Ministry of Health and

Welfare. <Amended by Act No. 9932, Jan. 18, 2010>

Article 55 (Training for Disinfection Service Providers)

- (1) A disinfection service provider (referring to a representative in cases of a corporation; hereafter the same shall apply in this Article) shall receive training on disinfection.
- (2) A disinfection service provider shall ensure his/her employees engaged in disinfection services receive training in relation thereto.
- (3) Matters necessary for the details and methods of training, hours of training, bearing of training expenses, etc. under paragraphs (1) and (2), shall be determined by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010>

Article 56 (Disinfection Service Agencies)

Where the Special Self-Governing Province Governor or the head of a *Si/Gun/Gu* is required to disinfect pursuant to subparagraph 5 of Article 47, Article 48 (1), Article 49 (1) 8, 9, and 13, Article 50, and Article 51 (1) and (3), he/she may authorize a disinfection service provider to disinfect on his/her behalf. <Amended by Act No. 13392, Jul. 6, 2015; Act No. 17067, Mar. 4, 2020>

Article 57 (Submission and Inspection of Documents)

- (1) The Special Self-Governing Province Governor or the head of a *Si/Gun/Gu* may assign a public official under his/her control to request disinfection service providers to submit relevant documents concerning rendering of disinfection services, or assign him/her to inspect such documents or ask questions to such disinfection service providers.
- (2) A public official who requests disinfection service providers to submit documents, inspects such documents, or asks questions to disinfection service providers pursuant to paragraph (1), shall carry a certificate indicating his/her authority and produce it to interested parties.

Article 58 (Corrective Orders)

Where a disinfection service provider falls under any of the following cases, the Special Self-Governing Province Governor or the head of the competent *Si/Gun/Gu* shall order him/her to correct the relevant violation within a specified period of at least one month:

1. Where he/she fails to satisfy requirements for facilities, equipment, and human resources under Article 52 (1);
2. Where he/she fails to receive training under Article 55 (1), or fails to have his/her employees engaging in disinfection services receive training under paragraph (2) of the same Article.

Article 59 (Suspension of Business)

(1) Where a disinfection service provider falls under any of the following cases, the Special Self-Governing Province Governor or the head of the competent *Si/Gun/Gu* may order him/her to close his/her place of business, or to suspend business for a specified period of by up to six months: *Provided*, That in cases falling under subparagraph 5, an order to close his/her place of business shall be issued: <Amended by Act No. 17067, Mar. 4, 2020>

1. Where he/she fails to file a report on modification prescribed in the latter part of Article 52 (1), or fails to file a report on the suspension, closure, or reopening of his/her business prescribed in Article 53 (1) and (2);
2. Where he/she conducts disinfection in disconformity with the standards and methods prescribed in Article 54 (1), or fails to record and retain matters concerning conducted disinfection, in violation of paragraph (2) of the same Article;
3. Where he/she fails to comply with an order to submit relevant documents under Article 57, or refuses, obstructs, or evades inspections and questions by public officials in charge;

4. Where he/she fails to comply with corrective orders issued under Article 58;
 5. Where he/she renders disinfection services during the suspension period of business.
- (2) Where a disinfection service provider continues his/her business after he/she is ordered to close his/her place of business under paragraph (1), or renders disinfection services without filing a report required under Article 52 (1), the Special Self-Governing Province Governor or the head of the competent *Si/Gun/Gu* may assign the relevant public officials to take the following measures in order to close the relevant place of business:
1. To remove or eliminate signboards of the relevant place of business, or any other business sign, etc.;
 2. To display a sign, etc. indicating that the relevant place of business is illegitimate.
- (3) Standards for administrative dispositions referred to in paragraph (1) shall be determined by Ordinance of the Ministry of Health and Welfare, in consideration of the types, severity, etc. of relevant violations. <Amended by Act No. 9932, Jan. 18, 2010>

CHAPTER IX Disease Control Officers, Epidemiological Investigation Officers, Quarantine Inspection Commissioners, and Disease Prevention Commissioners

Article 60 (Disease Control Officers)

- (1) The Minister of Health and Welfare and each Mayor/Do Governor shall appoint disease control officers in charge of the affairs of infectious disease prevention and control, from among public officials of said Ministry or City/Do: *Provided*, That if necessary for dealing with the affairs of infectious disease prevention and control, the head of a *Si/Gun/Gu* may appoint disease control officers from among public officials of said *Si/Gun/Gu*. <Amended by Act No. 17067, Mar. 4, 2020>
- (2) Each disease control officer shall be in charge of affairs specified in Article 4 (2) 1 through 7: *Provided*, That each disease control officer of the Ministry of Health and Welfare shall also be in charge of affairs specified in Article 4 (2) 8.
- (3) Where urgent responses are necessary due to the anticipated domestic transmission or epidemic of any infectious disease, a disease control officer shall have authority to take measures against the fields of an infectious disease, such as the restriction of passage, the evacuation of residents, the disposal and incineration of food, things, etc., through which an infectious disease is transmitted, the assignment of tasks on personnel in charge of infectious disease control including medical personnel, and the deployment of supplies for disease control, for conducting affairs prescribed in Article 4 (2) 1 and 2.
- (4) Relevant public officials, such as the head of a police agency prescribed in Article 2 of the Police Act, a fire-fighting government office prescribed in Article 3 of the Framework Act on Fire-Fighting Services, and the director of a public health center prescribed in Article 10 of the Regional Public Health Act, all of which have jurisdiction over an area of an infectious disease, and corporations, organizations, and individuals located in that area shall cooperate in measures taken by a disease control officer under paragraph (3) unless there is good cause.
- (5) Except as provided in paragraphs (1) through (4), matters necessary for the qualification and duties of disease control officers, the scope of their authority to take measures, and other relevant matters shall be prescribed by Presidential Decree.

[This Article Wholly Amended by Act No. 13392, Jul. 6, 2015]

Article 60-2 (Epidemiological Investigation Officers)

- (1) Epidemiological investigation officers shall be composed of at least 100 public officials of the Ministry of Health and Welfare and at least two public officials of a City/*Do*, respectively, to deal with affairs concerning epidemiological investigations. In such cases, at least one of the City/*Do* epidemiological investigation officers shall be a physician, among the medical personnel referred to in Article 2 (1) of the Medical Service Act. *<Amended by Act No. 15534, Mar. 27, 2018; Act No. 17067, Mar. 4, 2020>*
- (2) Where necessary for dealing with affairs concerning epidemiological investigations, the head of a *Si/Gun/Gu* may have epidemiological investigation officers as public officials of said *Si/Gun/Gu*: *Provided*, That the head of a *Si/Gun/Gu* that meets the criteria prescribed by Ordinance of the Ministry of Health and Welfare in consideration of the population, etc. shall have at least one epidemiological investigation officer as a public official of said *Si/Gun/Gu*. *<Newly Inserted by Act No. 17067, Mar. 4, 2020>*
- (3) Epidemiological investigation officers shall be appointed, from among any of the following persons who have completed the course of education and training on epidemiological investigations under Article 18-3:
 1. Public officials in charge of affairs of disease control, epidemiological investigation, or vaccination;
 2. Medical personnel prescribed in Article 2 (1) of the Medical Service Act;
 3. Other experts in fields related to infectious diseases and epidemiology, such as pharmacists prescribed in subparagraph 2 of Article 2 of the Pharmaceutical Affairs Act and veterinarians prescribed in subparagraph 1 of Article 2 of the Veterinarians Act.
- (4) An epidemiological investigation officer may temporarily take measures specified under each item of subparagraph 1 of Article 47, where an emergency, in which the spread of an infectious disease is anticipated, would be likely to cause serious harm to public health if measures thereagainst is not taken immediately.
- (5) Relevant public officials, such as the head of a police agency prescribed in Article 2 of the Police Act, the head of a fire-fighting government office prescribed in Article 3 of the Framework Act on Fire-Fighting Services, and the director of a public health center prescribed in Article 10 of the Regional Public Health Act, shall cooperate in measures taken by an epidemiological investigation officer under paragraph (4) unless there is good cause. *<Amended by Act No. 17067, Mar. 4, 2020>*
- (6) Where an epidemiological investigation officer takes measures under paragraph (4), he/she shall immediately report such fact to the Minister of Health and Welfare, the competent Mayor/*Do* Governor, or the head of the competent *Si/Gun/Gu*. *<Amended by Act No. 17067, Mar. 4, 2020>*
- (7) The Minister of Health and Welfare, a Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* may subsidize epidemiological investigation officers appointed pursuant to paragraph (3) for expenses necessary to perform their duties, etc., within budgetary limits. *<Amended by Act No. 17067, Mar. 4, 2020>*
- (8) Except as provided in paragraphs (1) through (7), matters necessary for the qualification, duties, and authority of epidemiological investigation officers, the subsidization therefor, and other relevant matters shall be prescribed by Presidential Decree. *<Amended by Act No. 17067, Mar. 4, 2020>*
[This Article Newly Inserted by Act No. 13392, Jul. 6, 2015]

Article 60-3 (Temporary Duty Orders)

- (1) Where an infectious disease is likely to be transmitted into or epidemic in the Republic of Korea, or already breaks out, the Minister of Health and Welfare or a Mayor/*Do* Governor may order any medical personnel prescribed in Article 2 (1) of the Medical Service Act to perform disease control duties for a specified period at a medical institution designated as an infectious disease control

institution under Article 36 or 37, or an infectious disease specialty hospital or infectious disease research hospital established or designated under Article 8-2.

- (2) In emergency situations where an infectious disease is transmitted into or epidemic in the Republic of Korea, the Minister of Health and Welfare may appoint any person falling under Article 60-2 (3) 2 or 3 as a disease control officer to perform disease control duties for a specified period. *<Amended by Act No. 17067, Mar. 4, 2020>*
- (3) Where epidemiological investigation personnel are undermanned due to the transmission or epidemic of an infectious disease, the Minister of Health and Welfare, a Mayor/Do Governor, or the head of a *Si/Gun/Gu* may appoint any person falling under Article 60-2 (3) 2 or 3 as an epidemiological investigation officer to perform duties related to epidemiological investigations for a specified period. *<Amended by Act No. 17067, Mar. 4, 2020>*
- (4) A disease control officer or epidemiological investigation officer appointed by the Minister of Health and Welfare, a Mayor/Do Governor, or the head of a *Si/Gun/Gu* under paragraph (2) or (3) shall be deemed appointed as a public official in a fixed term position defined in Article 26-5 of the State Public Officials Act. *<Amended by Act No. 17067, Mar. 4, 2020>*
- (5) Matters necessary for temporary duty orders issued under paragraph (1), and the period, procedures, etc. for appointment under paragraphs (2) and (3) shall be prescribed by Presidential Decree.

[This Article Newly Inserted by Act No. 13639, Dec. 29, 2015]

Article 61 (Quarantine Inspection Commissioners)

- (1) Where necessary for the prevention of infectious diseases, a Mayor/Do Governor may appoint a quarantine inspection commissioner to perform affairs concerning quarantine inspections, and if particularly necessary, may require the commissioner to quarantine any means of transportation, etc.
- (2) Quarantine inspection commissioners may board any means of transportation, etc. free of charge to perform affairs or quarantine inspections stipulated under paragraph (1).
- (3) Matters necessary for the appointment, duties, etc. of quarantine inspection commissioners under paragraph (1), shall be determined by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 9932, Jan. 18, 2010>*

Article 62 (Disease Prevention Commissioners)

- (1) Where an infectious disease is epidemic or likely to be epidemic, the Special Self-Governing Province Governor or the head of a *Si/Gun/Gu* may appoint a disease prevention commissioner at the relevant Special Self-Governing Province or *Si/Gun/Gu* (referring to an autonomous *Gu*; hereinafter the same shall apply) to perform affairs concerning the prevention of infectious diseases.
- (2) Disease prevention commissioners appointed under paragraph (1) shall serve without compensation: *Provided*, That a paid disease prevention commissioner may be appointed at the rate of one commissioner per 20,000 population of the Special Self-Governing Province or *Si/Gun/Gu*.
- (3) Matters necessary for the appointment, duties, etc. of disease prevention commissioners referred to in paragraph (1), shall be determined by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 9932, Jan. 18, 2010>*

Article 63 (Korea Association of Health Promotion)

- (1) The Korea Association of Health Promotion (hereinafter referred to as the "Association") shall be established to perform prevention projects including investigations and research on parasitic diseases defined in subparagraph 6 of Article 2. *<Amended by Act No. 15534, Mar. 27, 2018>*
- (2) The Association shall be a corporation.
- (3) Except as provided in this Act, the provisions concerning incorporated associations under the Civil Act shall apply *mutatis mutandis* to the Association.

CHAPTER X Expenses

Article 64 (Expenses to Be Borne by Special Self-Governing Province and Sis/Guns/Gus)

The following expenses shall be borne by the relevant Special Self-Governing Province or *Si/Gun/Gu*: <Amended by Act No. 13392, Jul. 6, 2015; Act No. 13639, Dec. 29, 2015>

1. Some expenses incurred in providing support to corporations or associations which perform preventive and treatment duties of Hansen's disease pursuant to Article 4 (2) 13;
2. Expenses incurred in conducting vaccinations pursuant to Articles 24 (1) and 25 (1);
3. All or some expenses incurred by medical institutions in conducting vaccinations pursuant to Articles 24 (2) and 25 (2);
4. Expenses incurred by infectious disease control institutions designated by the Special Self-Governing Province Governor or the head of a *Si/Gun/Gu* in establishing and operating infectious disease control facilities pursuant to Article 36;
5. Expenses incurred in establishing and operating isolation wards, sanatoriums, or clinics established by the Special Self-Governing Province Governor or the head of a *Si/Gun/Gu* pursuant to Article 37, and infectious disease control facilities of infectious disease control institutions designated under the same Article;
6. Subsidization for ensuring the minimum security level defined in subparagraph 6 of Article 2 of the National Basic Living Security Act to those who suffer difficulties in livelihood due to a traffic blockage or hospitalization under subparagraph 1 or 3 of Article 47;
7. Expenses incurred in disinfection or other measures conducted or taken by a Special Self-Governing Province and a *Si/Gun/Gu* pursuant to Articles 47, 48, 49 (1) 8, 9, and 13, and 51 (1);
8. Allowances, treatment expenses, or compounding fees for assigning physicians and for mobilizing medical persons, medical practitioners, and other medical personnel by the Special Self-Governing Province Governor or the head of a *Si/Gun/Gu* pursuant to Article 49 (1) 7 and 12;
9. Expenses incurred in supplying potable water pursuant to Article 49 (2);
10. Expenses incurred in assigning disease prevention commissioners pursuant to Article 62;
11. Other expenses incurred in conducting affairs concerning the prevention of infectious diseases by the Special Self-Governing Province and a *Si/Gun/Gu* pursuant to this Act.

Article 65 (Expenses to Be Borne by Cites/Dos)

The following expenses shall be borne by the relevant City/Do: <Amended by Act No. 13639, Dec. 29, 2015; Act No. 15534, Mar. 27, 2018>

1. Some expenses incurred in providing support to corporations or associations which perform preventive and treatment duties of Hansen's disease pursuant to Article 4 (2) 13;
2. Expenses incurred by infectious disease control institutions designated by a Mayor/Do Governor pursuant to Article 36 in establishing and operating their infectious disease control facilities;
3. Expenses incurred in establishing and operating isolation wards, sanatoriums, or clinics established by a Mayor/Do Governor pursuant to Article 37, and infectious disease control facilities of infectious disease control institutions designated under the same Article;
- 3-2. Expenses incurred in establishing and operating facilities for quarantining contacts designated by a Mayor/Do Governor pursuant to Article 39-3;
4. Expenses incurred in the inpatient treatment, investigations, medical diagnoses, etc. of Korean patients of an infectious disease, etc. under Articles 41 and 42;
5. Expenses incurred in conducting medical examinations, vaccination, etc. pursuant to Article 46;
6. Subsidization for ensuring the minimum security level defined in subparagraph 6 of Article 2 of the National Basic Living Security Act to those who suffer difficulties in livelihood due to the traffic blockage under Article 49 (1) 1;

- 6-2. Allowances, treatment expenses, or compounding fees for mobilizing medical persons, medical practitioners, and other medical personnel by a Mayor/*Do* Governor pursuant to Article 49 (1) 12;
- 7. Expenses incurred in supplying potable water pursuant to Article 49 (2);
- 7-2. Allowances and other expenses incurred in assigning medical persons, etc. to disease control duties by a Mayor/*Do* Governor pursuant to Article 60-3 (1) and (3);
- 8. Expenses incurred in assigning quarantine inspection commissioners pursuant to Article 61;
- 9. Other expenses incurred in conducting affairs concerning the prevention of infectious diseases by a City/*Do* pursuant to this Act.

Article 66 (Expenses to Be Subsidized by City/Do)

A City/*Do* (excluding a Special Self-Governing Province) shall subsidize expenses to be borne by respective *Si/Gun/Gu* pursuant to Article 64, as prescribed by Presidential Decree.

Article 67 (Expenses to Be Borne by National Treasury)

The following expenses shall be borne by the National Treasury: *<Amended by Act No. 9932, Jan. 18, 2010; Act No. 13392, Jul. 6, 2015; Act No. 13639, Dec. 29, 2015; Act No. 15534, Mar. 27, 2018; Act No. 16725, Dec. 3, 2019; Act No. 17067, Mar. 4, 2020>*

- 1. Expenses incurred in the medical treatment and protection of patients of an infectious disease, etc. under Article 4 (2) 2;
- 2. Expenses incurred in the education and publicity of infectious diseases under Article 4 (2) 4;
- 3. Expenses incurred in nurturing specialists for the prevention of infectious diseases under Article 4 (2) 8;
- 4. Expenses incurred in conducting sentinel surveillance activities under Article 16 (4);
- 4-2. Expenses incurred in conducting education and training under Article 18-3;
- 5. Expenses incurred in transporting corpses for autopsies under Article 20, and in disposal of them after autopsies;
- 5-2. Expenses incurred in conducting funerals for the deceased persons under Article 20-2;
- 6. Expenses incurred in the production, research, etc., of vaccines under Article 33;
- 6-2. Expenses incurred in stockpiling mandatory vaccines, etc. under Article 33-2 (1);
- 6-3. Expenses incurred by infectious disease control institutions designated by the Minister of Health and Welfare in establishing and operating their infectious disease control facilities pursuant to Article 36 (1);
- 7. Expenses incurred in establishing and operating isolation wards, sanatoriums, or clinics established by the Minister of Health and Welfare pursuant to Article 37, and infectious disease control facilities of infectious disease control institutions designated under the same Article;
- 7-2. Expenses incurred in establishing and operating facilities for quarantining contacts designated by the Minister of Health and Welfare pursuant to Article 39-3;
- 8. Expenses incurred in stockpiling and concluding contracts for long-term purchase of medicines and equipment found necessary after undergoing deliberation by the Committee pursuant to Article 40 (1);
- 9. Expenses incurred in conducting the inpatient treatment, investigations, medical examinations, etc. of foreign patients of an infectious disease, etc. under Articles 41 and 42;
- 9-2. Allowances, medical costs, or compounding fees for mobilizing medical persons, medical practitioners, and other medical personnel by the State pursuant to Article 49 (1) 12;
- 9-3. Allowances and other expenses incurred in assigning medical persons, etc. to disease control duties by the State pursuant to Article 60-3 (1) through (3);
- 10. Expenses incurred in compensating injuries caused by vaccinations, etc. under Article 71.

Article 68 (Expenses to Be Subsidized by the State)

The State shall subsidize the following expenses:

1. Some expenses incurred in providing support to corporations or associations which perform preventive and treatment duties of Hansen's disease pursuant to Article 4 (2) 13;
2. At least 1/2 of expenses to be borne by Cities/Dos pursuant to Articles 65 and 66.

Article 69 (Expenses Collectible from Patients)

The Special Self-Governing Province Governor or the head of a *Si/Gun/Gu* may collect expenses incurred in hospitalization, medical diagnosis, examination, treatment, etc. due to a person's chronic disease, newly-diagnosed disease, etc., other than expenses incurred in inpatient treatment under Articles 41 and 42, from the person or his/her guardian, as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010>

Article 70 (Compensation for Loss)

- (1) The Minister of Health and Welfare, a Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* shall pay compensation to a person suffering from any of the following losses, according to the results of deliberation and resolution by the relevant Compensation Deliberation Committee established under Article 70-2: <Amended by Act No. 13639, Dec. 29, 2015; Act No. 15534, Mar. 27, 2018>
 1. Loss resulting from the designation of an infectious disease control institution or the establishment and operation of an isolation ward, etc. under Article 36 or 37;
 - 1-2. Loss resulting from the establishment and operation of facilities for quarantining contacts under Article 39-3;
 2. Loss suffered by a medical institution who has given medical treatment to patients or probable patients of an infectious diseases, etc. in accordance with any measure taken under this Act;
 3. Loss suffered by a medical institution due to its closure, suspension of business, etc. under this Act;
 4. Loss resulting from a measure taken under subparagraph 1, 4, or 5 of Article 47, Article 48 (1), or Article 49 (1) 4, 6 through 10, 12, or 13;
 5. Loss equivalent to any loss specified in subparagraphs 1 through 4, which is suffered by a health care institution defined in Article 42 of the National Health Insurance Act due to the occurrence or visitation of a patient of an infectious disease, etc. or due to the disclosure thereof by the Minister of Health and Welfare, a Mayor/*Do* Governor, or the head of a *Si/Gun/Gu*, and the compensation for which is deliberated and resolved by the relevant Compensation Deliberation Committee established under Article 70-2.
- (2) Any person seeking compensation for loss under paragraph (1) shall file a claim for compensation for loss with the Minister of Health and Welfare, the relevant Mayor/*Do* Governor, or the head of the relevant *Si/Gun/Gu*, by appending relevant documents to the written claim for compensation for loss, as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 13639, Dec. 29, 2015>
- (3) In determining the amount of compensation under paragraph (1), if the person who has suffered a loss caused or expanded the loss in violation of obligation to take measures under this Act or the relevant statutes or regulations, the Minister of Health and Welfare, the relevant Mayor/*Do* Governor, or the head of the relevant *Si/Gun/Gu* may choose not to pay the relevant compensation, or may reduce the amount thereof. <Newly Inserted by Act No. 13639, Dec. 29, 2015>
- (4) Matters necessary for the subject matter and extent of compensation and the determination of the amount of compensation to be paid under paragraph (1), standards for choosing the non-payment of compensation and reducing the amount thereof under paragraph (3), and other relevant matters shall be prescribed by Presidential Decree. <Newly Inserted by Act No. 13639, Dec. 29, 2015>

Article 70-2 (Compensation Deliberation Committee)

- (1) In order to deliberate and resolve on issues regarding compensation provided for in Article 70, a Compensation Deliberation Committee (hereinafter referred to as “Deliberation Committee”) shall be established under the Ministry of Health and Welfare and each City/Do.
- (2) A Deliberation Committee shall be comprised of not exceeding 20 members, including two chairpersons; the Deliberation Committee established under the Ministry of Health and Welfare shall be co-chaired by the Vice Minister of Health and Welfare and a non-governmental member; and a Deliberation Committee established in each City/Do shall be co-chaired by its Vice Mayor/Governor and a non-governmental member.
- (3) Members of a Deliberation Committee shall be appointed or commissioned by the Minister of Health and Welfare or the competent Mayor/Do Governor, from among persons with substantial knowledge and experience in the relevant fields and related public officials, as prescribed by Presidential Decree.
- (4) If required for a deliberation and resolution process under paragraph (1), a Deliberation Committee may request interested parties to attend a Committee meeting or to submit data.
- (5) Other necessary matters concerning the composition, operation, etc., of Deliberation Committees shall be prescribed by Presidential Decree.

[This Article Newly Inserted by Act No. 13639, Dec. 29, 2015]

Article 70-3 (Subsidization to Medical Persons and Founders of Medical Institutions)

- (1) The Minister of Health and Welfare, a Mayor/Do Governor, and the head of a *Si/Gun/Gu* may subsidize the medical persons or founders of medical institutions who have supported activities for the surveillance, prevention, control, or epidemiological investigation of an infectious disease under this Act, within budgetary limits.
- (2) Necessary matters concerning the details, procedure, methods, etc. of subsidization referred to in paragraph (1), shall be prescribed by Presidential Decree.

[This Article Newly Inserted by Act No. 13639, Dec. 29, 2015]

Article 70-4 (Livelihood Assistance for Patients of Infectious Disease)

- (1) The Minister of Health and Welfare, a Mayor/Do Governor, and the head of a *Si/Gun/Gu* may provide treatment expenses, livelihood assistance, and other financial support to persons hospitalized, quarantined, or isolated under this Act, within budgetary limits.
- (2) Where a person specified in paragraph (1) or a medical person specified in Article 70-3 (1) is unable to care for his/her child because of hospitalization, quarantine, or isolation, or support for surveillance, prevention, control, or epidemiological investigation of an infectious disease, the relevant Mayor/Do Governor and the head of the relevant *Si/Gun/Gu* shall take necessary measures, including child-care support defined under the Child-Care Support Act.
- (3) Matters necessary for providing assistance and support under paragraphs (1) and (2) shall be prescribed by Presidential Decree.

[This Article Newly Inserted by Act No. 13639, Dec. 29, 2015]

Article 71 (Compensation by the State for Injury Caused by Vaccination)

- (1) Where a person who has been vaccinated pursuant to Articles 24 and 25, or a person who has been administered a preventive and therapeutic medicine pursuant to Article 40 (2) contracts a disease, becomes disabled, or dies due to such vaccination or preventive and therapeutic medicine, the State shall pay the following compensation according to the standards and procedures prescribed by Presidential Decree:
 1. A person who receives treatment for a disease: All medical expenses and a fixed amount of nursing expenses;

2. A person who becomes disabled: A lump-sum compensation;
 3. A deceased person: A lump-sum compensation for the bereaved family members and funeral expenses prescribed by Presidential Decree.
- (2) A disease, disability, or death eligible for the compensation under paragraph (1) shall be limited to cases recognized by the Minister of Health and Welfare, in which injury is caused by vaccination or administration of a preventive and therapeutic medicine, regardless of abnormality of the relevant vaccine, or negligence of the person who performed vaccination or administered the relevant preventive or therapeutic medicine. *<Amended by Act No. 9932, Jan. 18, 2010>*
- (3) The Minister of Health and Welfare shall determine whether a filed case is applicable to a disease, disability, or death under paragraph (2) within 120 days from the date a claim for compensation under paragraph (1) is filed. In such cases, he/she shall hear the opinions of the Committee in advance. *<Amended by Act No. 9932, Jan. 18, 2010>*
- (4) Matters necessary for the claims for compensation under paragraph (1), the methods of and procedures for determination under paragraph (3), and other relevant matters shall be prescribed by Presidential Decree.

Article 72 (Relationship to Claim for Injury)

- (1) Where the State has paid compensations for injury under Article 71 due to any abnormal vaccine, or an intentional or negligent conduct of a third party, including a person, etc. who performed vaccination or administered a preventive and therapeutic medicine, the State shall subrogate the relevant recipient of such compensation to a claim for compensation for injury against the third party, to the extent of the amount of such paid compensation.
- (2) Where a person who has been vaccinated or administered a preventive and therapeutic medicine, or his/her bereaved family member referred to in Article 71 (1) 3 has been paid compensations by a third party, the State shall not pay any of the compensations referred to in Article 71, to the extent of the amount of such paid compensation, and where the State has erroneously paid compensation, it may collect the relevant amount in the same manner as national taxes are collected.

Article 73 (Prohibition from Transferring, etc. Entitlement to Compensation by the State)

No entitlement to compensation pursuant to Articles 70 and 71 may be transferred or seized.

CHAPTER XI Supplementary Provisions

Article 74 (Prohibition on Divulgence of Confidential Information)

No person who is or has been engaged in duties relevant to infectious diseases, such as medical examinations, inpatient treatment, diagnosis, etc. under this Act shall divulge any confidential information he/she has obtained in the course of performing his/her duties to any third person.

Article 74-2 (Request for Providing Materials, and Inspection)

- (1) The Minister of Health and Welfare, a Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* may request the heads of infectious disease control institutions, etc., to provide materials concerning the establishment and operation of infectious disease control facilities, and isolation wards, sanatoriums, or clinics prescribed in Article 37, or facilities for quarantining contacts prescribed in Article 39-3, and may require public officials under his/her jurisdiction to enter the relevant facilities and inspect related documents, facilities, equipment, etc., and to make inquiries to relevant persons. *<Amended by Act No. 15534, Mar. 27, 2018>*
- (2) A public official who enters and conducts inspections pursuant to paragraph (1) shall carry an

identification indicating his/her authority and produce it to relevant persons.

[This Article Newly Inserted by Act No. 13392, Jul. 6, 2015]

Article 75 (Hearings)

The Special Self-Governing Province Governor or the head of a *Si/Gun/Gu* shall hold a hearing if he/she intends to issue an order to close a place of business pursuant to Article 59 (1).

Article 76 (Delegation and Entrustment)

- (1) The authority of the Minister of Health and Welfare stipulated under this Act may be partially delegated to the Director of the Korea Centers for Disease Control and Prevention, or a Mayor/*Do* Governor, as prescribed by Presidential Decree. *<Amended by Act No. 9932, Jan. 18, 2010>*
- (2) The Minister of Health and Welfare may entrust part of his/her duties under this Act to the relevant institutions or organizations, as prescribed by Presidential Decree. *<Newly Inserted by Act No. 11439, May 23, 2012>*

Article 76-2 (Request for Provision of Information and Verification of Information)

- (1) If necessary to prevent infectious diseases and block the spread of infection, the Minister of Health and Welfare or the Director of the Korea Centers for Disease Control and Prevention may request the heads of relevant central administrative agencies (including affiliated agencies and responsible administrative agencies thereof), the heads of local governments (including the superintendents of education prescribed in Article 18 of the Local Education Autonomy Act), public institutions designated under Article 4 of the Act on the Management of Public Institutions, medical institutions, pharmacies, corporations, organizations, and individuals to provide the following information concerning patients of infectious diseases, etc. and persons suspected of contracting infectious diseases, and persons in receipt of such request shall comply therewith: *<Amended by Act No. 14286, Dec. 2, 2016; Act No. 17067, Mar. 4, 2020>*
 1. Personal information, such as names, resident registration numbers prescribed in Article 7-2 (1) of the Resident Registration Act, addresses, and telephone numbers (including cell phone numbers);
 2. Prescriptions prescribed in Article 17 of the Medical Service Act and medical records, etc. prescribed in Article 22 of the same Act;
 3. Records of immigration control during the period determined by the Minister of Health and Welfare;
 4. Other information prescribed by Presidential Decree for monitoring the movement paths of such patients, etc.
- (2) If necessary to prevent infectious diseases and block the spread of infection, the Minister of Health and Welfare, a Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* may request the Commissioner General of the Korean National Police Agency, the commissioner of a district police agency, or the chief of a police station referred to in Article 2 of the Police Act (hereafter in this Article referred to as “police agency”) to provide location information of patients of an infectious disease, etc. and persons suspected of contracting an infectious disease. In such cases, notwithstanding Article 15 of the Act on the Protection and Use of Location Information and Article 3 of the Protection of Communications Secrets Act, the head of the relevant police agency, upon request by the Minister of Health and Welfare, a Mayor/*Do* Governor, or the head of a *Si/Gun/Gu*, may request any personal location information provider defined in Article 5 (7) of the Act on the Protection and Use of Location Information and any telecommunications business operator defined in subparagraph 8 of Article 2 of the Telecommunications Business Act to provide location information of patients of an infectious disease, etc. and persons suspected of contracting an infectious disease; and the personal location information provider and the telecommunications business operator in receipt of such

request shall comply therewith unless there is good cause. <Amended by Act No. 13639, Dec. 29, 2015; Act No. 15608, Apr. 17, 2018; Act No. 17067, Mar. 4, 2020>

- (3) The Minister of Health and Welfare may provide information collected pursuant to paragraphs (1) and (2) to the heads of the relevant central administrative agencies, the heads of local governments, the President of the National Health Insurance Service, the President of the Health Insurance Review and Assessment Service, health and medical services institutions defined in subparagraph 4 of Article 3 of the Framework Act on Health and Medical Services (hereinafter referred to as “health and medical services institutions”), other organizations, etc. In such cases, information provided to health and medical services institutions, etc. shall be limited to information related to the affairs of the relevant institutions, etc. for preventing infectious diseases and blocking the spread of infection. <Amended by Act No. 17067, Mar. 4, 2020>
- (4) Notwithstanding the former part of paragraph (3), if necessary to prevent infectious diseases and block the spread of infection, the Minister of Health and Welfare shall provide information prescribed in paragraph (1) 3 and information on movement paths prescribed in subparagraph 4 of the same paragraph to health and medical services institutions using any of the following information and communications systems. In such cases, information provided to health and medical services institutions shall be limited to information related to the affairs of the relevant institutions: <Newly Inserted by Act No. 17067, Mar. 4, 2020>
1. The information system of the National Health Insurance Service;
 2. The information system of the Health Insurance Review and Assessment Service;
 3. The information system of an institution deemed necessary and designated by the Minister of Health and Welfare to prevent any infectious disease from being transmitted into or spreading in the Republic of Korea.
- (5) When providing medical treatment or prescribing or preparing medicines, medical personnel, pharmacists, and the heads of health and medical services institutions shall check information provided pursuant to paragraph (4) using an information system prescribed in any subparagraph of the same paragraph. <Newly Inserted by Act No. 17067, Mar. 4, 2020>
- (6) No person provided with information pursuant to paragraphs (3) and (4) shall use such information for any purpose, other than conducting affairs related to infectious diseases under this Act, and shall, without delay, destroy all information after completing the relevant affairs and inform the Minister of Health and Welfare thereof. <Amended by Act No. 17067, Mar. 4, 2020>
- (7) The Minister of Health and Welfare, a Mayor/Do Governor, or the head of a *Si/Gun/Gu* shall notify the subject of information collected pursuant to paragraphs (1) and (2), of the following: <Amended by Act No. 17067, Mar. 4, 2020>
1. The fact that information necessary for preventing infectious diseases and blocking the spread of infection has been collected;
 2. Where information prescribed in subparagraph 1 has been provided to another agency, such fact;
 3. The fact that, even in cases prescribed in subparagraph 2, no information shall be used for any purpose, other than conducting affairs related to infectious diseases under this Act, and all the information shall be destroyed without delay when the relevant affairs are completed.
- (8) Where a person provided with information pursuant to paragraphs (3) and (4) processes the relevant information in violation of this Act, such person shall be governed by the Personal Information Protection Act. <Amended by Act No. 17067, Mar. 4, 2020>
- (9) Matters necessary for the target and scope of information provided under paragraph (3), the methods of notification under paragraph (7), and other relevant matters shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 17067, Mar. 4, 2020>

[This Article Newly Inserted by Act No. 13392, Jul. 6, 2015]

Article 76-3 (Provisions to Be Applied Mutatis Mutandis)

With respect to hospitalization, quarantine, or isolation referred to in Article 41 (1) and (2), subparagraph 3 of Article 47, and Article 49 (1) 14, Article 42 (6) shall apply *mutatis mutandis*.

[This Article Newly Inserted by Act No. 17067, Mar. 4, 2020]

Article 76-4 (Legal Fiction as Public Officials for Purposes of Penalty Provisions)

A non-public official member of the Deliberation Committee shall be deemed a public official for the purposes of penalty provisions pursuant to Articles 127 and 129 through 132 of the Criminal Act.

[This Article Newly Inserted by Act No. 17067, Mar. 4, 2020]

CHAPTER XII Penalty Provisions

Article 77 (Penalty Provisions)

Any of the following persons shall be punished by imprisonment with labor for not more than five years or by a fine not exceeding 50 million won:

1. A person who introduces high-risk pathogens into the domestic environment without obtaining permission therefor, in violation of Article 22 (1) or (2);
2. A person who possesses any pathogen of an infectious disease spread through bioterrorism without obtaining permission therefor, in violation of Article 23-3 (1);
3. A person who exports quasi-drugs, etc. or ships them out of the Republic of Korea, in violation of Article 40-3 (1).

[This Article Wholly Amended by Act No. 17067, Mar. 4, 2020]

Article 78 (Penalty Provisions)

Any of the following persons shall be punished by imprisonment with labor for not more than three years or by a fine not exceeding 30 million won: <Amended by Act No. 15183, Dec. 12, 2017; Act No. 16725, Dec. 3, 2019>

1. A person who establishes and operates a facility handling high-risk pathogens without obtaining permission prescribed in Article 23 (2) or without obtaining permission for modification prescribed in the main clause of paragraph (3) of the same Article;
2. A person who fails to obtain permission for modification prescribed in Article 23-3 (3);
3. A person who divulges any confidential information that he/she has become aware of in the course of performing his/her duties, in violation of Article 74.

Article 79 (Penalty Provisions)

Any of the following persons shall be punished by imprisonment with labor for not more than two years or by a fine not exceeding 20 million won: <Amended by Act No. 13392, Jul. 6, 2015; Act No. 15183, Dec. 12, 2017; Act No. 16725, Dec. 3, 2019; Act No. 17067, Mar. 4, 2020>

1. A person who violates Article 18 (3);
2. A person who fails to file a report prescribed in Article 21 (1) through (3) or 22 (3) or files a false report;
- 2-2. A person who refuses, obstructs, or evades an on-site inspection prescribed in Article 21 (5) without good cause;
- 2-3. A person who establishes and operates a facility handling high-risk pathogens without filing a report prescribed in Article 23 (2);
3. A person who refuses, obstructs, or evades an inspection for safety control prescribed in Article 23 (8);
- 3-2. A person who violates an order to close, or suspend the operation of, a facility handling high-risk

pathogens prescribed in Article 23-2;

4. A person who violates Article 60 (4) (except for public officials);
5. A person who violates Article 76-2 (6).

Article 79-2 (Penalty Provisions)

Any of the following persons shall be punished by imprisonment with labor for not more than one year or by a fine not exceeding 20 million won: <Amended by Act No. 16725, Dec. 3, 2019>

1. A person who handles high-risk pathogens, in violation of Article 23-4 (1);
2. A person who has another person handle high-risk pathogens, in violation of Article 23-4 (2);
3. A person who refuses to comply with a request made by the head of a police agency, in violation of the latter part of Article 76-2 (2).

[This Article Newly Inserted by Act No. 13639, Dec. 29, 2015]

Article 79-3 (Penalty Provisions)

Any of the following persons shall be punished by imprisonment with labor for not more than one year or by a fine not exceeding 10 million won:

1. A person who fails to receive inpatient treatment, in violation of Article 41 (1);
2. A person who refuses hospitalization or treatment, in violation of Article 41 (2);
3. A person who refuses medical treatment at his/her home or in an infectious disease control facility, in violation of Article 41 (3);
4. A person who refuses hospitalization, quarantine, or isolation prescribed in Article 42 (1), (2) 1, (3), or (7);
5. A person who violates any measure for hospitalization, quarantine, or isolation prescribed in subparagraph 3 of Article 47 or 49 (1) 14.

[This Article Newly Inserted by Act No. 17067, Mar. 4, 2020]

Article 79-4 (Penalty Provisions)

Any of the following persons shall be punished by a fine not exceeding five million won:

1. A physician, a dentist, an oriental medical doctor, a military doctor, the head of a medical institution, or the head of an institution for confirming pathogens of infectious diseases who fails to file a report required under Article 11 or files a false report, regarding Classes 1 and 2 infectious diseases;
2. A person who obstructs filing a report by a physician, a dentist, an oriental medical doctor, a military doctor, the head of a medical institution, or the head of an institution for confirming pathogens of infectious diseases under Article 11, regarding Classes 1 and 2 infectious diseases.

[This Article Newly Inserted by Act No. 15534, Mar. 27, 2018]

Article 80 (Penalty Provisions)

Any of the following persons shall be punished by a fine not exceeding three million won: <Amended by Act No. 15534, Mar. 27, 2018; Act No. 17067, Mar. 4, 2020>

1. A physician, a dentist, an oriental medical doctor, a military doctor, the head of a medical institution, the head of an institution for confirming pathogens of infectious diseases, or an institution of sentinel surveillance of infectious diseases that fails to file a report required under Article 11 or files a false report, regarding Classes 3 and 4 infectious diseases;
2. A person who obstructs filing a report by a physician, a dentist, an oriental medical doctor, a military doctor, the head of a medical institution, the head of an institution for confirming pathogens of infectious diseases, or an institution of sentinel surveillance of infectious diseases under Article 11, regarding Classes 3 and 4 infectious diseases;
- 2-2. A person who refuses infectious pathogen testing referred to in Article 13 (2);
3. A person who fails to establish infectious disease control facilities, in violation of Article 37 (4);

4. Deleted; <by Act No. 17067, Mar. 4, 2020>
5. A person who fails to comply with a compulsory disposition referred to in Article 42 (excluding persons who refuse hospitalization, quarantine, or isolation prescribed in Article 42 (1), (2) 1, (3), or (7));
6. A person who engages in an occupation involving frequent contact with the general public or who employs patients of an infectious disease, etc. for such occupation, in violation of Article 45;
7. A person who violates any measure taken under Article 47 (excluding subparagraph 3 of the same Article) or 49 (1) (excluding matters concerning medical examinations referred to in subparagraph 3 of the same paragraph, and subparagraph 14 of the same paragraph);
8. A person who renders disinfection services without reporting under Article 52 (1) or after reporting by fraud or other improper means;
9. A person who fails to conduct disinfection in compliance with standards and methods stipulated under Article 54 (1).

Article 81 (Penalty Provisions)

Any of the following persons shall be punished by a fine not exceeding two million won: <Amended by Act No. 13392, Jul. 6, 2015; Act No. 16725, Dec. 3, 2019>

1. and 2. Deleted; <by Act No. 15534, Mar. 27, 2018>
3. A person who neglects to file a report under Article 12 (1);
4. A person who requests a householder, manager, etc., not to file a report under Article 12 (1);
5. Deleted; <by Act No. 13392, Jul. 6, 2015>
6. A person who refuses to comply with an autopsy order issued under Article 20;
7. A person who issues a false certificate of vaccination, in violation of Article 27;
8. A person who refuses, obstructs, or evades an epidemiological investigation, in violation of Article 29;
9. A person who allows a person who fails to undergo a medical examination for sexually transmitted infectious diseases to engage in business, in violation of Article 45 (2);
10. A person who refuses or evades a medical examination, in violation of Article 46 or 49 (1) 3;
11. A person who fails to comply with a request to provide data prescribed in Article 74-2 (1) or provides false data or who refuses, obstructs, or evades any inspection or inquiry, without good cause.

Article 82 (Joint Penalty Provisions)

Where a representative of a corporation, or an agent or an employee of, or any other person employed by, a corporation or individual commits a violation under Articles 77 through 81 in connection with the business of the corporation or individual, in addition to the punishment of such violator, the corporation or individual shall be punished by a fine under the respective provisions: *Provided*, That where such corporation or individual has not been negligent in giving due attention and supervision concerning the relevant duties to prevent such violation, this shall not apply.

Article 83 (Administrative Fines)

- (1) Any of the following persons shall be subject to an administrative fine not exceeding 10 million won: <Newly Inserted by Act No. 13392, Jul. 6, 2015; Act No. 15183, Dec. 12, 2017; Act No. 16725, Dec. 3, 2019>
 1. A person who fails to file a report on modification under the proviso of Article 23 (3) or paragraph (4) of the same Article;
 2. A person who fails to file a report under Article 23 (5);
 3. A person who fails to file a report on modification under the proviso of Article 23-3 (3);
 4. A person who makes any false statement, presents any false materials, or intentionally omits or

conceals any fact, in violation of Article 35-2.

- (2) Any of the following persons shall be subject to an administrative fine not exceeding one million won: <Amended by Act No. 13392, Jul. 6, 2015; Act No. 16725, Dec. 3, 2019; Act No. 17067, Mar. 4, 2020>
1. A person who fails to file a report under Article 28 (2) or files a false report;
 2. A person who fails to file a report under Article 33-3 or files a false report;
 3. A person who fails to disinfect under Article 51 (3);
 4. A person who fails to report the suspension, permanent closure, or reopening of business under Article 53 (1) and (2);
 5. A person who fails to keep records of and retain matters concerning disinfection under Article 54 (2) or keeps false records thereof.
- (3) Administrative fines prescribed in paragraphs (1) and (2) shall be imposed and collected by the Minister of Health and Welfare, the competent Mayor/Do Governor, or the head of the competent Si/Gun/Gu, as prescribed by Presidential Decree. <Amended by Act No. 13392, Jul. 6, 2015>

Addenda <Act No. 17067, Mar. 4, 2020>

Article 1 (Enforcement Date)

This Act shall enter into force six months after the date of its promulgation: *Provided*, That the following provisions shall enter into force on the relevant respective dates classified as follows:

1. The amended provisions of Articles 2, 11 (1), 13, 16-2 (1), 22, 23, 23-2, 34-2, 40-3, 42, 47, 49, 52 (2) through (4), 53, 59, 60, 60-3 (limited to the part pertaining to the head of a Si/Gun/Gu), 76-2, and 76-3; subparagraphs 3 and 5 of Article 79; and Article 83 (2) 3: The promulgation date of this Act;
2. The amended provisions of Articles 7, 49-2, 51, 52 (1), 56, and 76-4; and the amended provisions of Article 83 (2) 3 of the Infectious Disease Control and Prevention Act (Act No. 16725): Three months after the promulgation date of this Act;
3. The amended provisions of Articles 21, 23, and 77, and subparagraph 2-2 of Article 79 of the Infectious Disease Control and Prevention Act (Act No. 16725): June 4, 2020;
4. The amended provisions of Articles 77, 79-3, 79-4, and 80: One month after the promulgation date of this Act.

Article 2 (Transitional Measures concerning Epidemiological Investigation Officers)

The epidemiological investigation officers assigned by a Mayor/Do Governor in a Si/Gun/Gu under the former provisions as at the time this Act enters into force shall be deemed epidemiological investigation officers appointed by the head of a Si/Gun/Gu under the amended provisions of Article 60-2.

2.2 Enforcement Decree of The Infectious Disease Control and Prevention Act

Presidential Decree No. 30596, Apr. 2, 2020

Article 1 (Purpose)

The purpose of this Decree is to prescribe matters delegated by the Infectious Disease Control and Prevention Act and other matters necessary for the enforcement of said Act.

Article 1-2 (Establishment and Operation of Organizations Supporting Infectious Disease Control Projects)

- (1) Under Article 8 (1) of the Infectious Disease Control and Prevention Act (hereinafter referred to as the "Act"), the Central Organization Supporting Infectious Disease Control Projects shall be established in the Ministry of Health and Welfare; and City/*Do* organizations supporting infectious disease projects in the Special Metropolitan City, Metropolitan Cities, Dos, and Special Self-Governing Province (hereinafter referred to as "City/Do"), as prescribed by the Minister of Health and Welfare.
- (2) Members of the Central Organization Supporting Infectious Disease Control Projects shall be commissioned by the Minister of Health and Welfare, from among the following:
 1. A person who has worked in infectious disease-related areas as a member of medical personnel defined in subparagraph 1 of Article 2 of the Medical Service Act;
 2. A person who has worked in infectious disease-related areas at universities prescribed in the Higher Education Act or public institutions prescribed in the Act on the Management of Public Institutions;
 3. A person with considerable knowledge and experience in the prevention and control of infectious diseases;
 4. A person with considerable knowledge and experience in the areas of epidemiological investigation, disease control, etc.;
 5. A person the Minister of Health and Welfare deems necessary for supporting infectious disease control projects.
- (3) If necessary for conducting its duties, the Central Organization Supporting Infectious Disease Control Projects may request the relevant institutions, organizations, experts, etc. to submit materials, opinions, etc.
- (4) The Central Organization Supporting Infectious Disease Control Projects shall report the status of its activities, etc. to the Minister of Health and Welfare as prescribed by the Minister of Health and Welfare every half year.
- (5) The Minister of Health and Welfare may provide the Central Organization Supporting Infectious Disease Control Projects with subsidies to cover the following costs within budgetary limits:
 1. Costs incurred in the collection of materials, investigation, analysis, consulting, etc.;
 2. Travel expenses, allowances, etc. incurred in the promotion of domestic and international cooperative projects;
 3. Other expenses the Minister of Health and Welfare deems particularly necessary for conducting duties.
- (6) Except as provided in paragraphs (2) through (5), details necessary for establishing, operating, subsidizing etc. the Central Organization Supporting Infectious Disease Control Projects shall be determined by the Minister of Health and Welfare.

- (7) Paragraphs (2) through (6) shall apply *mutatis mutandis* to commissioning of members, requests for submission of materials, reporting on the status of activities, subsidization, etc. of City/*Do* organizations supporting infectious disease control projects. In such cases, "Minister of Health and Welfare" and "Central Organization Supporting Infectious Disease Control Projects" shall be construed as "Special Metropolitan City Mayor, Metropolitan City Mayor, *Do* Governor, or Special Self-Governing Province Governor (hereinafter referred to as "Mayor/*Do* Governor") and "City/*Do* organization supporting infectious disease control projects," respectively.

[This Article Newly Inserted by Presidential Decree No. 27277, Jun. 28, 2016]

Article 1-3 (Designation of Infectious Disease Specialty Hospitals)

- (1) A medical institution (referring to a medical institution prescribed in Article 3 of the Medical Service Act; hereinafter referred to as "medical institution") eligible to be designated as an infectious disease speciality hospital prescribed in Article 8-2 (1) of the Act (hereinafter referred to as the "Central Infectious Disease Hospital") shall be a medical institution the Minister of Health and Welfare determines and publicly notifies, among general hospitals or superior general hospitals prescribed in Article 3-3 or 3-4 of the Medical Service Act.
- (2) The standards for designation of the Central Infectious Disease Hospital are as specified in attached Table 1.
- (3) Where the Minister of Health and Welfare designates the Central Infectious Disease Hospital, he/she may apply conditions to the standards for designation, conduct of duties, etc. thereof.
- (4) Where the Minister of Health and Welfare has designated the Central Infectious Disease Hospital, he/she shall deliver a certificate of designation and post the details of such designation on the website of the Ministry of Health and Welfare.
- (5) The Central Infectious Disease Hospital shall report the status of performance of duties, etc. to the Minister of Health and Welfare each quarter, as prescribed by the Minister of Health and Welfare.
- (6) The Minister of Health and Welfare may subsidize the Central Infectious Disease Hospital for building costs, operating costs, installation costs, etc., in consultation with the Minister of Economy and Finance under Article 8-2 (3) of the Act.
- (7) Except as provided in paragraphs (3) through (6), details necessary for procedures for designation, subsidies for expenses, etc. of the Central Infectious Disease Hospital shall be determined and publicly notified by the Minister of Health and Welfare.

[This Article Newly Inserted by Presidential Decree No. 27277, Jun. 28, 2016]

Article 1-4 (Designation of Regional Infectious Disease Speciality Hospitals)

- (1) A medical institution eligible to be designated as a regional infectious disease speciality hospital under Article 8-2 (2) of the Act (hereinafter referred to as a "regional infectious disease hospital"), shall be a medical institution the Minister of Health and Welfare determines and publicly announces, among general hospitals or superior general hospitals prescribed in Article 3-3 or 3-4 of the Medical Service Act.
- (2) The standards for designating regional infectious disease hospitals are as prescribed in attached Table 1-2.
- (3) Where the Minister of Health and Welfare designates a regional infectious disease hospital under Article 8-2 (2) of the Act, he/she shall consider the following matters comprehensively:
1. The level of distribution of medical service resources in the relevant region;
 2. The population and the range of habitate of the relevant region;
 3. The frequency of outbreak and the level of control of infectious diseases in the relevant region;
 4. The vicinity to harbors, airports, etc. in the relevant region;
 5. Other matters the Minister of Health and Welfare deems particularly necessary in connection with the control of infectious diseases by region.

- (4) If necessary to designate a regional infectious disease hospital, the Minister of Health and Welfare may listen to the opinions of the heads of local governments, of the relevant public institutions or organizations, etc. or request the same to submit materials.
- (5) Article 1-3 (3) through (7) shall apply *mutatis mutandis* to the public announcement of detailed matters necessary for the addition of conditions of designation, delivery of certificates of designation, public announcement of designation, reporting on the status of performance of duties, subsidies for costs, procedures for designation, etc. of regional infectious disease hospitals.

[This Article Newly Inserted by Presidential Decree No. 27277, Jun. 28, 2016]

Article 1-5 (Formulation of Measures for Controlling Resistant Bacteria)

- (1) Where the Minister of Health and Welfare intends to change important matters the Minister of Health and Welfare determines among the matters included in the measures for controlling resistant bacteria prescribed in Article 8-3 (1) of the Act (hereinafter referred to as "measures for controlling resistant bacteria"), he/she shall submit such changes for deliberation by the Infectious Disease Control Committee prescribed in Article 9 (1) of the Act.
- (2) Where the Minister of Health and Welfare formulates or changes measures for controlling resistant bacteria, he/she shall post such measures on the website of the Ministry of Health and Welfare and inform the heads of the relevant central administrative agencies, the President of the Health Insurance Review and Assessment Service under the National Health Insurance Act and the heads of other resistant bacteria-related institutions, corporations and organizations of the details thereof.
- (3) Except as otherwise provided for in paragraphs (1) and (2), detailed matters necessary for the formulation and change of measures for controlling resistant bacteria shall be determined by the Minister of Health and Welfare.

[This Article Newly Inserted by Presidential Decree No. 28070, May 29, 2017]

Article 1-6 (Establishment and Operation of Emergency Operations Center)

- (1) The Emergency Operations Center established pursuant to Article 8-5 of the Act (hereinafter referred to as "Emergency Operations Center") shall meet all the following requirements for establishment and operation:
 1. Establishing an information and communications system for promptly collecting and disseminating information on infectious diseases, comprehensively managing emergency conditions related to infectious diseases, etc.;
 2. Securing facilities and equipment for effectively responding to emergency conditions related to infectious diseases and a system for operating and managing such facilities and equipment;
 3. Securing dedicated personnel necessary to operate the Emergency Operations Center around the clock;
 4. Preparing operational regulations and work manuals to facilitate the operation of the Emergency Operations Center.
- (2) Detailed matters related to establishing and operating the Emergency Operations Center shall be determined by the Director of the Korea Centers for Disease Control and Prevention.

[This Article Newly Inserted by Presidential Decree No. 28962, Jun. 12, 2018]

Article 2 (Duties, and Terms of Office, of Members of Infectious Disease Control Committee)

- (1) The Chairperson of the Infectious Disease Control Committee (hereinafter referred to as the "Committee") established under Article 9 (1) of the Act, shall represent the Committee and exercise general control over the administrative affairs thereof. *<Amended by Presidential Decree No. 27277, Jun. 28, 2016>*
- (2) The vice-chairperson of the Committee shall assist the Chairperson and act on the Chairperson's behalf if the Chairperson is unable to perform any of his/her duties due to an extenuating

circumstance.

- (3) The term of office of any commissioned member of the Committee shall be two years.
- (4) If a vacancy occurs in the office of Committee member, the term of office of a member filling the vacancy shall be the remainder of his/her predecessor's term of office.

Article 3 (Meetings)

- (1) Committee meetings shall be convened upon request by the Minister of Health and Welfare, by a majority of the members thereof, or by the Chairperson when he/she deems necessary.
- (2) A majority of the members of the Committee shall constitute a quorum at Committee meetings and resolutions shall be passed with the concurrent vote of a majority of members present.
- (3) The Chairperson of the Committee shall report the resolutions adopted by the Committee to the Minister of Health and Welfare.
- (4) If deemed necessary for conducting its affairs, the Committee may request relevant public officials or experts to appear before the Committee to state their opinions.

Article 4 (Executive Secretary)

The Committee shall have one executive secretary to administer the clerical work thereof, who shall be appointed by the Chairperson, from among public officials of the Ministry of Health and Welfare.

Article 5 (Payment of Allowances)

A member who attends a Committee meeting may be paid allowances and reimbursed for travel expenses, within budgetary limits: *Provided*, That this shall not apply where a member who is a public official attends a Committee meeting directly in connection with any of his/her official duties.

Article 6 (Detailed Operating Rules)

Except as otherwise expressly provided for in this Decree, matters necessary for operating the Committee shall be determined by the Chairperson, following a resolution by the Committee.

Article 7 (Composition of Advisory Committees)

- (1) Pursuant to Article 10 (3) of the Act, the Committee shall establish the following advisory committees for each field: *<Amended by Presidential Decree No. 26024, Jan. 6, 2015; Presidential Decree No. 28070, May 29, 2017; Presidential Decree No. 30596, Apr. 2, 2020>*
 1. The advisory committee on vaccination;
 2. The advisory committee on vaccination injury compensation;
 3. The advisory committee on acquired immunodeficiency syndrome;
 4. The advisory committee on tuberculosis;
 5. The advisory committee on epidemiological investigation;
 6. The advisory committee on zoonoses;
 7. The advisory committee on infectious disease crisis control;
 8. The advisory committee on infectious disease research and planning;
 9. The advisory committee on antibiotic resistance;
 10. The advisory committee on quarantine.
- (2) Each advisory committee shall be comprised of not exceeding 25 members, including one chairperson. *<Amended by Presidential Decree No. 30596, Apr. 2, 2020>*
- (3) The chairperson of each advisory committee shall be appointed by the Chairperson of the Committee, from among Committee members.
- (4) Members of each advisory committee shall be appointed by the Chairperson of the Committee, from among Committee members, or commissioned by the Chairperson of the Committee, from among those recommended by the relevant academic society or organization or by Committee members.

Article 8 (Meetings and Operation of Advisory Committees)

- (1) Meetings of an advisory committee shall be convened upon request by the Chairperson of the Committee, by a majority of the members of the advisory committee, or by the chairperson of the advisory committee when he/she deems necessary.
- (2) A majority of the members of an advisory committee shall constitute a quorum at committee meetings and resolutions shall be passed with the concurrent vote of a majority of members present.
- (3) The chairperson of an advisory committee shall report the resolutions deliberated on and adopted by the advisory committee to the Chairperson of the Committee. *<Amended by Presidential Decree No. 26024, Jan. 6, 2015>*
- (4) Except as otherwise expressly provided for in this Decree, matters necessary for operating each advisory committee shall be determined by the chairperson of the advisory committee, following a resolution by the advisory committee.

Article 9 (Other Zoonoses)

“Other zoonoses prescribed by Presidential Decree” in Article 14 (1) 4 of the Act, means animal influenza. *<Amended by Presidential Decree No. 26865, Jan. 6, 2016>*

Article 10 (Public Institutions)

“Public institutions prescribed by Presidential Decree” in the former part of Article 16 (7) of the Act, means the Health Insurance Review and Assessment Service and the National Health Insurance Service established under the National Health Insurance Act. *<Amended by Presidential Decree No. 26865, Jan. 6, 2016>*

Article 11 (Information to Be Provided)

Information requestable under Article 16 (7) of the Act may include the following: *<Amended by Presidential Decree No. 26865, Jan. 6, 2016>*

1. The name, resident registration number, gender, address, telephone number, occupation, name of infectious disease, date of onset of symptoms, and date of diagnosis of a patient of an infectious disease, a probable patient of an infectious disease, or a pathogen carrier (hereinafter referred to as “patient of an infectious disease, etc.”);
2. The name, location, and telephone number of the medical institution that diagnosed the case of a patient of an infectious disease, etc. and the name of the physician who made such diagnosis.

Article 12 (Details of Epidemiological Investigations)

- (1) Matters to be identified through epidemiological investigations under Article 18 (1) of the Act, shall be as follows:
 1. The personal information of patients of an infectious disease, etc.;
 2. The date and place where a patient, etc. was infected with an infectious disease;
 3. The cause and route of infection for an infectious disease;
 4. The medical record of a patient of an infectious disease, etc.;
 5. Other matters necessary to reveal the cause of an infectious disease.
- (2) Matters to be identified through epidemiological investigations under Article 29 of the Act, shall be as follows:
 1. The personal information of persons showing adverse reactions to vaccinations;
 2. The vaccination service institution, date of vaccination, and details of vaccination;
 3. The record of medical treatment for adverse reactions to vaccinations;
 4. The details of vaccines;
 5. Other matters necessary to reveal the causes of adverse reactions to vaccinations.

Article 13 (Timing of Epidemiological Investigations)

Epidemiological investigations specified in Articles 18 (1) and 29 of the Act shall be conducted, upon occurrence of the relevant ground classified as follows: <Amended by Presidential Decree No. 27277, Jun. 28, 2016>

1. Where the Director of the Korea Centers for Disease Control and Prevention is required to conduct an epidemiological investigation:
 - (a) Where the epidemiological investigation is to be conducted simultaneously in at least two Cities/Dos;
 - (b) Where an urgent investigation is necessary, as to the outbreak or prevalence of an infectious disease or adverse reactions to vaccinations;
 - (c) Where an epidemiological investigation conducted by a Mayor/Do Governor is deemed insufficient or it is deemed impracticable for a Mayor/Do Governor to conduct an epidemiological investigation;
2. Where a Mayor/Do Governor or the head of a *Si/Gun/Gu* (referring to an autonomous *Gu*; hereinafter the same shall apply) is required to conduct an epidemiological investigation:
 - (a) Where an infectious disease is likely to occur and prevail within his/her jurisdiction;
 - (b) Where an infectious disease is likely to occur and prevail outside his/her jurisdiction, but suspected to have an epidemiological link within his/her jurisdiction;
 - (c) Where a case of an adverse reaction to a vaccination is found within his/her jurisdiction, thus making it necessary to conduct an investigation to identify the cause.

Article 14 (Methods of Epidemiological Investigation)

The methods of conducting epidemiological investigations under Articles 18 (1) and 29 of the Act shall be as set forth in attached Table 1-3. <Amended by Presidential Decree No. 27277, Jun. 28, 2016>

Article 15 (Composition of Epidemiological Investigation Teams)

- (1) To conduct an epidemiological investigation under Articles 18 (1) and 29 of the Act, a central epidemiological investigation team shall be established in the Korea Centers for Disease Control and Prevention; a *City/Do* epidemiological investigation team in a *City/Do*; and a *Si/Gun/Gu* epidemiological investigation team in a *Si/Gun/Gu* (referring to an autonomous *Gu*; hereinafter the same shall apply).
- (2) The central epidemiological investigation team shall be comprised of at least 30 members; *City/Do* epidemiological investigation teams and *Si/Gun/Gu* epidemiological investigation teams, respectively, shall be comprised of not exceeding 20 members; and a disease control officer appointed under Article 60 of the Act or an epidemiological investigation officer appointed under Article 60-2 of the Act shall serve as the chief of each epidemiological investigation team. <Amended by Presidential Decree No. 26865, Jan. 6, 2016>
- (3) Members of each epidemiological investigation team shall be appointed or commissioned by the Director of the Korea Centers for Disease Control and Prevention, a Mayor/Do Governor, or the head of a *Si/Gun/Gu*, respectively, from among the following: <Amended by Presidential Decree No. 26865, Jan. 6, 2016>
 1. Public officials who take charge of disease control, epidemiological investigations, or vaccination services;
 2. Epidemiological investigation officers specified in Article 60-2 of the Act;
 3. Public health doctors employed under the Act on Special Measures for Health and Medical Services in Agricultural and Fishing Villages;
 4. Medical personnel defined in Article 2 (1) of the Medical Service Act;
 5. Other experts in the field of infectious diseases or similar.

- (4) Each epidemiological investigation team shall be divided into two sections covering the area of infectious diseases and the area of adverse reactions to vaccinations, and matters necessary to operate those sections shall be determined by the Director of the Korea Centers for Disease Control and Prevention.

Article 16 (Functions of Epidemiological Investigation Teams)

- (1) The functions of each epidemiological investigation team shall be as follows:
1. The central epidemiological investigation team:
 - (a) Formulating, implementing, and evaluating an epidemiological investigation plan;
 - (b) Developing the standards and methods for conducting epidemiological investigations;
 - (c) Providing education and training for City/Do epidemiological investigation teams and Si/Gun/Gu epidemiological investigation teams;
 - (d) Conducting epidemiological research on infectious diseases;
 - (e) Collecting, analyzing, and providing for both the cases of outbreak and prevalence of infectious diseases and the cases of adverse reactions to vaccinations;
 - (f) Providing technical guidance for and evaluation of City/Do epidemiological investigation teams;
 2. City/Do epidemiological investigation teams:
 - (a) Formulating, implementing, and evaluating an epidemiological investigation plan for each jurisdiction;
 - (b) Developing detailed standards and methods for conducting epidemiological investigations in each jurisdiction;
 - (c) Reporting the findings of epidemiological investigations in each jurisdiction, to the central epidemiological investigation team;
 - (d) Collecting, analyzing, and providing for both the cases of outbreak and prevalence of infectious diseases, and for the cases of adverse reactions to vaccinations in each jurisdiction;
 - (e) Providing technical guidance for and evaluation of Si/Gun/Gu epidemiological investigation teams;
 3. Si/Gun/Gu epidemiological investigation teams:
 - (a) Formulating and implementing an epidemiological investigation plan for each jurisdiction;
 - (b) Reporting the findings of epidemiological investigations in each jurisdiction, to the relevant City/Do epidemiological investigation team;
 - (c) Collecting, analyzing, and providing for both the cases of outbreak and prevalence of infectious diseases and the cases of adverse reactions to vaccinations in each jurisdiction.
- (2) Each epidemiological investigation team member who conducts an epidemiological investigation shall carry a certificate of epidemiological investigator prescribed by Ordinance of the Ministry of Health and Welfare, and produce it to interested parties.
- (3) The Director of the Korea Centers for Disease Control and Prevention, a Mayor/Do Governor, or the head of a Si/Gun/Gu may pay allowances and reimburse travel expenses incurred in epidemiological investigative activities, within budgetary limits, to epidemiological investigation team members.

Article 16-2 (Institutions or Organizations Required to Present Materials)

“Institution or organization, etc. prescribed by Presidential Decree” in Article 18-4 (1) of the Act, means the following: <Amended by Presidential Decree No. 27277, Jun. 28, 2016>

1. A medical institution;
2. The National Health Insurance Service established under Article 13 of the National Health Insurance Act;
3. The Health Insurance Review and Assessment Service established under Article 62 of the National

Health Insurance Act.

[This Article Newly Inserted by Presidential Decree No. 26865, Jan. 6, 2016]

Article 16-3 (Extent of Request for Assistance)

The Minister of Health and Welfare may request the head of a relevant central administrative agency to dispatch its personnel and provide goods necessary for conducting epidemiological investigations, to manage persons and institutions subject to epidemiological investigations, to conduct examinations and analyze information for identifying the source and route of infection, and provide other necessary assistance, pursuant to Article 18-4 (2) of the Act.

[This Article Newly Inserted by Presidential Decree No. 26865, Jan. 6, 2016]

Article 17 (Permit Requirements for Introducing High-Risk Pathogens)

A person who intends to obtain a permit to introduce high-risk pathogens under Article 22 (1) of the Act shall satisfy each of the following requirements: <Amended by Presidential Decree No. 28962, Jun. 12, 2018>

1. To establish and operate a high-risk pathogen handling facility referred to in Article 23 (1) of the Act (hereinafter referred to as "high-risk pathogen handling facility");
2. To formulate a plan for safe transportation of high-risk pathogens and emergency response;
3. To employ a manager who takes exclusive charge of high-risk pathogens.

Article 18 (Matters to Be Reported in Changing Permit for Introducing High-Risk Pathogens)

"Minor matters prescribed by Presidential Decree" in the proviso of Article 22 (2) of the Act means the following:

1. The name (in cases of a legal entity, referring to its name) and address of the person permitted to introduce high-risk pathogens;
2. The name and position of the manager who takes exclusive charge of high-risk pathogens.

Article 19 (Designation of Place to Acquire High-Risk Pathogens)

A person who intends to acquire and transfer high-risk pathogens under Article 22 (3) of the Act, shall designate the place of acquisition from among those determined by the Minister of Health and Welfare.

Article 19-2 (Permission for and Report on Establishment and Operation of High-Risk Pathogen Handling Facilities)

- (1) The classification of safety control grades of high-risk pathogen handling facilities as well as high-risk pathogen handling facilities subject to permission or reporting shall be as specified in attached Table 1-4.
- (2) The Minister of Health and Welfare shall determine and publicly notify the standards for permitting or accepting reports on the establishment and operation of high-risk pathogen handling facilities with regard to each of the following by safety control grade of high-risk pathogen handling facilities:
 1. The types of high-risk pathogen handling facilities;
 2. The equipment, personnel, and safety control necessary to inspect, store, manage and transport high-risk pathogens;
 3. The equipment, personnel, and safety control for facilities that can prevent harm to the human body during the process of inspecting, storing, managing or transporting high-risk pathogens (hereinafter referred to as "facilities for preventing health harm").
- (3) Any person who intends to establish and operate a high-risk pathogen handling facility subject to permission prescribed in Article 23 (2) of the Act and attached Table 1-4 shall submit an application for permission prescribed by Ordinance of the Ministry of Health and Welfare, along with the following documents, to the Minister of Health and Welfare:

1. Drawings and specifications of the high-risk pathogen handling facility or a copy thereof;
2. Documents certifying the scope of the high-risk pathogen handling facility, and the ownership or use rights thereto;
3. Basic drawings and specifications of a facility for preventing health harm, or a copy thereof;
4. Documents certifying compliance with the standards for permission prescribed in paragraph (2).
- (4) The Minister of Health and Welfare shall notify the applicant of whether permission is to be granted within 60 days from the date of receiving the application for permission referred to in paragraph (3). In such cases, when granting permission, the Minister of Health and Welfare shall issue a permit to establish and operate the high-risk pathogen handling facility prescribed by Ordinance of the Ministry of Health and Welfare.
- (5) Any person who intends to establish and operate a high-risk pathogen handling facility subject to reporting prescribed in Article 23 (2) of the Act and attached Table 1-4 shall submit a report prescribed by Ordinance of the Ministry of Health and Welfare, along with the following documents, to the Minister of Health and Welfare:
 1. Documents certifying compliance with the standards for accepting reports prescribed in paragraph (2);
 2. Documents prescribed in paragraph (3) 1 through 3.
- (6) The Minister of Health and Welfare shall notify the applicant of whether his/her report is to be accepted within 60 days from the date of receiving the report referred to in paragraph (5). In such cases, when accepting the report, the Minister of Health and Welfare shall issue a certificate of the report on establishing and operating the high-risk pathogen handling facility prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Presidential Decree No. 28962, Jun. 12, 2018]

Article 19-3 (Permission for Changes to High-Risk Pathogens Handling Facilities)

- (1) Any person who intends to obtain permission for changes pursuant to the main sentence of Article 23 (3) of the Act shall submit an application for permission for changes prescribed by Ordinance of the Ministry of Health and Welfare, along with documents certifying the grounds and details of the relevant changes of permitted matters, to the Minister of Health and Welfare.
- (2) The Minister of Health and Welfare shall notify the applicant of whether permission for changes is to be granted within 60 days from the date of receiving the application for permission for changes referred to in paragraph (1). In such cases, when granting permission for changes, the Minister of Health and Welfare shall issue a permit for changes prescribed by Ordinance of the Ministry of Health and Welfare.
- (3) "Minor matters prescribed by Presidential Decree" referred to in the proviso to Article 23 (3) of the Act means any of the following:
 1. The name, address and contact information of a person who establishes and operates the high-risk pathogen handling facility (limited to natural persons);
 2. The name, address and contact information of a person who establishes and operates the high-risk pathogen handling facility (limited to corporations), and the name and contact information of the representative thereof;
 3. The name and address of a person responsible for establishing and operating the high-risk pathogen handling facility referred to in Article 19-6 (1) 1, a manager in the exclusive charge of high-risk pathogens, and a person responsible for biological safety control.
- (4) Any person who intends to report changes pursuant to the proviso to Article 23 (3) of the Act shall submit a report on changes of permitted matters prescribed by Ordinance of the Ministry of Health and Welfare to the Minister of Health and Welfare.
- (5) Upon receipt of a report on changes in permitted matters referred to in paragraph (4), the Minister of Health and Welfare shall issue a certificate of the report on changes prescribed by Ordinance of the

Ministry of Health and Welfare.

[This Article Newly Inserted by Presidential Decree No. 28962, Jun. 12, 2018]

Article 19-4 (Report on Changes to High-Risk Pathogen Handling Facilities)

- (1) Any person who intends to report changes pursuant to Article 23 (4) of the Act shall submit a report on changes prescribed by Ordinance of the Ministry of Health and Welfare to the Minister of Health and Welfare.
- (2) Upon receipt of a report on changes referred to in paragraph (1), the Minister of Health and Welfare shall issue a certificate of the report on changes prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Presidential Decree No. 28962, Jun. 12, 2018]

Article 19-5 (Report on Closure of High-Risk Pathogen Handling Facilities)

- (1) Any person who intends to report the closure of a high-risk pathogen handling facility pursuant to Article 23 (5) of the Act shall submit a closure report prescribed by Ordinance of the Ministry of Health and Welfare, along with documents certifying the disposal of high-risk pathogens, to the Minister of Health and Welfare.
- (2) The Minister of Health and Welfare shall notify the reporter of whether his/her report is to be accepted within 10 days from the date of receiving the closure report referred to in paragraph (1). In such cases, when accepting the report, the Minister of Health and Welfare shall issue a certificate of the closure report prescribed by Ordinance of the Ministry of Health and Welfare.
- (3) Where the high-risk pathogen handling facility is closed pursuant to Article 23 (5) of the Act, the Minister of Health and Welfare shall determine and publicly notify the methods, procedures, etc. for closing the high-risk pathogen handling facility, such as disinfecting high-risk pathogen handling facilities and disposing of high-risk pathogens.

[This Article Newly Inserted by Presidential Decree No. 28962, Jun. 12, 2018]

Article 19-6 (Safety Control Guidelines regarding Establishment and Operation of High-Risk Pathogen Handling Facilities)

- (1) "Safety control guidelines prescribed by Presidential Decree" in Article 23 (7) of the Act means the following: <Amended by Presidential Decree No. 30596, Apr. 2, 2020>
 1. There shall be a person responsible for establishing and operating a high-risk pathogen handling facility, a manager in the exclusive charge of high-risk pathogens, and a person responsible for biological safety control;
 2. He/she shall establish and operate a deliberative body composed of external experts, persons responsible for biological safety control, etc. at a high-risk pathogen handling facility in order to deliberate on matters related to safety control concerning the inspection, storage, management, and transport of high-risk pathogens;
 3. Any high-risk pathogen shall be stored in a storage unit container indicating the relevant information, such as the name of high-risk pathogen, identification number including control number, and the date of manufacture, which shall be kept in a separate storage box or storage equipment with a locking device;
 4. He/she shall operate a security system to control access to any area for handling or storing high-risk pathogens and to check the handling of high-risk pathogens;
 5. Where he/she intends to use any high-risk pathogen after inactivating it (referring to treatment that permanently prevents its survival without disposing of it), he/she shall undergo deliberation by the deliberative body referred to in subparagraph 2;
 6. He/she shall comply with the standards for granting permission and accepting reports prescribed in Article 19-2 (2).

- (2) Except as provided in paragraph (1), the details of safety control and matters pertaining to the composition, operation, etc. of the deliberative body referred to in paragraph (1) 2 shall be determined and publicly notified by the Minister of Health and Welfare.

[This Article Newly Inserted by Presidential Decree No. 28962, Jun. 12, 2018]

Article 19-7 (Supplement of Documents Submitted for Permission for or Report on High-Risk Pathogen Handling Facilities)

Where the Minister of Health and Welfare deems it necessary to supplement documents submitted for the purpose of obtaining permission for or reporting the establishment and operation of a high-risk pathogen handling facility pursuant to Article 19-2; obtaining permission for or reporting any change in permitted matters regarding the establishment and operation of a high-risk pathogen handling facility pursuant to Article 19-3; reporting any change of a high-risk pathogen handling facility pursuant to Article 19-4; or reporting the closure of a high-risk pathogen handling facility pursuant to Article 19-5, the Minister of Health and Welfare may require the submission of necessary documents for a specified period of not exceeding 30 days. In such cases, the period for submitting additional documents shall not be counted in determining the period prescribed in Article 19-2 (4) or (6), 19-3 (2), or 19-5 (2).

[This Article Newly Inserted by Presidential Decree No. 28962, Jun. 12, 2018]

Article 20 (Entrustment of Vaccination Services)

- (1) A Special Self-Governing Province Governor or the head of a *Si/Gun/Gu* may entrust vaccination services beyond the capability of public health centers or for residents, etc. having difficulty visiting public health centers, under Articles 24 (2) and 25 (2) of the Act, to medical institutions designated by the Special Self-Governing Province Governor or the head of the *Si/Gun/Gu*, from among general hospitals, hospitals, convalescent hospitals (limited to those in which medical services are rendered by physicians), and medical clinics specified in Article 3 of the Medical Service Act. In such cases, the Special Self-Governing Province Governor or the head of the *Si/Gun/Gu* shall publicly announce the institutions so entrusted.
- (2) When entrusting vaccination services under paragraph (1), the Special Self-Governing Province Governor or the head of the *Si/Gun/Gu* shall prepare an entrustment contract providing for each of the following: <Newly Inserted by Presidential Decree No. 26024, Jan. 6, 2015>
1. The scope of the vaccination services entrusted;
 2. The period for the entrustment contract;
 3. The terms and conditions of the entrustment contract;
 4. The cancellation of the entrustment contract.
- (3) Matters necessary for the procedures, etc. for calculating and refunding vaccination expenses incurred in relation to vaccination services entrusted under paragraph (1), shall be determined and publicly announced by the Minister of Health and Welfare. <Amended by Presidential Decree No. 26024, Jan. 6, 2015>

Article 20-2 (Pre-Checking of Vaccination Records)

The director of each public health center that provides vaccination services under Articles 24 (1) and 25 (1) of the Act and the head of each medical institution entrusted with vaccination services under Article 24 (2) (including where the said Article applies *mutatis mutandis* in Article 25 (2) of the Act) of the Act (hereinafter referred to as the "director of each public health center, etc.") shall obtain written consent from those who intend to be vaccinated or from their legal representatives on the following matters under the main clause of Article 26-2 (1) of the Act:

1. The fact that they have confirmed the details of the vaccination;
2. The method of confirming the details of the vaccination.

[This Article Newly Inserted by Presidential Decree No. 27277, Jun. 28, 2016]

Article 21 (Organization of Vaccination Injury Investigation Teams)

- (1) A vaccination injury investigation team prescribed under Article 30 (2) of the Act (hereinafter referred to as “injury investigation team”) shall be comprised of not exceeding ten members.
- (2) Members of the injury investigation team shall be appointed or commissioned by the Director of the Korea Centers for Disease Control and Prevention, from among public officials under his/her control or from among the following:
 1. Experts in the field of vaccination and adverse reactions to vaccinations;
 2. Medical personnel defined in Article 2 (1) of the Medical Service Act.
- (3) The injury investigation team shall investigate the following matters and report the findings therefrom to the advisory committee on vaccination injury compensation:
 1. The evaluation and supplementation of the findings of a basic investigation submitted by a Mayor/*Do* Governor under Article 31 (2);
 2. The intention or negligence on the part of a third party provided for in Article 72 (1) of the Act;
 3. Other matters determined by the advisory committee on vaccination injury compensation in relation to vaccination injury compensation.
- (4) An injury investigation team member who conducts an injury investigation under paragraph (3), shall carry a certificate of vaccination injury investigator prescribed by Ordinance of the Ministry of Health and Welfare, and produce it to interested parties.
- (5) The Director of the Korea Centers for Disease Control and Prevention may pay allowances and reimburse travel expenses incurred in conducting injury investigations, within budgetary limits, to injury investigation team members.
- (6) Detailed matters for operating the injury investigation team shall be determined by the Director of the Korea Centers for Disease Control and Prevention, following a resolution by the advisory committee on vaccination injury compensation.

Article 21-2 (Personal Information of Persons Eligible for Vaccination)

- (1) The personal information details of those eligible for vaccination which the Minister of Health and Welfare may request from the relevant institutions and organizations under Article 33-2 (2) 1 of the Act, are as follows: *<Amended by Presidential Decree No. 28962, Jun. 12, 2018>*
 1. Where a person eligible for vaccination is a national: The following materials:
 - (a) The name, resident registration number and address of a person eligible for vaccination;
 - (b) The following details on to which a person eligible for vaccination belongs:
 - (i) Details of the school prescribed in Article 2 of the Elementary and Secondary Education Act, to which a person eligible for vaccination belongs;
 - (ii) Details of the kindergarten prescribed in subparagraph 2 of Article 2 of the Early Childhood Education Act to which a person eligible for vaccination belongs;
 - (iii) Details of the child care center prescribed in subparagraph 3 of Article 2 of the Infant Care Act to which a person eligible for vaccination belongs;
 - (iv) Details of the child welfare facility prescribed in subparagraph 10 of Article 3 of the Child Welfare Act to which a person eligible for vaccination belongs;
 - (c) The following details of a person eligible for vaccination:
 - (i) Whether a person eligible for vaccination is a person with disabilities registered pursuant to Article 32 of the Act on Welfare of Persons with Disabilities;
 - (ii) Whether a person eligible for vaccination is a member of a multicultural family prescribed in subparagraph 1 of Article 2 of the Multicultural Families Support Act;
 - (iii) Whether a person eligible for vaccination is a recipient prescribed in subparagraph 2 of Article 2 of the National Basic Living Security Act (including persons of the second lowest income bracket prescribed in subparagraph 10 of the same Article) or a child of

such recipient;

2. Where a person eligible for vaccination is a foreigner or a foreign nationality Korean: The following materials:
 - (a) Information on the registration of aliens prescribed in Article 31 of the Immigration Act;
 - (b) Information on reporting on the place of residence in Korea of a foreign nationality Korean prescribed in Article 6 of the Act on the Immigration and Legal Status of Overseas Koreans;
 3. Other information on the personal information of those eligible for vaccination, which the Minister of Health and Welfare publicly announces in recognition that such information is particularly necessary in connection with conducting vaccination.
- (2) Materials the Minister of Health and Welfare may request from the relevant institutions and organizations as materials necessary for vaccination under Article 33-2 (2) 3 of the Act are as follows:
1. Information on the establishment of a medical institution entrusted with vaccination services under Article 24 (2) of the Act (including where the said Article applies *mutatis mutandis* in Article 25 (2) of the Act);
 2. The details of a request for compensation for damage caused by vaccination;
 3. Information on the control, etc. of diseases or illness, or infectious diseases for which vaccination is impracticable.

[This Article Newly Inserted by Presidential Decree No. 27277, Jun. 28, 2016]

Article 21-3 (Input of Vaccination Information)

Where the director of a public health center, etc. provides a vaccination service, he/she shall, without delay, input the following information into the Integrated Vaccination Management System prescribed in Article 33-2 (1) of the Act (hereinafter referred to as the "integrated management system") pursuant to Article 33-2 (3) of the Act:

1. The following information on persons vaccinated:
 - (a) Name;
 - (b) Resident registration number: *Provided*, That where the person vaccinated is a foreigner or a foreign nationality Korean, it refers to the foreigner registration number or the domestic residence report number;
2. The following information on the details of vaccination:
 - (a) Name of vaccination;
 - (b) Number of vaccination;
 - (c) Date/month/year of vaccination;
 - (d) Name of the vaccine used in vaccination;
 - (e) Names of the physician who made a preliminary diagnosis and the physician who vaccinated.

[This Article Newly Inserted by Presidential Decree No. 27277, Jun. 28, 2016]

Article 21-4 (Provision of Details of Vaccination)

- (1) Where the Minister of Health and Welfare provides the parents of children eligible for vaccination with the details of the vaccination under the former part of Article 33-2 (4) of the Act, he/she shall do so by the method of reading by utilizing the integrated management system: *Provided*, That where the Minister of Health and Welfare deems it necessary, such details may be provided by text message, electronic mail, telephone, mail or other methods equivalent thereto.
- (2) Where the Minister of Health and Welfare issues a certificate of vaccination under the former part of Article 33-2 (4) of the Act, he/she may issue such certificate directly from the integrated management system as prescribed by the Minister of Health and Welfare or issue such certificate through an electronic civil petition window prescribed in Article 9 (3) of the Electronic Government Act.

[This Article Newly Inserted by Presidential Decree No. 27277, Jun. 28, 2016]

Article 22 (Procedures, etc. for Formulating Crisis Control Measures against Infectious Diseases)

- (1) The Minister of Health and Welfare may request relevant administrative agencies, local governments, public institutions prescribed in Article 4 of the Act on the Management of Public Institutions, etc. to submit materials to formulate crisis control measures against infectious diseases under Article 34 (1) of the Act.
- (2) The Minister of Health and Welfare shall notify the heads of the relevant central administrative agencies of the crisis control measures against infectious diseases formulated under Article 34 (1) of the Act.

Article 23 (Methods and Procedures for Home-Care and Inpatient Treatment)

Methods, procedures, etc. for home-care and inpatient treatment under Article 41 (4) of the Act shall be as prescribed in attached Table 2.

Article 23-2 (Providing Subsidies for Costs for Paid Leave)

- (1) Subsidies for paid leave provided to employers under Article 41-2 (3) of the Act shall be in the amount calculated by multiplying the amount the Minister of Health and Welfare publicly notifies in consultation with the Minister of Economy and Finance by the period during which an employee is hospitalized, quarantined, or isolated under the Act.
- (2) An employer who intends to be subsidized under Article 41-2 (3) of the Act shall file a written application (including written applications in electronic documents) prescribed by Ordinance of the Ministry of Health and Welfare with the Minister of Health and Welfare along with the following documents (including electronic documents):
 1. Documents verifying the fact that an employee is hospitalized, quarantined, or isolated and the period of such hospitalization, quarantine, or isolation;
 2. Documents evidencing that an employee continues to hold office, such as proof of employment;
 3. Documents evidencing that the employer has given a paid leave to the relevant employee, such as a pay slip;
 4. Other documents deemed particularly necessary by the Minister of Health and Welfare to provide subsidies for paid leave.
- (3) Where the Minister of Health and Welfare receives a written application prescribed in paragraph (2), he/she shall verify the certificate of business registration through administrative data matching prescribed in Article 36 (1) of the Electronic Government Act: *Provided*, That where the relevant employer disagrees therewith, he/she shall require the relevant employer to attach such certificate to the written application.
- (4) Where the Minister of Health and Welfare receives a written application prescribed in paragraph (2), he/she shall determine whether to grant subsidies for paid leave and the amount of subsidies and inform the relevant employer thereof in writing.
- (5) Except as provided in paragraphs (2) through (4), matters necessary for procedures for applying for subsidies for paid leave, notification of the results thereof, etc. shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Presidential Decree No. 27277, Jun. 28, 2016]

Article 23-3 (Designation of Infectious Disease Control Institutions for Quarantine or Isolation of Patients of Infectious Diseases)

- (1) An institution eligible to be designated as an infectious disease control institution to take charge of the investigation, diagnosis, quarantine or isolation, treatment, etc. of patients of infectious diseases, etc. under Article 42 (4) and (7) of the Act shall be an infectious disease control institution having

single-occupancy hospital rooms (referring to hospital rooms with anterooms and negative pressure facilities) for patients of infectious diseases, etc., from among infectious disease control institutions designated under Article 36 (1) of the Act (hereinafter referred to as "infectious disease control institution"). *<Amended by Presidential Decree No. 30596, Apr. 2, 2020>*

- (2) Where the Minister of Health and Welfare, a Mayor/Do Governor, or the head of a *Si/Gum/Gu* designates an infectious disease control institution for conducting examination, medical diagnosis, quarantine or isolation, and treatment under Article 42 (11) of the Act, he/she shall consider the findings of evaluation of infectious disease control facilities prescribed in Article 39-2 of the Act. *<Amended by Presidential Decree No. 30596, Apr. 2, 2020>*
- (3) Where the Minister of Health and Welfare, a Mayor/Do Governor, or the head of a *Si/Gum/Gu* designates an infectious disease control institution for conducting examination, medical diagnosis, quarantine or isolation, and treatment under Article 42 (11) of the Act, he/she shall issue a certificate of designation, as prescribed by the Minister of Health and Welfare. *<Amended by Presidential Decree No. 30596, Apr. 2, 2020>*

[This Article Newly Inserted by Presidential Decree No. 27277, Jun. 28, 2016]

Article 24 (Facilities Requiring Disinfection)

Facilities that require disinfection necessary for preventing infectious diseases under Article 51 (2) of the Act, shall be as follows: *<Amended by Presidential Decree No. 23356, Dec. 8, 2011; Presidential Decree No. 25448, Jul. 7, 2014; Presidential Decree No. 26024, Jan. 6, 2015; Presidential Decree No. 26916, Jan. 19, 2016; Presidential Decree No. 27277, Jun. 28, 2016; Presidential Decree No. 27445, Aug. 11, 2016; Presidential Decree No. 27971, Mar. 29, 2017>*

1. Lodging establishments (limited to those with at least 20 guest rooms) specified in the Public Health Control Act and tourist accommodation establishments specified in the Tourism Promotion Act;
2. Food service business places (hereinafter referred to as "food service establishments") with a total floor area of at least 300 square meters specified in subparagraph 8 (excluding item (e) thereof) of Article 21 of the Enforcement Decree of the Food Sanitation Act;
3. Intra-city buses, rural buses, shuttle buses, cross-country buses, chartered buses, and funeral coaches specified in the Passenger Transport Service Act; aircraft specified in the Aviation Safety Act and airport facilities specified in the Airport Facilities Act; passenger ships specified in the Marine Transportation Act; waiting lounges with a total floor area of at least 300 square meters specified in the Harbor Act; and rolling stock for passenger transportation, stations, and station facilities specified in the Railroad Service Act and the Urban Railroad Act;
4. Superstores, specialty stores, department stores, shopping centers, multiplex shopping malls, and other large-scale stores specified in the Distribution Industry Development Act, and traditional markets specified in the Special Act on the Development of Traditional Markets and Shopping Districts;
5. General hospitals, hospitals, convalescent hospitals, dental hospitals, and oriental medical hospitals, prescribed in subparagraph 3 of Article 3 of the Medical Service Act;
6. Meal service facilities (limited to those capable of providing meals continuously for at least 100 persons simultaneously) specified in subparagraph 12 of Article 2 of the Food Sanitation Act;
- 6-2. Food service establishments engaged in catering service business, with a total floor area of at least 300 square meters, specified in subparagraph 8 (e) of Article 21 of the Enforcement Decree of the Food Sanitation Act;
7. Dormitories specified in subparagraph 2 (d) of Table 1 attached to the Enforcement Decree of the Building Act;
- 7-2. Lodging houses (limited to those to accommodate for at least 50 persons) specified in subparagraph 8 (a) of Table 2 attached to the Enforcement Decree of the Act on Fire Prevention and Installation, Maintenance, and Safety Control of Fire-Fighting Systems;

8. Performance halls (limited to those with a seating capacity of at least 300) specified in the Public Performance Act;
9. Schools specified in Article 2 of the Elementary and Secondary Education Act and Article 2 of the Higher Education Act;
10. Private teaching institutes with a total floor area of at least 1,000 square meters specified in the Act on the Establishment and Operation of Private Teaching Institutes and Extracurricular Lessons;
11. Office buildings and multiple-purpose buildings with a total floor area of at least 2,000 square meters;
12. Nursery facilities specified in the Infant Care Act and kindergartens specified in the Early Childhood Education Act (limited to nursery facilities and kindergartens to accommodate at least 50 persons);
13. Multi-family housing specified in the Multi-Family Housing Management Act (limited to those with at least 300 households).

Article 25 (Eligibility to Become Disease Control Officers and Duties)

- (1) Disease control officers specified in Article 60 (1) of the Act, shall be appointed from among public officials of at least Grade IV with substantial experience in a field related to infectious diseases: *Provided*, That disease control officers of each *Sil/Gun/Gu* may be appointed, from among public officials of at least Grade V with substantial experience in a field related to infectious diseases. *<Amended by Presidential Decree No. 26865, Jan. 6, 2016>*
- (2) In addition to the authority to take measures specified in Article 60 (3) of the Act, each disease control officer shall have the authority to take the following measures in the outbreak area of an infectious disease: *<Amended by Presidential Decree No. 26865, Jan. 6, 2016>*
 1. Hospitalizing or quarantining persons suspected of being infected by the pathogen of an infectious disease for a certain period at an appropriate place;
 2. Disinfecting places or buildings contaminated by the pathogen of an infectious disease, or taking other necessary measures;
 3. Issuing orders to prohibit laundering at certain places or to handle wastes at designated places;
 4. Taking measures to prevent zoonoses, against persons who have involved in slaughter or persons, etc. exposed to zoonoses.
- (3) Deleted. *<by Presidential Decree No. 26865, Jan. 6, 2016>*

Article 26 (Qualifications for and Duties of Epidemiological Investigation Officers)

- (1) Deleted. *<by Presidential Decree No. 26865, Jan. 6, 2016>*
- (2) Each epidemiological investigation officer shall perform the following duties:
 1. Formulating epidemiological investigation plans;
 2. Conducting, and analyzing the findings of, epidemiological investigations;
 3. Developing the criteria and methods for conducting epidemiological investigations;
 4. Providing technical guidance on epidemiological investigations;
 5. Providing education and training on epidemiological investigations;
 6. Conducting epidemiological research on infectious diseases.
- (3) Deleted. *<by Presidential Decree No. 26865, Jan. 6, 2016>*
- (4) The Minister of Health and Welfare and Mayors/*Do* Governors may pay research expenses and reimburse travel expenses to epidemiological investigation officers, within budgetary limits.

Article 26-2 (Ordering Medical Personnel to Perform Disease Control Duties)

- (1) Where the Minister of Health and Welfare or a Mayor/*Do* Governor issues an order to perform disease control duties under Article 60-3 (1) of the Act, he/she shall issue a certificate of order to perform disease control duties. In such cases, the relevant certificate of order shall include the institution to perform disease control duties, period of performing disease control duties, disease

control duties to be performed, etc.

- (2) The period of performing disease control duties prescribed in Article 60-3 (1) of the Act shall not exceed 30 days: *Provided*, That where the person in question agrees in writing in advance, such period may be determined otherwise.
- (3) Where the Minister of Health and Welfare or a Mayor/*Do* Governor extends the period of performing disease control duties prescribed in paragraph (2), he/she shall obtain written consent from the person in question before the relevant period of performing disease control duties expires. In such cases, the period to be extended shall not exceed 30 days, on condition that where the person in question agrees, the period to be extended may be determined otherwise.
- (4) Where the Minister of Health and Welfare or a Mayor/*Do* Governor extends the period of performing disease control duties under paragraph (3), he/she shall issue a new certificate of order to perform disease control duties.

[This Article Newly Inserted by Presidential Decree No. 27277, Jun. 28, 2016]

Article 26-3 (Appointment of Disease Control Officers)

- (1) Where the Minister of Health and Welfare or a Mayor/*Do* Governor appoints a disease control officer or epidemiological investigation officer under Article 60-3 (2) or (3) of the Act, he/she shall issue a certificate of appointment. In such cases, the relevant certificate of appointment shall include the period for conducting duties.
- (2) Article 26-2 (2) through (4) shall apply *mutatis mutandis* to periods for conducting duties, extension of periods for conducting duties, issuance of certificates of appointment following the extension of periods for conducting duties, etc. of disease control officers and epidemiological investigation officers.

[This Article Newly Inserted by Presidential Decree No. 27277, Jun. 28, 2016]

Article 27 (Ratio of Subsidy on Part of Cities/Dos)

The amount of expenses subsidized by a City/*Do* (excluding a Special Self-Governing Province) under Article 66 of the Act shall be 2/3 of the amount to be borne by Sis/Guns/Gus.

Article 28 (Objects and Scope of Compensation for Loss)

- (1) Objects and scope of compensation for loss prescribed in Article 70 (1) of the Act are as prescribed in attached Table 2-2.
- (2) If necessary to calculate the amount of compensation for loss under Article 70 (1) of the Act, the Compensation Deliberation Committee prescribed in Article 70-2 (1) of the Act (hereinafter referred to as the "Deliberation Committee") may have specialized institutions or experts in the relevant areas appraise, evaluate, investigate, etc. the subject-matter of the loss.
- (3) Where the Deliberation Committee calculates compensation for the loss in Article 70 (1) 1 through 3 of the Act, it shall consider the annual average revenue, business profits, etc. of the relevant medical institution.

[This Article Wholly Amended by Presidential Decree No. 27277, Jun. 28, 2016]

Article 28-2 (Exclusion from Payment and Standards for Reducing Compensation for Loss)

- (1) The types of misconduct for which compensation for the loss shall not be paid or curtailed on the ground of violating the duty to take measures prescribed by this Act or by the relevant statutes or regulations, under Article 70 (3) of the Act, are as follows:
 1. Neglecting or interfering with reporting prescribed in Article 11 of the Act or making such report falsely;
 2. Neglecting the obligation to report prescribed in Article 12 of the Act or interference with reporting of persons obligated to report prescribed in the subparagraphs of paragraph (1) of the

same Article;

3. Engaging in misconduct in conducting an epidemiological investigation prescribed in Article 18 (3) of the Act;
 4. Failure in installing infectious disease control facilities prescribed in Article 36 (2) or 37 (2) of the Act;
 5. Violating the duty to render cooperation prescribed in Article 60 (4) of the Act;
 6. Violating directions and orders prescribed in Article 59 (1) of the Medical Service Act;
 7. Violating the duties to make measures the Minister of Health and Welfare publicly announces in recognition that such duties are particularly important among statutory duties to take measures.
- (2) Where compensation for loss is not paid or curtailed under Article 70 (3) of the Act, such non-payment or curtailed amount shall be based on whether the misconduct in the subparagraphs of paragraph (1) is directly related to the occurrence or expansion of the loss and whether such misconduct is a major cause of the loss.
- (3) Where the Deliberation Committee recognizes the existence of the causal relationship between the misconduct in the subparagraphs of paragraph (1) and the occurrence or expansion of loss under paragraph (2), it shall consider the motives for, details, nature, type, etc. of, the relevant misconduct comprehensively.
- (4) The Minister of Health and Welfare shall determine and publicly announce detailed matters necessary for exclusion from payment, standards for payment in reduced amounts, etc. of compensation for loss prescribed in paragraphs (2) and (3).

[This Article Newly Inserted by Presidential Decree No. 27277, Jun. 28, 2016]

Article 28-3 (Composition and Operation of the Compensation Deliberation Committee)

- (1) Members of the Deliberation Committee established in the Ministry of Health and Welfare shall be appointed or commissioned by the Minister of Health and Welfare, from among the following persons duly considering gender:
1. Persons recommended by medical personnel organizations and medical institution organizations established under the Medical Service Act, and by the Korean Pharmaceutical Association and the Association of Korean Oriental Pharmacy established under the Pharmaceutical Affairs Act;
 2. Persons recommended by organizations recognized by the Minister of Health and Welfare to be closely related to the field of health and medical services as non-profit, non-governmental organizations established under the Assistance for Non-Profit, Non-Governmental Organizations Act;
 3. Persons recommended by the President of the National Health Insurance Service or by the President of the Health Insurance Review and Assessment Service under the National Health Insurance Act;
 4. Persons holding office or have held office in the position of at least associate professor or in a position equivalent thereto at health and medical services-related departments of universities prescribed in the Higher Education Act;
 5. Persons with considerable knowledge and experience in the prevention and control of infectious diseases;
 6. Persons with considerable knowledge and experience in compensation for loss;
 7. Members of the Senior Executive Service in charge of policies for health and medical services.
- (2) The term of office of commissioned members prescribed in paragraph (1) 1 through 6 shall be three years: *Provided*, That the term of office of members newly commissioned resulting from the dismissal, etc. of another member shall be their predecessor's remaining term of office.
- (3) Where a commissioned member of the Deliberation Committee falls under any of the following cases, the Minister of Health and Welfare may dismiss the relevant commissioned member:
1. Where a commissioned member of the Deliberation Committee becomes unable to perform

- his/her duties due to mental or physical disability;
2. Where a commissioned member of the Deliberation Committee engages in any misconduct in connection with his/her duties;
 3. Where a commissioned member of the Deliberation Committee is deemed unsuitable as a member due to neglect of a duty, loss of dignity, or any other reason;
 4. Where a commissioned member of the Deliberation Committee voluntarily expresses that he/she has difficulties in performing his/her duties.
- (4) The Chairperson of the Deliberation Committee prescribed in paragraph (1) shall represent the Deliberation Committee and exercise general supervision over its affairs.
 - (5) Meetings of the Deliberation Committee prescribed in paragraph (1) shall be convened at the request of a majority of members registered or when the Chairperson of the Deliberation Committee deems necessary, and the Chairperson of the Deliberation Committee shall preside over such meetings.
 - (6) A majority of the members of the Deliberation Committee prescribed in paragraph (1) shall constitute a quorum at all its meetings, and any decision thereof shall require the concurring vote of at least a majority of those present.
 - (7) To efficiently conduct affairs, the Deliberation Committee prescribed in paragraph (1) may have advisory committees organized by experts of the relevant areas.
 - (8) Except as provided in paragraphs (1) through (7), matters necessary for the composition, operation, etc. of the Deliberation Committee prescribed in paragraph (1) and advisory committees shall be determined by the Chairperson of the Deliberation Committee through resolutions by the Deliberation Committee.
 - (9) Paragraphs (1) through (8) shall apply *mutatis mutandis* to the composition, operation, etc. of Deliberation Committees established in Cities/Dos under Article 70-2 (1) of the Act. In such cases, "Minister of Health and Welfare" shall be construed as "Mayor/Do Governor."
- [This Article Newly Inserted by Presidential Decree No. 27277, Jun. 28, 2016]

Article 28-4 (Subsidization to Medical Personnel or Founders of Medical Institutions)

- (1) The Minister of Health and Welfare, a Mayor/Do Governor, or the head of a *Si/Gun/Gu* may subsidize expenses, such as allowances and travel expenses, to the medical personnel or founders of medical institutions which have rendered assistance for the surveillance, prevention, control, or epidemiological investigation of infectious diseases under Article 70-3 (1) of the Act.
- (2) Any person who intends to receive subsidization prescribed in paragraph (1) shall file an application therefor with the Minister of Health and Welfare, the competent Mayor/Do Governor, or the head of the competent *Si/Gun/Gu* along with materials evidencing that he/she has rendered assistance for the surveillance, prevention, control, or epidemiological investigation of infectious diseases.
- (3) Upon receipt of an application for subsidization prescribed in paragraph (2), the Minister of Health and Welfare, the competent Mayor/Do Governor, or the head of the competent *Si/Gun/Gu* shall determine whether to grant subsidization, items of subsidization, amount of subsidization, etc. and inform the applicant thereof.

[This Article Newly Inserted by Presidential Decree No. 27277, Jun. 28, 2016]

Article 28-5 (Livelihood Assistance for Patients of Infectious Diseases)

The Minister of Health and Welfare, a Mayor/Do Governor, or the head of a *Si/Gun/Gu* may provide the following subsidies under Article 70-4 (1) of the Act: *Provided*, That no subsidies prescribed in subparagraph 2 shall be provided where paid leave is granted under Article 41-2 (1) of the Act:

1. Medical costs and hospitalization costs: The medical costs and hospitalization costs to be borne by the person in question: *Provided*, That costs prescribed by the Minister of Health and Welfare, such as costs excluded from costs eligible to be covered by medical care benefits prescribed by the National Health Insurance Act, shall be excluded;

2. Costs for supporting livelihood: The amount publicly notified by the Minister of Health and Welfare after consulting with the Minister of Economy and Finance.

[This Article Newly Inserted by Presidential Decree No. 27277, Jun. 28, 2016]

Article 29 (Compensation Standards for Injuries Caused by Vaccination)

Standards for paying compensation under Article 71 (1) of the Act shall be as follows: <Amended by Presidential Decree No. 26024, Jan. 6, 2015; Presidential Decree No. 28070, May 29, 2017; Presidential Decree No. 29180, Sep. 18, 2018; Presidential Decree No. 29961, Jul. 9, 2019>

1. Medical expenses: The balance of the medical expenses for a disease contracted by an injury resulting from vaccination, less the amount borne or paid by an insurer under the National Health Insurance Act, or less the amount borne by the medical care fund under the Medical Care Assistance Act: *Provided*, That when the lump-sum compensation is paid under subparagraph 3, no medical expenses shall be paid;
2. Nursing expenses: 50,000 won per day only for inpatient treatment;
3. Lump-sum compensation for those who become disabled:
 - (a) Persons with disabilities prescribed in the Act on Welfare of Persons with Disabilities:
 - (i) A person with severe disabilities: 100/100 of the lump-sum compensation for death;
 - (ii) A person with minor disabilities: 55/100 of the lump-sum compensation for death;
 - (b) Other than persons with disabilities referred to in item (a), in cases of persons with disabilities who fall under the grades of disability or grades of personal damage prescribed in the Acts the Minister of Health and Welfare determines and publicly announces, such as the National Pension Act, the Public Officials Pension Act, the Public Officials' Accident Compensation Act, and the Industrial Accident Compensation Insurance Act: An amount the Minister of Health and Welfare determines and publicly notifies by standard for the relevant grade of disability or personal damage within the scope of 20/100 of the lump-sum compensation for death;
4. Lump-sum compensation for death: An amount equivalent to the monthly minimum wage prescribed under the Minimum Wage Act as at the time of death, multiplied by 240;
5. Funeral expenses: 300,000 won.

Article 30 (Persons Eligible for Compensation for Injuries Caused by Vaccination)

- (1) A person eligible for compensation under Article 71 (1) of the Act, shall be as follows:
 1. For cases falling under Article 71 (1) 1 and 2 of the Act: Victims;
 2. For cases falling under Article 71 (1) 3 of the Act: Bereaved family members determined based on the order of priority.
- (2) “Bereaved family members prescribed by Presidential Decree” in Article 71 (1) 3 of the Act, means the spouse (including a person in a *de facto* marital relationship), children, parents, grandsons and granddaughters, grandparents, and siblings.
- (3) The priority order of bereaved family members shall coincide with the order listed in paragraph (2), excluding those to whom the compensation cannot be provided due to missing, etc.; and if at least two bereaved family members are in the same order of priority, the lump-sum compensation for death shall be apportioned equally among them.

Article 31 (Compensation Procedures for Injuries Caused by Vaccination)

- (1) Any person who intends to receive compensation under Article 71 (1) of the Act shall submit a written claim for compensation to the competent Special Self-Governing Province Governor or head of *Si/Gun/Gu*, along with a document evidencing his/her injury, as prescribed by Ordinance of the Ministry of Health and Welfare.
- (2) The head of a *Si/Gun/Gu* shall submit documents received under paragraph (1) (hereinafter referred to as “claim documents for injury compensation”) to the competent Mayor/*Do* Governor, and the

Mayor/Do Governor in receipt of the claim documents for injury compensation or the Special Self-Governing Province Governor in receipt of the claim documents for injury compensation under paragraph (1), shall forward the claim documents for injury compensation without delay to the Minister of Health and Welfare, along with the findings of basic investigation conducted by him/her regarding the injury that has resulted from vaccination and the statement of his/her views thereon.

- (3) The Minister of Health and Welfare shall determine whether to provide compensation after gather consensus from the advisory committee on vaccination injury compensation and notify the relevant Mayor/Do Governor of the determination, and the Mayor/Do Governor (excluding a Special Self-Governing Province Governor) shall notify the head of the relevant *Si/Gun/Gu* thereof. In such cases, the Special Self-Governing Province Governor or the head of the *Si/Gun/Gu* so notified shall notify the relevant claimant for compensation under paragraph (1) of the details of the determination. *<Amended by Presidential Decree No. 26024, Jan. 6, 2015>*
- (4) The Minister of Health and Welfare shall pay a person determined eligible for compensation under paragraph (3) the amount of compensation under the compensation standards under Article 29.
- (5) Except as otherwise expressly provided for in this Decree, matters necessary for the procedures and methods for deliberation on compensation for injuries caused by vaccination shall be determined by the Minister of Health and Welfare.

Article 32 (Delegation of Authority and Entrustment of Duties)

- (1) The Minister of Health and Welfare shall delegate the following authority to the Director of the Korea Centers for Disease Control and Prevention, pursuant to Article 76 (1) of the Act: *<Amended by Presidential Decree No. 26024, Jan. 6, 2015; Presidential Decree No. 26865, Jan. 6, 2016; Presidential Decree No. 27277, Jun. 28, 2016; Presidential Decree No. 28962, Jun. 12, 2018>*
 1. The following affairs concerning the organization for supporting infectious disease control projects established in the Ministry of Health and Welfare under Article 8 (1) of the Act:
 - (a) Affairs concerning commissioning members prescribed in Article 1-2 (2);
 - (b) Affairs concerning reporting prescribed in Article 1-2 (4);
 - (c) Affairs concerning providing subsidies prescribed in Article 1-2 (5);
 - 1-2. Affairs concerning designating, operating and subsidizing regional infectious disease hospitals prescribed in Article 8-2 (2) and (3) of the Act and Article 1-4 of this Decree;
 - 1-3. Affairs concerning operating advisory committees established under Article 10 (3) of the Act;
 2. Affairs concerning reporting on infectious diseases prescribed in Article 11 (3) and (5) of the Act;
 3. Affairs concerning reporting by a Special Self-Governing Province Governor or the head of a *Si/Gun/Gu* under Article 13 of the Act;
 4. Affairs concerning the sentinel surveillance, etc. of infectious diseases conducted under Article 16 of the Act;
 5. Affairs concerning fact-finding surveys conducted under Article 17 of the Act;
 - 5-2. Affairs concerning requests for epidemiological investigation prescribed in Article 18-2 (1) and (2) of the Act;
 - 5-3. Affairs concerning fostering personnel for epidemiological investigation prescribed in Article 18-3 (1) of the Act;
 - 5-4. Affairs concerning submitting materials necessary for epidemiological investigation and affairs concerning requests for providing assistance, such as dispatching personnel for conducting epidemiological investigation, which are prescribed in Article 18-4 (1) and (2) of the Act;
 - 5-5. Affairs concerning funerals for the dead bodies of patients of infectious diseases, etc. prescribed in Article 20-2 of the Act;
 6. Affairs concerning reporting on extraction and transfer of high-risk pathogens under Article 21 of the Act;
 7. Affairs concerning permits, etc. to introduce high-risk pathogens under Article 22 of the Act;

8. Affairs concerning permission for or reports on the establishment and operation of high-risk pathogen handling facilities, permission for changes, reports on changes, reports on closure, and safety control prescribed in Article 23 of the Act;
- 8-2. Affairs concerning revocation of permission for high-risk pathogen handling facilities prescribed in Article 23-2 of the Act, an order for closure, and an order for suspension of operation;
9. Affairs concerning requests for special vaccinations under Article 25 (1) 1 of the Act;
10. Affairs concerning reporting on records on vaccinations under Article 28 of the Act;
11. Affairs concerning Vaccination Week, standards for conducting vaccinations, etc. specified under Article 32 of the Act;
12. Affairs concerning the planned production of vaccines, provision of subsidies, and reimbursement of expenses under Article 33 of the Act;
- 12-2. Affairs concerning establishing and operating the integrated management system; collecting, managing and keeping materials; requesting submission of materials; providing details of vaccination; issuing certificates of vaccination; and requesting for materials from the head of the National Court Administration, which are prescribed in Article 33-2 (1), (2) and (4) of the Act;
13. Affairs concerning establishing, etc. infectious disease control institutions as at the time of infectious disease emergencies under Article 37 of the Act;
- 13-2. Affairs concerning evaluating infectious disease control facilities prescribed in Article 39-2 of the Act;
14. Affairs concerning the stockpiling of, conclusion of contracts for, requirement for production of, and epidemiological investigations into, medicines and equipment for infectious diseases, etc. spread by biological terrorism under Article 40 of the Act;
- 14-2. Affairs concerning the distribution standards including priorities in supplying medicines stockpiled and produced in preparation for a pandemic of infectious diseases and other necessary matters prescribed in Article 40-2 of the Act;
15. Affairs concerning controlling patients of infectious diseases, etc. under Article 41 of the Act;
16. Affairs concerning making compulsory dispositions with respect to infectious diseases under Article 42 of the Act;
17. Affairs concerning giving hospitalization notice to patients of infectious diseases, etc. under Article 43 of the Act;
- 17-2. Affairs concerning measures to conduct medical examinations, vaccinations, etc. under Article 46 of the Act;
- 17-3. Affairs concerning measures to prevent the prevalence or spread of an infectious disease upon the outbreak of the infectious disease under Article 47 of the Act;
- 17-4. Affairs concerning measures to prevent an infectious disease under Article 49 of the Act;
18. Affairs concerning disease control officers and epidemiological investigative officers appointed under Articles 60 and 60-2 of the Act;
- 18-2. Affairs concerning orders for conducting disease control duties, and appointment and management of disease control officers and epidemiological investigation officers prescribed in Article 60-3 (1) through (3) of the Act;
19. Affairs concerning providing subsidies prescribed in Article 70-3 (1) of the Act;
- 19-2. Administrative affairs concerning medical costs, livelihood assistance and providing subsidies prescribed in Article 70-4 (1) of the Act;
20. Affairs concerning compensation by the State for injuries caused by vaccinations, etc. under Article 71 of the Act.
- 20-2. Affairs concerning requests for location information; providing information collected; and information and notification of destruction of information provided by persons provided with

such information prescribed in Article 76-2 (2) through (5) of the Act.

- (2) The Minister of Health and Welfare may entrust the duties provided for in Article 4 (2) 4 through 9 and 14 through 17 of the Act to any of the following entities, pursuant to Article 76 (2) of the Act: *<Newly Inserted by Presidential Decree No. 26024, Jan. 6, 2015; Presidential Decree No. 26865, Jan. 6, 2016>*
1. Government-funded research institutes established under the Act on the Establishment, Operation and Fostering of Government-Funded Research Institutes, Etc.;
 2. Schools defined in Article 2 of the Higher Education Act;
 3. Non-profit corporations established under the Civil Act or other Acts to conduct affairs concerning the prevention and control of infectious diseases;
 4. Other institutions or organizations deemed by the Minister of Health and Welfare to have expertise in the prevention and control of infectious diseases.
- (3) Where the Minister of Health and Welfare entrusts duties pursuant to paragraph (2), he/she shall publicly announce the entities and details of duties entrusted. *<Newly Inserted by Presidential Decree No. 26024, Jan. 6, 2015>*

Article 32-2 (Information Requestable to be Provided)

“Information prescribed by Presidential Decree” in Article 76-2 (1) 4 of the Act, means the following:

1. Credit card, debit card, and pre-paid card statements defined in subparagraphs 3, 6, and 8 of Article 2 of the Specialized Credit Finance Business Act;
2. Transportation card statements specified in Article 10-2 (1) of the Act on the Support and Promotion of Utilization of Mass Transit System;
3. Image data compiled through image data processing equipment defined in subparagraph 7 of Article 2 of the Personal Information Protection Act.

[This Article Newly Inserted by Presidential Decree No. 26865, Jan. 6, 2016]

Article 32-3 (Processing Sensitive Information and Personally Identifiable Information)

- (1) The State and local governments (including any person to whom relevant authority is delegated or entrusted) may process data containing information on health prescribed in Article 23 of the Personal Information Protection Act and resident registration numbers or foreigner registration numbers prescribed in subparagraph 1 or 4 of Article 19 of the Enforcement Decree of the same Act, if essential to conduct the following:
1. Affairs concerning the medical treatment and protection of patients of infectious diseases, etc. under Article 4 (2) 2 of the Act;
 2. Affairs concerning training experts for the prevention of infectious diseases under Article 4 (2) 8 of the Act;
 3. Affairs concerning international cooperation for the exchange, etc. of infectious disease control information under Article 4 (2) 9 of the Act.
- (2) The Minister of Health and Welfare, the Director of the Korea Centers for Disease Control and Prevention, the Mayors/*Do* Governors, the heads of *Sis/Guns/Gus* (including any medical institution entrusted with vaccination services by the head of a *Si/Gun/Gu* under Article 20), the directors of public health centers, or the institutions of sentinel surveillance of infectious diseases designated under Article 16 (1) of the Act may process data containing personal information prescribed in paragraph (1), with the exception of its subparagraphs, if essential to conduct the following: *<Amended by Presidential Decree No. 27277, Jun. 28, 2016>*
1. Affairs concerning the reporting, detection, and management of patients of infectious diseases, etc. under Articles 11 through 13 and 15 of the Act;
 2. Affairs concerning the sentinel surveillance, etc. of infectious diseases under Article 16 of the Act;

3. Affairs concerning fact-finding surveys conducted under Article 17 of the Act;
4. Affairs concerning epidemiological investigations conducted under Article 18 of the Act;
5. Affairs concerning medical examinations conducted under Article 19 of the Act;
6. Affairs concerning autopsy orders issued under Article 20 of the Act;
7. Affairs concerning high-risk pathogens specified in Articles 21 through 23 of the Act;
8. Affairs concerning vaccinations specified in Articles 24, 25, 26-2, 27 through 32, and 33-2 of the Act;
9. Affairs concerning the designation of infectious disease control institutions and the establishment and operation of infectious disease control facilities, isolation wards, sanatoriums, and clinics under Articles 36 and 37 of the Act;
10. Affairs concerning the control of patients of infectious diseases, etc. and measures for controlling and preventing infectious diseases under Articles 41 through 43, 45 through 47, 49, and 50 of the Act;
11. Affairs concerning reporting on disinfection services under Articles 52 and 53 of the Act;
12. Affairs concerning training for disinfection service providers, etc. under Article 55 of the Act;
13. Affairs concerning compensation for loss and compensation by the State for injuries caused by vaccinations, etc. under Articles 70 through 72 of the Act.

[This Article Newly Inserted by Presidential Decree No. 25532, Aug. 6, 2014]

Article 33 (Imposition of Administrative Fines)

The criteria for imposing administrative fines under Article 83 (1) and (2) of the Act shall be specified in attached Table 3. *<Amended by Presidential Decree No. 28962, Jun. 12, 2018>*

[This Article Wholly Amended by Presidential Decree No. 26865, Jan. 6, 2016]

Addendum *<Presidential Decree No. 30596, Apr. 2, 2020>*

This Decree shall enter into force on the date of its promulgation.

2.3 Quarantine Act

Act No. 17068, Mar. 4, 2020

CHAPTER I General Provisions

Article 1 (Purpose)

The purpose of this Act is to prevent the spread of infectious diseases within the Republic of Korea and overseas by providing for matters concerning procedures for quarantining all means of transport, persons and cargo which enter or depart from the Republic of Korea and measures for preventing infectious diseases, thereby contributing to the maintenance and protection of the public health.

#Article 1 (Purpose)

The purpose of this Act is to prevent the spread of infectious diseases within the Republic of Korea and overseas by providing for matters concerning the procedures for quarantining persons, all means of transport and cargo, which enter or depart from the Republic of Korea and measures for preventing infectious diseases, thereby contributing to the maintenance and protection of the public health.

<Amended by Act No. 17068, Mar. 4, 2020>

<<Enforcement Date: Mar. 5, 2021>>

Article 2 (Definitions)

The definitions of terms used in this Act shall be as follows: <Amended by Act No. 9932, Jan. 18, 2010; Act No. 13980, Feb. 3, 2016; Act No. 15266, Dec. 19, 2017; Act No. 17068, Mar. 4, 2020>

1. The term "quarantinable infectious disease" means any of the following diseases:
 - (a) Cholera;
 - (b) Pest;
 - (c) Yellow fever;
 - (d) Severe Acute Respiratory Syndrome (SARS);
 - (e) Animal influenza infection in humans;
 - (f) Novel influenza;
 - (g) Middle East Respiratory Syndrome (MERS);
 - (h) Infectious diseases deemed and publicly notified by the Minister of Health and Welfare as requiring emergency quarantine measures because they have occurred in other countries and are likely to spread within the Republic of Korea or they have occurred within the Republic of Korea and are likely to spread into other countries, except as otherwise prescribed in items (a) through (g);
2. The term "means of transport" means any ship, aircraft, train or motor vehicle;
3. The term "patient of a quarantinable infectious disease" means a person infected with the pathogen of a quarantinable infectious disease to show symptoms and confirmed by a physician through diagnosis and laboratory test;
4. The term "probable patient of a quarantinable infectious disease" means a person suspected of being infected with the pathogen of a quarantinable infectious disease and in the stage prior to being confirmed;
5. The term "person suspected of contracting a quarantinable infectious disease" means a person who has been in contact with a patient or probable patient of a quarantinable infectious disease or exposed to the pathogen of a quarantinable infectious disease and is suspected of contracting a quarantinable infectious disease despite showing no symptoms;
6. The term "vector of infectious diseases" means a rat or vermin that transports harmful infection

substances to public health;

7. The term “quarantine inspection required area” means any area designated under Article 5 because a quarantinable infectious disease is, or is likely to be, epidemic in such area and is likely to be introduced to the Republic of Korea;
8. The term “strict quarantine inspection required area” means any area designated under Article 5 from among quarantine inspection required areas as strict quarantine is required due to the fatality and high infectivity of a quarantinable infectious disease that is, or is likely to be, epidemic in such area.

#Article 2 (Definitions)

The definitions of terms used in this Act shall be as follows: <Amended by Act No. 9932, Jan. 18, 2010; Act No. 13980, Feb. 3, 2016; Act No. 15266, Dec. 19, 2017; Act No. 17068, Mar. 4, 2020>

1. The term "quarantinable infectious disease" means any of the following diseases:
 - (a) Cholera;
 - (b) Pest;
 - (c) Yellow fever;
 - (d) Severe Acute Respiratory Syndrome (SARS);
 - (e) Animal influenza infection in humans;
 - (f) Novel influenza;
 - (g) Middle East Respiratory Syndrome (MERS);
 - (h) Ebola virus disease;
 - (i) Infectious diseases deemed and publicly notified by the Minister of Health and Welfare as requiring emergency quarantine measures because they have occurred in other countries and are likely to spread within the Republic of Korea or they have occurred within the Republic of Korea and are likely to spread into other countries, except as otherwise prescribed in items (a) through (h);
2. The term "means of transport" means any ship, aircraft, train or motor vehicle;
- 2-2. The term “the head of a means of transport” means a person who operates or runs a means of transport, a person responsible for operating or running a means of transport, or an owner of a means of transport;
3. The term "patient of a quarantinable infectious disease" means a person infected with the pathogen of a quarantinable infectious disease to show symptoms and confirmed by a physician, a dentist, or an oriental medical doctor through diagnosis and laboratory test;
4. The term "probable patient of a quarantinable infectious disease" means a person suspected of being infected with the pathogen of a quarantinable infectious disease and in the stage prior to being confirmed;
5. The term “contact of a patient of a quarantinable infectious disease, etc.” means a person who has, or is suspected of having, contact with a patient or probable patient of a quarantinable infectious disease or with a pathogen carrier (hereinafter referred to as “patient of a quarantinable infectious disease, etc.”);
6. The term "vector of infectious diseases" means a rodent or vermin prescribed by Ordinance of Ministry of Health and Welfare that can transmit infectious pathogens harmful to public health;
7. The term “quarantine inspection required area” means any area designated under Article 5 because a quarantinable infectious disease is, or is likely to be, epidemic in such area and is likely to be introduced into the Republic of Korea;
8. The term “strict quarantine inspection required area” means any area designated under Article 5 from among quarantine inspection required areas because strict quarantine is required due to the fatality and high infectivity of a quarantinable infectious disease that is, or is likely to be, epidemic in such area.

<<Enforcement Date: Mar. 5, 2021>>

Article 3 (Responsibilities)

- (1) The State shall protect human rights during which quarantine services are provided.
- (2) The State shall establish countermeasures to promptly cope with the spread of quarantinable infectious diseases in the Republic of Korea and overseas.
- (3) Citizens shall fully cooperate with the State's policies to prevent the spread of quarantinable infectious diseases in the Republic of Korea and overseas.

#Article 3 (Responsibilities of the State)

- (1) The State shall protect human rights during which quarantine services are provided.
- (2) The State shall establish countermeasures to promptly cope with the spread of quarantinable infectious diseases in the Republic of Korea and overseas.
- (3) Deleted. <by Act No. 17068, Mar. 4, 2020>
<<Enforcement Date: Mar. 5, 2021>>

#Article 3-2 (Rights and Obligations of Citizens)

- (1) Citizens have the right to know information about the outbreaks, prevention and control of quarantinable infectious diseases and how to deal with, the quarantinable infectious diseases.
- (2) Citizens, if quarantined or isolated due to quarantinable infectious diseases, can be compensated for any damage caused by such quarantine or isolation.
- (3) Citizens shall fully cooperate with the State or a local government in its policies to prevent the spread of quarantinable infectious diseases in the Republic of Korea and overseas.

[This Article Newly Inserted by Act No. 17068, Mar. 4, 2020]

<<Enforcement Date: Mar. 5, 2021>>

Article 4 (Relationship to Other Acts)

This Act shall apply to quarantine-related duties except as otherwise provided for in other Acts.

#Article 4-2 (Establishment and Implementation of Quarantine Control Master Plans)

- (1) The Minister of Health and Welfare shall establish and implement a quarantine control master plan (hereinafter referred to as “master plan”) every five years following deliberation by the quarantine advisory committee (which means the advisory committee in the field of quarantine established under the infectious disease control committee under Articles 9 and 10 (3) of the Infectious Disease Control and Prevention Act; hereinafter the same applies).
- (2) Master plans shall contain the following:
 1. Basic objectives of quarantine and directions for accomplishing such objectives;
 2. Quarantine project plans and methods for promoting such plans;
 3. A scheme to manage statistics and information on quarantine;
 4. A scheme to train, and strengthen the capabilities of, public officials in charge of quarantine under Article 30;
 5. Other matters necessary for quarantine control.
- (3) The director of every quarantine station shall establish and implement an annual plan under his or her jurisdiction in accordance with the master plan established under paragraph (1).
- (4) The Minister of Health and Welfare and the director of every quarantine station may request relevant administrative agencies or organizations to provide materials necessary to establish and implement master plans and annual plans.
- (5) Upon receipt of a request under paragraph (4), the heads of relevant administrative agencies or organizations shall comply with the request unless good cause exists.

[This Article Newly Inserted by Act No. 17068, Mar. 4, 2020]

<<Enforcement Date: Mar. 5, 2021>>

Article 5 (Designation and Cancellation of Quarantine Inspection Required Area or Similar Area)

- (1) The Minister of Health and Welfare may designate or cancel the designation of a quarantine inspection required area or strict quarantine inspection required area (hereinafter referred to as “quarantine inspection required area or similar area”) following deliberation by the quarantine advisory committee. <Amended by Act No. 9932, Jan. 18, 2010; Act No. 17068, Mar. 4, 2020>
- (2) The standards and procedure for designating and cancelling the designation of quarantine inspection required areas or similar areas under paragraph (1) and other necessary matters shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010; Act No. 17068, Mar. 4, 2020>

Article 5-2 (Control of Adjacent Areas to Contaminated Areas)

- (1) The Minister of Health and Welfare, if necessary to prevent the spread of quarantinable infectious disease, may require a person who has stayed in, or traveled via, an adjacent area to a contaminated area designated under Article 5 (1) in which a quarantinable infectious disease is likely to occur (hereinafter referred to as “adjacent area to a contaminated area”) to submit health condition questionnaires or undergo fever checks or may take other quarantine measures.
- (2) The scope and selection of adjacent areas to a contaminated area referred to in paragraph (1) and other necessary matters shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 13980, Feb. 3, 2016]

#Article 5-2 Deleted. <by Act No. 17068, Mar. 4, 2020>

<<Enforcement Date: Mar. 5, 2021>>

CHAPTER II Quarantine Inspection

Article 6 (Means of Transport Requiring Quarantine)

- (1) A means of transport, persons and cargo (including containers, furnished supplies, consumable goods, and personal belongings carried by a means of transport; hereinafter the same shall apply) that falls under any of the following shall undergo quarantine inspections under Article 12: *Provided*, That the quarantine inspection of a means of transport, persons or cargo that departs from the Republic of Korea may be omitted if the Minister of Health and Welfare deems that any quarantinable infectious disease occurred within the Republic of Korea is unlikely to spread abroad: <Amended by Act No. 9932, Jan. 18, 2010>
 1. Means of transport, persons and cargo that enter or depart from the Republic of Korea;
 2. Means of transport, persons and cargo that have had contact with the means of transport provided for in subparagraph 1 while conducting duties to prevent or investigate crimes or arrest suspects.
- (2) Means of transport, persons and cargo that have not undergone a quarantine inspection provided for in paragraph (1) may not enter or depart from the Republic of Korea before the quarantine procedure is completed.
- (3) Notwithstanding paragraphs (1) and (2), all or part of a quarantine inspection may be omitted for a means of transport prescribed by Ordinance of the Ministry of Health and Welfare if the means of transport temporarily stays in the Republic of Korea to be supplied with fuel, materials, daily necessities, etc., as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010>

#Article 6 (Those Subject to Quarantine Inspection)

- (1) Any of the following persons, means of transport and cargo (including containers, furnished

supplies, consumable goods, and personal belongings carried by a means of transport; hereinafter the same applies) shall undergo quarantine inspections under Article 12: <Amended by Act No. 9932, Jan. 18, 2010; Act No. 17068, Mar. 4, 2020>

1. All persons, including passengers and crew members, (hereinafter referred to as “persons entering or departing from the Republic of Korea”), the means of transport, and cargo prescribed by Ordinance of Ministry of Health and Welfare that enter or depart from the Republic of Korea;
 2. Persons, means of transport and cargo that have had contact with the means of transport provided for in subparagraph 1 on the grounds prescribed by Presidential Decree while conducting duties to prevent or investigate crimes or arrest suspects.
- (2) Means of transport, persons and cargo that have not undergone a quarantine inspection provided for in paragraph (1) may not enter or depart from the Republic of Korea before the quarantine procedure is completed.
- (3) Notwithstanding paragraphs (1) and (2), all or part of a quarantine inspection may be omitted for any of the following means of transport in which there is no patient of a quarantinable infectious disease, etc. or deceased case, as prescribed by Presidential Decree: <Amended by Act No. 9932, Jan. 18, 2010; Act No. 17068, Mar. 4, 2020>
1. A means of transport departing from the Republic of Korea (including persons and cargo), if the Minister of Health and Welfare deems that a quarantinable infectious disease occurred within the Republic of Korea is unlikely to spread overseas;
 2. A means of transport prescribed by Ordinance of Ministry of Health and Welfare among those that temporarily stay in the Republic of Korea to be supplied with fuel, materials, necessities, etc.;
 3. A means of military transport, if the head of such means of military transport notifies that there is no patient of a quarantinable infectious disease, etc. and vector of any infectious disease therein;
 4. A means of transport requested by the Minister of Unification under Article 23 (2) of the Inter-Korean Exchange and Cooperation Act (In such cases, the quarantine inspection or some of quarantine inspection procedures can be omitted.);
 5. A means of transport deemed by Ordinance of Ministry of Health and Welfare, if the head of a relevant central administrative agency requests omission of the quarantine inspection for such means of transport.

<<Enforcement Date: Mar. 5, 2021>>

Article 7 (Quarantine of Means of Military Transport)

The director of the quarantine station may omit the quarantine inspection of a means of military transport if the head of the means of military transport notifies as follows:

1. Where the head of the means of military transport notifies that there is no patient or probable patient of a quarantinable infectious disease in the means of military transport;
2. Where the head of the means of military transport notifies that vectors of infectious diseases are not found in the means of military transport.

#Article 7 Deleted. <by Act No. 17068, Mar. 4, 2020>

<<Enforcement Date: Mar. 5, 2021>>

Article 8 (Quarantine of Means of Transport for Evacuation)

- (1) Where a means of transport inevitably arrives at any place other than a place for quarantine to escape imminent danger, a person who operates or runs the means of transport, or a person responsible for operating or running the means of transport (hereinafter referred to as "head of a means of transport") shall report the matters prescribed by Ordinance of the Ministry of Health and Welfare, including whether there is a patient of a quarantinable infectious disease and sanitary state to the director of the quarantine station having jurisdiction over the quarantine location nearest to the place of arrival.

<Amended by Act No. 9932, Jan. 18, 2010>

- (2) The director of the quarantine station in receipt of the report provided for in paragraph (1) may give the head of the means of transport instructions to take necessary measures, such as measures for the patient of a quarantinable infectious disease.
- (3) The head of the means of transport given instructions provided for in paragraph (2) shall comply with such instructions.

#Article 8 Deleted. *<by Act No. 17068, Mar. 4, 2020>*

<<Enforcement Date: Mar. 5, 2021>>

Article 9 (Notification of Quarantine)

Where a means of transport approaches a place for quarantine, the head of the means of transport shall notify the director of the quarantine station having jurisdiction over the relevant place for quarantine of the matters prescribed by Ordinance of the Ministry of Health and Welfare, including whether there is a patient of a quarantinable infectious disease and the sanitary state, as prescribed by Ordinance of the Ministry of Health and Welfare: *Provided*, That where a means of transport approaches for such reasons as seizure, surrender or distress, the head of an investigation agency may notify such matters. *<Amended by Act No. 9932, Jan. 18, 2010>*

#Article 9 (Notification of Quarantine)

- (1) Where a means of transport subject to quarantine inspection under Article 6 approaches a place for quarantine, the head of the means of transport shall notify the director of the quarantine station having jurisdiction over the place for quarantine of the matters prescribed by Ordinance of the Ministry of Health and Welfare, including whether there is a patient of a quarantinable infectious disease, etc. and the sanitary state, as prescribed by Ordinance of the Ministry of Health and Welfare: *Provided*, That where a means of transport inevitably arrives at any place other than a place for quarantine in order to escape imminent danger, the head of the means of transport shall notify the director of the quarantine station having jurisdiction over the quarantine location nearest to the place of arrival of such matters. *<Amended by Act No. 9932, Jan. 18, 2010; Act No. 17068, Mar. 4, 2020>*
- (2) The director of the quarantine station being notified under the proviso of paragraph (1) may give the head of a means of transport instructions to take necessary measures, such as measures for a patient of a quarantinable infectious disease, etc. and the head of the means of transport given the instructions shall follow such instructions. *<Newly Inserted by Act No. 17068, Mar. 4, 2020>*
- (3) Notwithstanding paragraph (1), if a means of transport approaches for such reasons as seizure, surrender or distress, the head of an investigation agency may give notification to the director of the competent quarantine station. *<Newly Inserted by Act No. 17068, Mar. 4, 2020>*
- (4) If there is any change to the matters notified under paragraph (1) or (3), the head of the means of transport or the head of the investigation agency shall immediately notify the head of the quarantine station of such change. *<Newly Inserted by Act No. 17068, Mar. 4, 2020>*
- (5) Methods and procedures for notification under paragraphs (1) through (4) and other necessary matters shall be prescribed by Ordinance of Ministry of Health and Welfare. *<Newly Inserted by Act No. 17068, Mar. 4, 2020>*

<<Enforcement Date: Mar. 5, 2021>>

Article 10 (Place for Quarantine)

- (1) The Minister of Health and Welfare shall designate a place for quarantine in consultation with the head of a related central administrative agency. *<Amended by Act No. 9932, Jan. 18, 2010>*
- (2) A means of transport to be quarantined shall undergo a quarantine inspection after arriving at the place for quarantine. In such cases, any ship shall undergo a quarantine inspection after flying a

yellow flag or turning on a yellow headlight to indicate a state of quarantine.

- (3) The director of the quarantine station may conduct a quarantine inspection in any place, other than a place for quarantine provided for in paragraph (1) due to weather conditions or other unavoidable reasons specified by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 11972, Jul. 30, 2013>
- (4) A means of transport departing from the Republic of Korea shall undergo a quarantine inspection in a quarantine area designated by Ordinance of the Ministry of Health and Welfare (hereinafter referred to as "quarantine area"). <Amended by Act No. 9932, Jan. 18, 2010>

#Article 10 (Place for Quarantine)

- (1) The Minister of Health and Welfare shall designate a place for quarantine in consultation with the head of a related central administrative agency. <Amended by Act No. 9932, Jan. 18, 2010>
- (2) Any person or means of transport entering or departing from the Republic of Korea that intends to be quarantined shall undergo a quarantine inspection after arriving at the place for quarantine: *Provided*, That if the person or the means of transport has difficulty in undergoing, or can not complete, a quarantine inspection at the place for quarantine, the person or the means of transport may undergo a quarantine inspection at any quarantine area prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 17068, Mar. 4, 2020>
- (3) Notwithstanding paragraph (2), a quarantine inspection can be conducted at a place for quarantine designated by the director of the quarantine station in any of the following cases: <Amended by Act No. 17068, Mar. 4, 2020>
 1. If it is unavoidable for such reasons as seizure, surrender, distress or an emergency patient;
 2. In cases prescribed by Ordinance of the Ministry of Health and Welfare due to weather conditions or other unavoidable causes.
- (4) Deleted. <by Act No. 17068, Mar. 4, 2020>
<<Enforcement Date: Mar. 5, 2021>>

Article 11 (Quarantine Time)

- (1) The director of the quarantine station shall conduct a quarantine inspection immediately after a ship arrives at a place for quarantine from sunrise to sunset except in exceptional circumstances, such as weather conditions and a ship falling under any of the following shall be quarantined immediately after arrival even if the ship arrives at a place for quarantine after sunset:
 1. A ship with any emergency patient on board;
 2. A ship which carries cargo needed to be urgently unloaded;
 3. A ship in which any emergency situation, such as an accident, occurs.
- (2) The director of the quarantine station shall conduct a quarantine inspection immediately after a means of transport, other than a ship, arrives at a place for quarantine and may permit passengers and crew members to get off and cargo to be unloaded on condition that they wait or are quarantined in a quarantine area if unavoidable causes make an immediate quarantine impossible.
- (3) The head of a means of transport departing from the Republic of Korea shall notify the director of the quarantine station of a scheduled departure time.
- (4) The director of the quarantine station shall complete a quarantine inspection before a scheduled departure time notified pursuant to paragraph (3).

#Article 11 (Quarantine Time)

- (1) Deleted. <by Act No. 17068, Mar. 4, 2020>
- (2) The director of the quarantine station shall conduct a quarantine inspection immediately after a person or means of transport subject to quarantine inspection under Article 6 arrives at a place for quarantine: *Provided*, That if unavoidable causes prescribed by Ordinance of the Ministry of

Health and Welfare make an immediate quarantine inspection impossible, the director of the quarantine station may permit passengers and crew members to get off and cargo to be unloaded on condition that they wait or are quarantined in a specified place for quarantine. <Amended by Act No. 17068, Mar. 4, 2020>

- (3) The head of a means of transport departing from the Republic of Korea shall notify the director of the quarantine station of a scheduled departure time.
- (4) The director of the quarantine station shall complete a quarantine inspection before a scheduled departure time notified pursuant to paragraph (3).

<<Enforcement Date: Mar. 5, 2021>>

Article 12 (Quarantine Inspection)

- (1) The director of the quarantine station shall conduct a quarantine inspection on the following matters: *Provided*, That in cases of a motor vehicle, the matters, other than those provided for in subparagraph 2, may be omitted:
 1. Progress and current status of health and sanitary conditions of a means of transport;
 2. Matters concerning the prevention and control of quarantinable infectious diseases for passengers, crew members and persons entering or departing from the Republic of Korea by land (hereinafter referred to as "persons entering or departing by land");
 3. The storage status of food and the status of the cargo loaded in a means of transport;
 4. Whether vectors for infectious diseases inhabit and the state of their breeding.
- (2) Any person entering or departing by land shall undergo a quarantine inspection at a quarantine area or a place designated by Ordinance of the Ministry of Health and Welfare before entering or departing from the Republic of Korea. <Amended by Act No. 9932, Jan. 18, 2010; Act No. 11972, Jul. 30, 2013>
- (3) The director of the quarantine station may request the head, passengers and crew members of a means of transport or persons entering or departing by land to submit or present necessary documents and question them about necessary matters to conduct the quarantine inspection referred to in paragraph (1).
- (4) Necessary matters concerning methods of and procedures for a quarantine inspection referred to in paragraphs (1) through (3) shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010>

#Article 12 (Quarantine Inspection)

- (1) The director of the quarantine station shall conduct a quarantine inspection on the following matters: *Provided*, That in cases of a motor vehicle, the matters, other than those provided for in subparagraph 2, may be omitted: <Amended by Act No. 17068, Mar. 4, 2020>
 1. Progress and current status of health and sanitary conditions of a means of transport and cargo;
 2. Whether persons entering or departing from the Republic of Korea are infected with any quarantinable infectious disease and have any risk factors of quarantinable infectious diseases, and prevention and control thereof;
 3. The storage status of food in a means of transport;
 4. Whether vectors for infectious diseases inhabit and the state of their breeding.
- (2) Persons entering or departing from the Republic of Korea by land shall undergo a quarantine inspection at a quarantine area or a place designated by Ordinance of the Ministry of Health and Welfare before entering or departing from the Republic of Korea. <Amended by Act No. 9932, Jan. 18, 2010; Act No. 11972, Jul. 30, 2013; Act No. 17068, Mar. 4, 2020>
- (3) In order to conduct a quarantine inspection under paragraph (1), the director of the quarantine station may request persons and the heads of means of transport entering or departing from the Republic of Korea to submit or present necessary documents and may ask necessary questions to, or inspect or

investigate, them. <Amended by Act No. 17068, Mar. 4, 2020>

- (4) The directors of quarantine stations may utilize such equipment as IT devices, image processing devices and electronic-sensing devices in order to perform quarantine duties promptly and accurately. <Newly Inserted by Act No. 17068, Mar. 4, 2020>
- (5) Necessary matters concerning methods of and procedures for a quarantine inspection referred to in paragraphs (1) through (4) shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010; Act No. 17068, Mar. 4, 2020>
- <<Enforcement Date: Mar. 5, 2021>>

#Article 12-2 (Duty to Report and Measures)

- (1) Any of the following persons shall report his or her health conditions and other relevant matters to the director of the quarantine station, as prescribed by Ordinance of the Ministry of Health and Welfare, if the maximum incubation period for a quarantinable infectious disease under Article 17 (3) has not expired since his or her departure from a quarantine inspection required area or strict quarantine inspection required area:
1. A person who has any suspected symptom of a quarantinable infectious disease among those who enter the Republic of Korea after staying in or via the quarantine inspection required area;
 2. A person who enters the Republic of Korea after staying in or via the strict quarantine inspection required area.
- (2) The Minister of Health and Welfare shall establish an overseas infectious disease reporting center at every arrival hall of airports, ports and land-border crossings so that the persons referred to in the subparagraphs of paragraph (1) can report their health conditions and other relevant matters.
- (3) If the director of the quarantine station determines that a quarantinable infectious disease is likely to spread, the director may take the following measures in relation to a person who reports under paragraph (1):
1. Requesting information about the area and duration of his or her travel;
 2. Requesting information about his or her health conditions in relation to the quarantinable infectious disease;
 3. Requesting a document certifying that he or she is vaccinated;
 4. Testing and examining the person to check if he or she is infected with the quarantinable infectious disease;
 5. Other measures prescribed by Ordinance of the Ministry of Health and Welfare as necessary to prevent the spread of the quarantinable infectious disease.
- (4) If a quarantinable infectious disease that has broken out in the Republic of Korea is likely to spread overseas, a person having a suspected symptom of the quarantinable infectious disease among those who go abroad shall report his or her health conditions and other relevant matters to the overseas infectious disease reporting center established under paragraph (2). In such cases, the director of the quarantine station may take the measures provided in paragraph (3) in relation to the person who reports his or her health conditions and other relevant matters.
- (5) Procedures and methods for reporting under paragraphs (1) and (4), the establishment and operations of the overseas infectious disease reporting centers under paragraph (2), and other necessary matters shall be prescribed by Ordinance of the Ministry of Health and Welfare.
- [This Article Newly Inserted by Act No. 17068, Mar. 4, 2020] <<Enforcement Date: Mar. 5, 2021>>

#Article 12-3 (Aircraft Quarantine Inspection)

- (1) The head of a means of transport who intends to undergo an aircraft quarantine inspection shall submit documents necessary for such quarantine inspection to the director of the quarantine station, as prescribed by Ordinance of the Ministry of Health and Welfare.
- (2) If the director of the quarantine station determines that a quarantinable infectious disease is unlikely

to spread in the Republic of Korea by reviewing the documents submitted under paragraph (1), the director may conduct a quarantine inspection through document review: *Provided*, That the director shall conduct a quarantine inspection onboard the aircraft if there is a high risk of the spread of a quarantinable infectious disease or in cases prescribed by Ordinance of the Ministry of Health and Welfare.

- (3) Submittal of documents under paragraph (1) and quarantine inspections through document review under the main sentence of paragraph (2) may be done using an electronic system.
- (4) If any information contained in the documents submitted under paragraph (1) is found to be false, necessary measures including re-quarantine shall be taken, as prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 17068, Mar. 4, 2020] <<Enforcement Date: Mar. 5, 2021>>

#Article 12-4 (Ship Quarantine Inspection)

- (1) The head of a means of transport who intends to undergo a ship quarantine inspection shall submit documents necessary for such quarantine inspection to the director of the quarantine station, as prescribed by Ordinance of the Ministry of Health and Welfare. In such cases, the head of the means of transport shall fly a yellow flag or turn on a yellow headlight to indicate a state of quarantine after arriving at the place for quarantine.
- (2) In requesting the head of a means of transport to submit documents under Article 12 (3), the director of the quarantine station may require the representative of a shipping agency registered under Article 33 of the Marine Transportation Act to submit or present the relevant documents before the arrival of the means of transport.
- (3) If the director of the quarantine station determines that a quarantinable infectious disease is unlikely to spread in the Republic of Korea by reviewing the documents submitted under paragraph (1), the director may conduct a quarantine inspection through document review: *Provided*, That the director shall conduct a quarantine inspection onboard the ship if there is a high risk of the spread of a quarantinable infectious disease or in cases prescribed by Ordinance of the Ministry of Health and Welfare.
- (4) Submittal of documents under paragraph (1) and quarantine inspections through document review under the main sentence of paragraph (3) may be done using an electronic system.
- (5) The director of the quarantine station may select a ship and conduct a health and sanitation inspection after a quarantine inspection, as prescribed by Ordinance of the Ministry of Health and Welfare, in order to verify whether the information contained in the documents submitted under paragraph (1) is accurate and for health and sanitation control.
- (6) If any information contained in the documents submitted under paragraph (1) is found to be false, necessary measures including re-quarantine shall be taken, as prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 17068, Mar. 4, 2020] <<Enforcement Date: Mar. 5, 2021>>

#Article 12-5 (Quarantine Inspection for Entry and Departure by Land)

- (1) Persons and means of transport entering or departing from the Republic of Korea by land shall undergo a quarantine inspection, as prescribed by Ordinance of the Ministry of Health and Welfare.
- (2) If the Minister of Unification requests consultation about persons and means of transport entering or departing from the Republic of Korea under the proviso of Article 23 (2) of the Inter-Korean Exchange and Cooperation Act, the Minister of Health and Welfare may omit some of the procedures for quarantine notification under Article 9 (1), as prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 17068, Mar. 4, 2020] <<Enforcement Date: Mar. 5, 2021>>

Article 13 (Boarding Prior to Quarantine)

- (1) Anyone, other than public officials in charge of quarantine under Article 30, shall be prohibited from boarding a means of transport subject to a quarantine inspection before a quarantine certificate is issued: *Provided*, That this shall not apply to persons permitted by the director of the quarantine station as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010>
- (2) Anyone who has boarded a means of transport without any permission from the director of the quarantine station shall undergo a quarantine inspection.

#Article 13 (Boarding Prior to Quarantine)

- (1) Anyone, other than public officials in charge of quarantine under Article 30, shall be prohibited from boarding a means of transport subject to a quarantine inspection before a quarantine certificate is issued after completion of the quarantine inspection: *Provided*, That this shall not apply to persons permitted by the director of the quarantine station as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010; Act No. 17068, Mar. 4, 2020>
 - (2) Anyone who has boarded a means of transport without any permission from the director of the quarantine station shall undergo a quarantine inspection and, if a person onboard a ship or aircraft with permission of the director of the quarantine station under the proviso of paragraph (1) has any symptom of a quarantinable infectious disease or has contact with a patient of a quarantinable infectious disease, etc., the person shall immediately report to the director of the quarantine station. <Amended by Act No. 17068, Mar. 4, 2020>
 - (3) Upon receipt of reporting under paragraph (2), the director of the quarantine station shall immediately conduct a quarantine inspection on the relevant person. <Newly Inserted by Act No. 17068, Mar. 4, 2020>
 - (4) Methods for quarantine inspections under paragraph (3) shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Newly Inserted by Act No. 17068, Mar. 4, 2020>
- <<Enforcement Date: Mar. 5, 2021>>

Article 14 (Electronic Quarantine)

- (1) Where the head of a means of transport submits an application for quarantine in electronic form, the director of the quarantine station may notify the head of the means of transport of the completion of the quarantine procedures, upon its arrival, and issue a quarantine certificate if the director deems that the quarantinable infectious disease is unlikely to spread in the Republic of Korea by confirming the quarantine information pertaining to the relevant means of transport.
- (2) Where any information contained in electronic application submitted under paragraph (1) is found to be false, the director of the quarantine station may take necessary measures including re-quarantine as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010>
- (3) Necessary matters concerning procedures and methods for electronic quarantine referred to in paragraphs (1) and (2) shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010>

#Article 14 Deleted. <by Act No. 17068, Mar. 4, 2020> <<Enforcement Date: Mar. 5, 2021>>

Article 15 (Quarantine Measures)

- (1) The director of the quarantine station may take all or some of the following measures in relation to a confirmed or suspected case or means of transport or cargo contaminated or suspected of being contaminated by the pathogen of a quarantinable infectious disease or suspected of being inhabited by vectors of a quarantinable infectious disease: <Amended by Act No. 13980, Feb. 3, 2016>

1. Isolating a patient or probable patient of a quarantinable infectious disease (hereinafter referred to as "patient of a quarantinable infectious disease, etc.");
 2. Monitoring or quarantining a person suspected of contracting a quarantinable infectious disease;
 3. Disinfecting, destructing, or prohibiting the transfer of, cargo contaminated with or suspected of being contaminated with the pathogen of a quarantinable infectious disease;
 4. Disinfecting any place contaminated or suspected of being contaminated with the pathogen of a quarantinable infectious disease, and prohibiting or restricting the use of such place;
 5. Performing an autopsy to examine a corpse (including any dead fetus; hereinafter the same shall apply) that is contaminated or suspected of being contaminated with a quarantinable infectious disease;
 6. Ordering the head of a means of transport or the owner or manager of cargo to disinfect the means of transport or the cargo, and eradicating vectors of an infectious disease;
 7. Medically examining or testing persons if it is deemed necessary to confirm whether they are infected with a quarantinable infectious disease;
 8. Vaccinating persons for the prevention of a quarantinable infectious disease.
- (2) The performance of an autopsy pursuant to paragraph (1) 5 shall require the consent from a relative under subparagraph 16 of Article 2 of the Act on Funeral Services, Etc. (where no person of senior rank is available as provided for in each item of the same subparagraph, referring to the person in subsequent order; hereinafter referred to as "relative"): *Provided*, That in any of the following cases, the consent of the relative need not be obtained:
1. Where the relative lives abroad or in an island, a secluded area, etc. or the whereabouts of the relative is unknown;
 2. Where it is impossible to obtain the consent of the relative due to other reasons;
 3. Where it is impossible to achieve the objective of autopsy if it is delayed until the consent of the relative is obtained.
- (3) The head of a means of transport or the owner or the manager of cargo who has received an order referred to in paragraph (1) 6 shall outsource disinfection, etc. to any other person qualified as prescribed by Ordinance of the Ministry of Health and Welfare and shall submit the results of such disinfection, etc. to the director of the quarantine station for confirmation. *<Amended by Act No. 9932, Jan. 18, 2010>*
- (4) Where the director of the quarantine station can not take proper measures pursuant to paragraph (1), the director may notify the head of the means of transport of the reason and give instructions to return or move his or her means of transport to any other place for quarantine. In such cases, the head of the relevant means of transport shall comply with such instruction.
- (5) Where necessary to take quarantine measures pursuant to paragraph (1), the director of the quarantine station may request cooperation from the relevant agency, and the head of the relevant agency in receipt of the request shall comply with such request unless any extenuating circumstance exists.

#Article 15 (Quarantine Measures)

- (1) To block the introduction and spread of quarantinable infectious diseases, the Minister of Health and Welfare may take all or some of the following measures in relation to a confirmed or suspected case or means of transport or cargo contaminated or suspected of being contaminated with the pathogen of a quarantinable infectious disease or suspected of being inhabited by vectors of a quarantinable infectious disease: *<Amended by Act No. 13980, Feb. 3, 2016; Act No. 17068, Mar. 4, 2020>*
1. Monitoring or isolating a patient of a quarantinable infectious disease, etc.;
 2. Monitoring or quarantining a contact of a patient of a quarantinable infectious disease, etc. or a person exposed to a risk factor of a quarantinable infectious disease prescribed by Ordinance of Ministry of Health and Welfare (hereinafter referred to as "person exposed to a risk factor of a

- quarantinable infectious disease”);
3. Disinfecting, destructing, or prohibiting the transfer of cargo contaminated with or suspected of being contaminated with the pathogen of a quarantinable infectious disease;
 4. Disinfecting any place contaminated or suspected of being contaminated with the pathogen of a quarantinable infectious disease, and prohibiting or restricting the use of such place;
 - 4-2. Inspecting a means of transport or cargo, if it is deemed necessary to confirm whether such means of transport or cargo is contaminated with the pathogen of a quarantinable infectious disease;
 5. Deleted; <by Act No. 17068, Mar. 4, 2020>
 6. Ordering the head of a means of transport or the owner or manager of cargo to disinfect the means of transport or the cargo in which vectors of a quarantinable infectious disease live or are suspected of living, and to eradicate the vectors of a quarantinable infectious disease;
 7. Medically examining or testing persons if it is deemed necessary to confirm whether they are infected with a quarantinable infectious disease;
 8. Vaccinating persons for the prevention of a quarantinable infectious disease.
- (2) Deleted. <by Act No. 17068, Mar. 4, 2020>
- (3) The head of a means of transport or the owner or manager of cargo who has received an order referred to in paragraph (1) 6 shall outsource disinfection, etc. to any other person qualified as prescribed by Ordinance of the Ministry of Health and Welfare and shall submit the results of such disinfection to the director of the quarantine station for confirmation. <Amended by Act No. 9932, Jan. 18, 2010; Act No. 17068, Mar. 4, 2020>
- (4) Where the director of the quarantine station can not take proper measures pursuant to paragraph (1), the director may notify the head of the means of transport of the reason and give instructions to move the means of transport to a place the director designates. In such cases, the head of the relevant means of transport shall comply with such instruction. <Amended by Act No. 17068, Mar. 4, 2020>
- (5) Where necessary to take quarantine measures pursuant to paragraph (1), the Minister of Health and Welfare may request cooperation from the relevant agency, as prescribed by Presidential Decree, and the head of the relevant agency in receipt of the request shall comply with such request unless any extenuating circumstance exists. <Amended by Act No. 17068, Mar. 4, 2020>
- <<Enforcement Date: Mar. 5, 2021>>

Article 16 (Isolation of Patients of Quarantinable Infectious Disease)

- (1) The director of the quarantine station shall isolate patients of a quarantinable infectious disease, etc. in any of the following facilities pursuant to Article 15 (1) 1: <Amended by Act No. 9932, Jan. 18, 2010; Act No. 15266, Dec. 19, 2017>
1. Isolation wards in the quarantine station designated by the Minister of Health and Welfare;
 2. Infectious disease control agencies, places of isolation, sanatoriums or clinics provided for in Article 36 or 37 of the Infectious Disease Control and Prevention Act;
 3. At home;
 4. Infectious diseases specialty hospitals under Article 8-2 of the Infectious Disease Control and Prevention Act.
- (2) Where isolation wards or infectious disease control agencies provided for in paragraph (1) are deficient due to high occurrence of patients of a quarantinable infectious disease, etc., the director of the quarantine station may install and operate temporary isolation facilities, as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010>
- (3) Where it is deemed necessary to take isolation measures (including transfer) referred to in paragraph (1), the director of the quarantine station may request cooperation from a Special Metropolitan City Mayor, Metropolitan City Mayor, Do Governor or Special Self-Governing Province Governor (hereinafter referred to as "Mayor/Do Governor"), or the head of a *Si/Gun/Gu* (referring to the head

of an autonomous *Gu*; hereinafter the same shall apply). In such cases, the Mayor/*Do* Governor or the head of the *Si/Gun/Gu* shall comply with such request unless any extenuating circumstance exists.

- (4) The isolation period of a patient of a quarantinable infectious disease, etc. shall be until the time such patient, etc. is completely free from infectivity.
- (5) Any person isolated during the period referred to in paragraph (4) shall be prohibited from having contact with any other person without permission from the director of the quarantine station.
- (6) Where the director of the quarantine station isolates a patient of a quarantinable infectious disease, etc., the director shall notify the isolated person, his or her family member or guardian or a person designated by the isolated person of such fact, as prescribed by Ordinance of the Ministry of Health and Wealth. <Amended by Act No. 9932, Jan. 18, 2010>

#Article 16 (Isolation of Patients of Quarantinable Infectious Disease)

- (1) The Minister of Health and Welfare shall isolate patients of a quarantinable infectious disease, etc. in any of the following facilities pursuant to Article 15 (1) 1: *Provided*, That the Minister of Health and Welfare may exclude those patients, etc. from isolation if the possibility of person-to-person transmission is low or in cases prescribed by Ordinance of the Ministry of Health and Welfare: <Amended by Act No. 9932, Jan. 18, 2010; Act No. 15266, Dec. 19, 2017; Act No. 17068, Mar. 4, 2020>
 1. Isolation facilities in the quarantine station designated by the Minister of Health and Welfare;
 2. Infectious disease control agencies, places of isolation, sanatoriums, or clinics provided for in Article 36 or 37 of the Infectious Disease Control and Prevention Act;
 3. At home;
 4. Infectious disease specialty hospitals under Article 8-2 of the Infectious Disease Control and Prevention Act;
 5. A facility or place designated by the Minister of Health and Welfare if they have no residence in the Republic of Korea.
 - (2) Where isolation facilities or infectious disease control agencies provided for in paragraph (1) are deficient due to high occurrence of patients of a quarantinable infectious disease, etc., the Minister of Health and Welfare may install and operate temporary isolation facilities, as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010; Act No. 17068, Mar. 4, 2020>
 - (3) Where it is deemed necessary to take isolation measures (including transfer) referred to in paragraph (1), the Minister of Health and Welfare may request cooperation from a Special Metropolitan City Mayor, Metropolitan City Mayor, Special Self-Governing City Mayor, *Do* Governor, Special Self-Governing Province Governor (hereinafter referred to as "Mayor/*Do* Governor"), or the head of a *Si/Gun/Gu* (referring to the head of an autonomous *Gu*; hereinafter the same shall apply). In such cases, the Mayor/*Do* Governor or the head of the *Si/Gun/Gu* shall cooperate with such request unless any extenuating circumstance exists. <Amended by Act No. 17068, Mar. 4, 2020>
 - (4) The isolation period of a patient of a quarantinable infectious disease, etc. shall be until the time such patient, etc. is completely free from infectivity, and such patient, etc. shall be released from isolation immediately upon the expiration of the isolation period. <Amended by Act No. 17068, Mar. 4, 2020>
 - (5) Any person isolated during the period referred to in paragraph (4) shall be prohibited from having contact with any other person without permission from the director of the quarantine station.
 - (6) Where the director of the quarantine station isolates a patient of a quarantinable infectious disease, etc., the director shall notify the isolated person or his or her family member or guardian or a person designated by the isolated person of such fact, as prescribed by Ordinance of the Ministry of Health and Wealth. <Amended by Act No. 9932, Jan. 18, 2010; Act No. 17068, Mar. 4, 2020>
- <<Enforcement Date: Mar. 5, 2021>>

Article 17 (Monitoring of Person Suspected of Contracting Quarantinable Infectious Disease)

- (1) The director of the quarantine station may request a Special Self-Governing Province Governor or the head of a *Si/Gun/Gu* in which a person suspected of contracting a quarantinable infectious disease resides or stays after entering the Republic of Korea as provided for in Article 15 (1) 2 to monitor such person's health conditions or quarantine him or her in facilities referred to in Article 16 (1) or (2).
- (2) Where a person suspected of contracting a quarantinable infectious disease is confirmed as a patient or probable patient of a quarantinable infectious disease while being monitored under paragraph (1), the Special Self-Governing Province Governor and the head of a *Si/Gun/Gu* shall without delay take necessary measures, such as isolation, and immediately notify the director of the quarantine station of the case.
- (3) The period of monitoring or isolation under paragraph (1) shall not exceed the following relevant periods: *<Amended by Act No. 13980, Feb. 3, 2016; Act No. 15266, Dec. 19, 2017>*
 1. Cholera: Five days;
 2. Pest: Six days;
 3. Yellow fever: Six days;
 4. Severe Acute Respiratory Syndrome (SARS): Ten days;
 5. Animal influenza infection in humans: Ten days;
 6. Infectious diseases referred to in subparagraph 1 (f) through (h) of Article 2: The maximum incubation period of such disease.

#Article 17 (Monitoring of Contacts of Patient of Quarantinable Infectious Disease)

- (1) The Minister of Health and Welfare may request the Special Self-Governing Province Governor or the head of a *Si/Gun/Gu* in which a contact of a patient of a quarantinable infectious disease, etc. or a person exposed to a risk factor of a quarantinable infectious disease resides or stays after entering the Republic of Korea to monitor such person's health conditions under Article 15 (1) 2 or to quarantine him or her under Article 49 (1) of the Infectious Disease Control and Prevention Act. *<Amended by Act No. 17068, Mar. 4, 2020>*
 - (2) Where a contact of a patient of a quarantinable infectious disease, etc. or a person exposed to a risk factor of a quarantinable infectious disease is confirmed as a patient of a quarantinable infectious disease, etc. while being monitored under paragraph (1), the Special Self-Governing Province Governor or the head of a *Si/Gun/Gu* shall without delay take necessary measures, such as isolation, and immediately report the case to the Minister of Health and Welfare. *<Amended by Act No. 17068, Mar. 4, 2020>*
 - (3) The period of monitoring or quarantine under paragraph (1) shall not exceed the maximum incubation period for each quarantinable infectious disease prescribed by Ordinance of Ministry of Health and Welfare: *<Amended by Act No. 13980, Feb. 3, 2016; Act No. 15266, Dec. 19, 2017; Act No. 17068, Mar. 4, 2020>*
 1. through 6. Deleted. *<by Act No. 17068, Mar. 4, 2020>*
- <<Enforcement Date: Mar. 5, 2021>>*

Article 18 (Prohibition on Removing Cargo from Isolation Facility)

No cargo used or kept in an isolation ward or temporary isolation facility under Article 16 may be removed therefrom without permission of the director of the quarantine station.

#Article 18 (Prohibition on Removing Goods from Isolation Facility)

No goods used or kept in an isolation facility and temporary isolation facility under Article 16 may be removed therefrom without permission of the director of the quarantine station. *<Amended by Act No. 17068, Mar. 4, 2020>*

<<Enforcement Date: Mar. 5, 2021>>

Article 19 (Prohibition of Transfer of Contaminated Means of Transport)

- (1) The director of the quarantine station may, as prescribed by Ordinance of the Ministry of Health and Welfare, take measures, including prohibition of transfer, for passengers, crew members and persons entering or departing from the Republic of Korea by land who are infected with or suspected of being infected with quarantinable infectious diseases, and means of transport and cargo contaminated or suspected of being contaminated by the pathogen of a quarantinable infectious disease (hereafter referred to in this Article as "contaminated means of transport, etc.") until the measures, such as inspection on whether a confirmed or suspected case occurs, disinfection, and destruction of goods, are completed at a place designated by the director of the quarantine station. <Amended by Act No. 9932, Jan. 18, 2010>
- (2) The director of the quarantine station shall cancel the measures, such as prohibition of transfer, where it is deemed that a quarantinable infectious disease is unlikely to spread within the Republic of Korea by taking measures in relation to the contaminated means of transport, etc. In such cases, the criteria for lifting the prohibition of transfer shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010>

#Article 19 (Prohibition of Transfer of Contaminated Means of Transport)

- (1) The Minister of the Health and Welfare may, as prescribed by Ordinance of the Ministry of Health and Welfare, take measures, including prohibition of transfer, for passengers, crew members, and persons entering or departing from the Republic of Korea by land, who are infected with or suspected of being infected with a quarantinable infectious disease, and means of transport and cargo that are contaminated or are suspected of being contaminated with the pathogen of a quarantinable infectious disease (hereafter referred to in this Article as "contaminated means of transport, etc.") until the measures, such as inspection on whether a confirmed or suspected case occurs, disinfection, and destruction of goods, are completed at a place designated by the director of the quarantine station. In such cases, no one shall come in contact with or board the contaminated means of transport, etc. without the permission of the director of the quarantine station. <Amended by Act No. 9932, Jan. 18, 2010; Act No. 17068, Mar. 4, 2020>
- (2) The director of the quarantine station shall cancel the measures, such as prohibition of transfer, where it is deemed that a quarantinable infectious disease is unlikely to spread within the Republic of Korea by taking measures in relation to the contaminated means of transport, etc. In such cases, the criteria for lifting the prohibition of transfer, shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010>

<<Enforcement Date: Mar. 5, 2021>>

Article 20 (Preventive Measures against Non-Quarantinable Infectious Diseases)

The director of the quarantine station may take necessary preventive measures, such as a medical examination, testing and disinfection, as prescribed by Ordinance of the Ministry of Health and Welfare upon finding of any patient infected with a non-quarantinable infectious disease or any person who died of a non-quarantinable infectious disease, or the relevant means of transport contaminated or highly likely to be contaminated with the pathogen of a non-quarantinable infectious disease while conducting quarantine inspections. <Amended by Act No. 9932, Jan. 18, 2010>

#Article 20 (Preventive Measures against Non-Quarantinable Infectious Diseases)

The director of the quarantine station may take necessary preventive measures, such as medical examination, testing and disinfection, as prescribed by Ordinance of the Ministry of Health and Welfare, upon finding of any of the following persons while conducting quarantine inspections: <Amended by

Act No. 9932, Jan. 18, 2010; Act No. 17068, Mar. 4, 2020>

1. A patient of a non-quarantinable infectious disease;
2. A probable patient of a non-quarantinable infectious disease;
3. A person who died of a non-quarantinable infectious disease;
4. A means of transport contaminated or likely to be contaminated with the pathogen of a non-quarantinable infectious disease.

<<Enforcement Date: Mar. 5, 2021>>

Article 21 (Keeping of Goods Requiring Disinfection)

The director of the quarantine station may request the head of the relevant customs office to isolate goods deemed to require disinfection from other goods in order to keep the former from having contact with the latter among goods on the list of loaded goods.

Article 22 (Quarantine Certificates)

Where the director of the quarantine station determines that no problem is found by the quarantine inspection of a means of transport, persons, or cargo, the director shall issue a quarantine certificate to the head of the means of transport, as prescribed by Ordinance of the Ministry of Health and Welfare.

<Amended by Act No. 9932, Jan. 18, 2010>

#Article 22 (Quarantine Certificates)

Where the director of the quarantine station determines that a person, a means of transport or cargo entering or departing from the Republic of Korea poses no risk of spreading any quarantinable infectious disease in Korea or overseas and no problem is found by a quarantine inspection, the director shall, upon request, issue a quarantine certificate to the person or the head of the means of transport, as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 9932, Jan. 18, 2010; Act No. 17068, Mar. 4, 2020>*

<<Enforcement Date: Mar. 5, 2021>>

Article 23 (Conditional Quarantine Certificates)

- (1) Where the director of the quarantine station determines that a means of transport is permitted to arrive on condition of quarantine disinfection, etc., the director may issue a conditional quarantine certificate to the head of the means of transport.
- (2) Where the head of a means of transport issued a conditional quarantine certificate fulfills the imposed condition, the director of the quarantine station shall retrieve the conditional quarantine certificate and issue a quarantine certificate to the head of the means of transport.
- (3) Where the head of a means of transport fails to meet the condition imposed in a conditional quarantine certificate referred to in paragraph (1), the director of the quarantine station may take measures, such as the prohibition of transfer.
- (4) Where the director of the quarantine station determines that the head of a means of transport issued a conditional quarantine certificate under paragraph (1) has difficulty fulfilling the condition imposed on the means of transport, the director may give instructions to return or move the means of transport to a place the director designates, stating the reasons therefor, as prescribed by Ordinance of the Ministry of Health and Welfare. In such cases, the head of the relevant means of transport shall comply with such instructions. *<Amended by Act No. 9932, Jan. 18, 2010>*

#Article 23 (Conditional Quarantine Certificates)

- (1) The director of the quarantine station may issue a conditional quarantine certificate to the head of a means of transport on condition of quarantine disinfection, etc. as a result of its quarantine inspection. *<Amended by Act No. 17068, Mar. 4, 2020>*

- (2) Where the head of a means of transport issued a conditional quarantine certificate fulfills the imposed condition, the director of the quarantine station shall issue a quarantine certificate to the head of the means of transport. In such cases, the head of the means of transport shall discard the conditional quarantine certificate previously issued. <Amended by Act No. 17068, Mar. 4, 2020>
 - (3) Where the head of a means of transport fails to meet the condition imposed in a conditional quarantine certificate referred to in paragraph (1), the director of the quarantine station may take measures, such as the prohibition of transfer.
 - (4) Where the director of the quarantine station determines that the head of a means of transport issued a conditional quarantine certificate under paragraph (1) has difficulty fulfilling the condition imposed on the means of transport, the director may give instructions to move the means of transport to a place the director designates, stating the reasons therefor, as prescribed by Ordinance of the Ministry of Health and Welfare. In such cases, the head of the means of transport shall comply with such instructions. <Amended by Act No. 9932, Jan. 18, 2010; Act No. 17068, Mar. 4, 2020>
- <<Enforcement Date: Mar. 5, 2021>>

Article 24 (Request for Prohibition or Suspension of Entry and Departure)

Where the Minister of Health and Welfare deems that the following persons are likely to pose a substantial risk to public health, the Minister of Health and Welfare may request the Minister of Justice to prohibit or suspend the entry and departure of such persons: *Provided*, That a request for prohibition or suspension of entry shall apply to foreigners alone: <Amended by Act No. 9932, Jan. 18, 2010; Act No. 13980, Feb. 3, 2016; Act No. 17068, Mar. 4, 2020>

1. A patient of a quarantinable infectious disease, etc.;
2. A contact of a patient of a quarantinable infectious disease, etc.;
3. A person exposed to a risk factor of a quarantinable infectious disease;
4. A person entering the Republic of Korea from or via a quarantine inspection required area or similar area.

Article 25 (Bringing-In and Inspection of Dead Body)

- (1) Any person who intends to bring a dead body into the Republic of Korea shall submit or present necessary documents as prescribed by Ordinance of the Ministry of Health and Welfare to confirm whether the dead person has been infected with a quarantinable infectious disease. <Amended by Act No. 9932, Jan. 18, 2010>
- (2) If the corpse, bones or remains of a person who died of a quarantinable infectious disease fail to be treated by preservation and sealed in the impenetrable coffin or fail to be cremated, the director of the quarantine station shall not grant a permit to bring them into the Republic of Korea.
- (3) The dead bodies during the operation of a means of transport shall undergo a quarantine inspection, as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010>

#Article 25 (Bringing-In and Inspection of Dead Body)

- (1) Any person who intends to bring a dead body into the Republic of Korea shall submit or present necessary documents as prescribed by Ordinance of the Ministry of Health and Welfare to confirm whether the dead person has been infected with a quarantinable infectious disease. <Amended by Act No. 9932, Jan. 18, 2010>
- (2) If the corpse, bones, or remains of a person who died of a quarantinable infectious disease fail to be treated by preservation and sealed in the impenetrable coffin or fail to be cremated, the director of the quarantine station shall not grant a permit to bring them into the Republic of Korea.
- (3) Dead bodies during the operation of a means of transport shall undergo a quarantine inspection, as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18,

2010; Act No. 17068, Mar. 4, 2020>

- (4) If the cause of death of a person is unidentified or a dead person is suspected of being infected with a quarantinable infectious disease by a quarantine inspection conducted under paragraph (1) or (3), the director of the quarantine station may order an autopsy on the dead person for testing, and, if necessary, may request cooperation from related agencies. In such case, Article 20 of the Infectious Disease Control and Prevention Act shall apply *mutatis mutandis* to methods and procedures for autopsy, and “the Director of the Korea Center for Disease Control and Prevention” shall be construed as “the director of the quarantine station”. <Newly Inserted by Act No. 17068, Mar. 4, 2020>
- (5) If a patient of a quarantinable infectious disease, etc. died or a dead person is confirmed to have the pathogen of a quarantinable infectious disease after his or her death, the director of the quarantine station may impose such restrictions as the funeral handling of the dead person to the extent necessary to block, and prevent the spread of, the quarantinable infectious disease. In such cases, Article 20-2 of the Infectious Disease Control and Prevention Act shall apply *mutatis mutandis* to funeral handling methods and procedures, and “the Minister of Health and Welfare” shall be construed as “the director of the quarantine station”. <Newly Inserted by Act No. 17068, Mar. 4, 2020>
- <<Enforcement Date: Mar. 5, 2021>>

Article 26 (Measures for Public Health)

The director of the quarantine station may take any of the following measures in relation to a person who intends to enter or depart from the Republic of Korea when a quarantinable infectious disease is likely to spread:

1. Requesting information about the area and duration of his or her travel;
2. Requesting information about his or her health conditions in relation to the quarantinable infectious disease;
3. Requesting a document certifying that he or she is vaccinated;
4. Testing and examining the person to check if he or she is infected with the quarantinable infectious disease.

#Article 26 Deleted. <by Act No. 17068, Mar. 4, 2020> <<Enforcement Date: Mar. 5, 2021>>

Article 27 (Issuance of Ship Sanitation Certificates, etc.)

- (1) Where the captain or owner of a ship requests the issuance of a ship sanitation certificate, the director of the quarantine station shall conduct an inspection as to whether the ship is contaminated with the pathogen of a quarantinable infectious disease or carries vectors of an infectious disease. If the director of the quarantine station determines that the ship is suspected of being contaminated with the pathogen of a quarantinable infectious disease or vectors of an infectious disease are suspected of inhabiting therein, the director shall entrust a person qualified as prescribed by Ordinance of the Ministry of Health and Welfare to disinfect the ship or to eradicate the vectors of the infectious disease and shall issue a ship sanitation certificate valid for six months. <Amended by Act No. 9932, Jan. 18, 2010>
- (2) Where the director of the quarantine station determines that a ship is not contaminated with the pathogen of a quarantinable infectious disease and free from vectors of an infectious disease by an inspection as provided in paragraph (1), the director shall issue a ship sanitation control exemption certificate valid for six months.
- (3) Where the captain or the owner of a ship disinfects the ship or eradicates vectors of an infectious disease as provided for in Article 15 (3) upon an order referred to in Article 15 (1) 6 and requests the issuance of a certificate of compliance with the order, the director of the quarantine station shall issue a ship sanitation certificate valid for six months.

- (4) Where a ship returns to the place of shipment or a quarantine inspection or quarantine measures under Articles 12 and 15 can not be performed for a special reason, the director of the quarantine station shall extend the term of validity of a ship sanitation control exemption certificate provided for in paragraph (2) by up to one month.
- (5) The director of the quarantine station shall conduct a quarantine inspection referred to in Article 12 for a ship with an expired certificate under paragraphs (1) through (3), a ship without a certificate, or a ship with a certificate in which the necessity of reinspection is specified.
- (6) Necessary matters concerning the procedure for application for and issuance of a ship sanitation certificate and a ship sanitation control exemption certificate shall be prescribed by Ordinance of the Ministry of Health and Wealth. *<Amended by Act No. 9932, Jan. 18, 2010>*

#Article 27 (Issuance of Ship Sanitation Certificates)

- (1) Where the captain or owner of a ship requests the issuance of a ship sanitation certificate, the director of the quarantine station shall conduct an investigation as to whether the ship is contaminated with the pathogen of a quarantinable infectious disease or carries vectors of an infectious disease and shall issue a ship sanitation control exemption certificate valid for six months if the ship is found to have not been contaminated with the pathogen of any quarantinable infectious disease and free from vectors of an infectious disease by such investigation. *<Amended by Act No. 9932, Jan. 18, 2010; Act No. 17068, Mar. 4, 2020>*
- (2) Where the director of the quarantine station determines that a ship is suspected of being contaminated with the pathogen of a quarantinable infectious disease and vectors of an infectious disease inhibit in a ship by an investigation as provided in paragraph (1), the director shall issue a ship sanitation certificate valid for six months after requiring a person who has the qualifications prescribed by Ordinance of Health and Welfare to disinfect the ship or eradicate vectors of an infectious disease. *<Amended by Act No. 17068, Mar. 4, 2020>*
- (3) Where the captain or the owner of a ship disinfects the ship or eradicates vectors of an infectious disease as provided for in Article 15 (3) upon an order referred to in Article 15 (1) 6 requests the issuance of a certificate of compliance of the order, the director of the quarantine station shall issue a ship sanitation certificate valid for six months.
- (4) Where a ship returns to the place of shipment or the quarantine inspection and quarantine measures under Articles 12 and 15 can not be performed for a special reason, the director of the quarantine station shall extend the term of validity of the ship sanitation control exemption certificate issued under paragraph (1) by up to one month. *<Amended by Act No. 17068, Mar. 4, 2020>*
- (5) The director of the quarantine station shall conduct a quarantine inspection referred to in Article 12 for a ship with an expired certificate under paragraphs (1) through (3), a ship without a certificate or a ship with a certificate in which the necessity of reinspection is specified.
- (6) Details of investigations under paragraph (1), the procedure for application for and issuance of ship sanitation certificates and ship sanitation control exemption certificates and other necessary matters shall be prescribed by Ordinance of the Ministry of Health and Wealth. *<Amended by Act No. 9932, Jan. 18, 2010; Act No. 17068, Mar. 4, 2020>*
<<Enforcement Date: Mar. 5, 2021>>

Article 28 (Issuance of Other Certificates)

- (1) Upon request of the head or the owner of a means of transport, the director of the quarantine station shall issue a certificate of deratting and disinsection after taking measures to eradicate vectors of infectious diseases, such as the disinfection of the relevant means of transport, and, as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 9932, Jan. 18, 2010>*
- (2) Upon request of a person who intends to export goods, the director of the quarantine station shall issue a certificate falling under any of the following after taking preventive measures against

quarantinable infectious diseases, as prescribed by Ordinance of the Ministry of Health and Welfare: *<Amended by Act No. 9932, Jan. 18, 2010>*

1. A certificate of disinfection of the goods: Inspection on whether the goods are infected with a quarantinable infectious disease, disinfection and eradication of vectors of infectious diseases;
 2. A certificate of bacteriological test on the goods: Bacteriological tests on whether the goods carry pathogens of quarantinable infectious diseases.
- (3) Upon request of a person who intends to travel overseas, such as a passenger or a crew member, the director of the quarantine station shall issue a certificate falling under any of the following after taking preventive measures against quarantinable infectious diseases, as prescribed by Ordinance of the Ministry of Health and Welfare: *<Amended by Act No. 9932, Jan. 18, 2010>*
1. An international certificate of vaccination: Vaccinations;
 2. A certificate of bacteriological and serological tests: Inspections on whether the person is infected with a quarantinable infectious disease and carries the pathogen of a quarantinable infectious disease.
- (4) Necessary matters concerning the issuance of a certificate, other than certificates referred to in paragraphs (1) through (3), the details of preventative measures and the procedure for issuance of certificates shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 9932, Jan. 18, 2010>*
- (5) Disinfection and eradication of vectors of infectious diseases as required under paragraphs (1) and (2) shall be conducted by a person qualified as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 9932, Jan. 18, 2010>*

#Article 28 (Issuance of Other Certificates)

- (1) Upon request of the head of a means of transport, the director of the quarantine station shall issue a certificate of deratting and disinsection after verifying whether the head of the means of transport has eradicated vectors of infectious diseases therein, as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 9932, Jan. 18, 2010; Act No. 17068, Mar. 4, 2020>*
- (2) Upon request of a person who intends to export goods, the director of the quarantine station shall issue a certificate falling under any of the following after taking preventive measures against quarantinable infectious diseases or verifying whether the person has taken such preventive measures, as prescribed by Ordinance of the Ministry of Health and Welfare: *<Amended by Act No. 9932, Jan. 18, 2010; Act No. 17068, Mar. 4, 2020>*
 1. A certificate of disinfection of the goods: Inspection on whether the goods are infected with quarantinable infectious diseases, disinfection and eradication of vectors of infectious diseases;
 2. A certificate of bacteriological test on the goods: Bacteriological tests on whether the goods carry pathogens of quarantinable infectious diseases.
- (3) Upon request of a person who intends to travel overseas, such as a passenger or crew member, the director of the quarantine station shall issue a pathogen test certificate after conducting a test to check whether the person is infected with any quarantinable infectious disease and has pathogens of quarantinable infectious diseases as prescribed by Ordinance of the Ministry of Health and Welfare: *<Amended by Act No. 9932, Jan. 18, 2010; Act No. 17068, Mar. 4, 2020>*
 1. and 2. Deleted. *<by Act No. 17068, Mar. 4, 2020>*
- (4) Necessary matters concerning the issuance of a certificate, other than certificates referred to in paragraphs (1) through (3), the details of preventative measures and the procedure for issuance of certificates shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 9932, Jan. 18, 2010>*
- (5) Disinfection and eradication of vectors of infectious diseases as required under paragraphs (1) and (2) shall be conducted by a person qualified as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 9932, Jan. 18, 2010>*

<<Enforcement Date: Mar. 5, 2021>>

Article 28-2 (Designation of Internationally Certified Vaccination Center)

- (1) Where it is impracticable to provide internationally certified vaccination under Article 28 (3) at a quarantine station or it is inconvenient for residents to visit a quarantine station, etc., the Minister of Health and Welfare may designate an institution that can provide internationally certified vaccinations (hereinafter referred to as "internationally certified vaccination center") from among the following institutions. In such cases, the Minister of Health and Welfare shall publicly announce such designation:
 1. Medical institutions under Article 3 of the Medical Service Act;
 2. National institutions, local governmental institutions and public institutions established under the Act on the Management of Public Institutions which have dispensaries with full-time physicians.
- (2) Where an internationally certified vaccination center falls under any of the following, the Minister of Health and Welfare may revoke the designation of such center:
 1. Where it has no record of vaccinations against quarantinable infectious diseases during the last three years;
 2. Where it violates this Act or medical services-related statutes in connection with vaccinations against quarantinable infectious diseases.
- (3) Except as otherwise prescribed in paragraphs (1) and (2), the standards and procedures for designating internationally certified vaccination centers, and revocation of the designation and other necessary matters shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 12445, Mar. 18, 2014]

#Article 28-2 (Internationally Certified Vaccinations)

- (1) Upon request of a person who intends to travel overseas, the Minister of Health and Welfare shall provide the person with vaccines against quarantinable infectious diseases and issue an international certificate of vaccination to such person.
- (2) The Minister of Health and Welfare shall make available first aid supplies to prepare for adverse reactions occurring after vaccinations against quarantinable infectious diseases.
- (3) Upon vaccinating a person against a quarantinable infectious disease, the head of an internationally certified vaccination center designated under Article 28-3 shall issue a vaccination certificate to the person, and the director of the quarantine station shall issue an international certificate of vaccination to the person after verifying the information stated in the vaccination certificate.
- (4) Procedures for issuing international certificates of vaccination under paragraphs (1) and (3), control of adverse reactions under paragraph (2) and other necessary matters shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 17068, Mar. 4, 2020] <<Enforcement Date: Mar. 5, 2021>>

#Article 28-3 (Designation of Internationally Certified Vaccination Center)

- (1) The Minister of Health and Welfare may designate an institution that can provide internationally certified vaccinations (hereinafter referred to as "internationally certified vaccination center") from among the following institutions. In such cases, the Minister of Health and Welfare shall publicly announce such designation: *<Amended by Act No. 17068, Mar. 4, 2020>*
 1. Medical institutions under Article 3 of the Medical Service Act;
 2. National institutions, local governmental institutions and public institutions established under the Act on the Management of Public Institutions which have dispensaries with full-time physicians.
- (2) Where an internationally certified vaccination center falls under any of the following, the Minister of Health and Welfare may revoke the designation of such center:
 1. Where it has no record of vaccinations against quarantinable infectious diseases during the last

- three years;
2. Where it violates this Act or medical services-related statutes in connection with vaccinations against quarantinable infectious diseases.
- (3) Except as otherwise prescribed in paragraphs (1) and (2), the standards and procedures for designating internationally certified vaccination centers, and revocation of the designation, and other necessary matters shall be prescribed by Ordinance of the Ministry of Health and Welfare.
- [This Article Newly Inserted by Act No. 12445, Mar. 18, 2014] <<Enforcement Date: Mar. 5, 2021>>

Article 29 (Management of Health and Sanitation in Quarantine Areas)

- (1) Where the director of the quarantine station deems that a quarantinable infectious disease or non-quarantinable infectious disease is, or is likely to be, epidemic, the director may take any of the following measures in relation to any means of transport, facilities, buildings, and goods within the quarantine area and other places or give necessary instructions to the persons concerned: <Amended by Act No. 9932, Jan. 18, 2010; Act No. 13980, Feb. 3, 2016>
1. Epidemiological investigations of the quarantinable infectious disease or non-quarantinable infectious disease;
 2. Disinfection to kill insects and germs and eradicate vectors of the infectious disease;
 3. Inspection to find germ carriers and vaccination against the quarantinable infectious disease or non-quarantinable infectious disease;
 4. Inspection of food materials, food and portable water loaded into means of transport;
 5. Sanitary guidance, education, and public relations for persons who handle fish and shellfish as well as foodstuff;
 6. Survey of distribution of inhabitation, etc. of vectors of the infectious disease in the quarantine area;
 7. Inspection of ballast water within a ship;
 8. Other matters the Minister of Health and Welfare deems necessary for the prevention of quarantinable infectious diseases and non-quarantinable infectious diseases.
- (2) The director of the quarantine station may request cooperation from the relevant agencies or business entities, if necessary to take the measures or give instructions pursuant to paragraph (1) and the relevant agencies business entities in receipt of the request shall comply with such request unless any extenuating circumstance exists.

#Article 29 (Management of Health and Sanitation in Quarantine Areas)

- (1) Where the Minister of Health and Welfare deems that a quarantinable infectious disease or a non-quarantinable infectious disease is, or is likely to be, epidemic, the Minister may take any of the following measures necessary for health and sanitation control in relation to any means of transport, facilities, buildings and goods within the quarantine area and other places or give necessary instructions to the persons concerned, as prescribed by Ordinance of the Ministry of Health and Welfare: <Amended by Act No. 9932, Jan. 18, 2010; Act No. 13980, Feb. 3, 2016; Act No. 17068, Mar. 4, 2020>
1. Epidemiological investigation of the quarantinable infectious disease or non-quarantinable infectious disease;
 2. Disinfection to kill insects and germs and eradicate vectors of infectious diseases;
 3. Inspection to find germ carriers and vaccination against the quarantinable infectious disease or non-quarantinable infectious disease;
 4. Inspection of food materials, food and portable water loaded into means of transport;
 5. Sanitary guidance, education, and public relations for persons who handle fish and shellfish as well as foodstuff;
 6. Survey of distribution of vectors of the infectious disease in the quarantine area;
 7. Inspection of ballast water within a ship;

8. Other matters the Minister of Health and Welfare deems necessary for the prevention of quarantinable infectious diseases and non-quarantinable infectious diseases.

- (2) The director of the quarantine station may request cooperation from relevant persons or agencies, if necessary to take the measures or give instructions under paragraph (1) and the relevant persons or agencies in receipt of the request shall comply with such request unless any extenuating circumstance exists. <Amended by Act No. 17068, Mar. 4, 2020>

<<Enforcement Date: Mar. 5, 2021>>

Article 29-2 (Establishment and Operation of Quarantine Information System)

- (1) The Minister of Health and Welfare may establish and operate an information system that can electronically process information about persons subject to quarantine in order to efficiently provide quarantine services, including early detection of persons who are, or are suspected to be, infected with a quarantinable infectious disease.
- (2) The Minister of Health and Welfare shall not use the information processed through the system established under paragraph (1) for other than the purpose of efficiently providing quarantine services and shall manage such information to prevent privacy infringement.
- (3) The establishment and operation of the system referred to in paragraph (1) and other necessary matters shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 13980, Feb. 3, 2016]

#Article 29-2 (Establishment and Operation of Quarantine Information System)

- (1) The Minister of Health and Welfare may establish and operate a quarantine information system that can electronically process information about persons subject to quarantine in order to efficiently perform quarantine work, including early detection of persons who are, or are suspected to be, infected with a quarantinable infectious disease and means of transport suspected to be contaminated. <Amended by Act No. 17068, Mar. 4, 2020>
- (2) To perform quarantine work, the Minister of Health and Welfare may request quarantine-related information from the heads of relevant agencies via the following information systems. In such cases, the heads of the relevant agencies shall comply with such request unless good cause exists: <Newly Inserted by Act No. 17068, Mar. 4, 2020>
1. The information system for safe use of drugs (DUR, Drug Utilization Review) established under Article 23-3 (1) of the Pharmaceutical Affairs Act;
 2. The Passport Information Comprehensive Administration System established under Article 8 (2) of the Passport Act;
 3. The information system processing immigration information under the Immigration Act;
 4. The Comprehensive Customs Duties Information Network of Korea (UNI-PASS) established under Article 327 of the Customs Act;
 5. Other information systems prescribed by Ordinance of the Ministry of Health and Welfare.
- (3) The Minister of Health and Welfare shall not use the information processed through the system under paragraph (1) for other than the purpose of efficiently performing quarantine work and shall manage such information to prevent privacy infringement.
- (4) Except as provided in this Act, the protection and management of information under paragraphs (1) and (2) shall be governed by the provisions of the Personal Information Protection Act. <Newly Inserted by Act No. 17068, Mar. 4, 2020>
- (5) The establishment and operation of systems under paragraphs (1) and (2) and other necessary matters shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 17068, Mar. 4, 2020>

[This Article Newly Inserted by Act No. 13980, Feb. 3, 2016]

<<Enforcement Date: Mar. 5, 2021>>

CHAPTER II-2 Requests for Submission of Data

Article 29-3 (Duty to Report)

- (1) A person who has stayed at a contaminated area designated under Article 5 (1) or entered the Republic of Korea via such area shall report to the director of the quarantine station if the period specified in any of the subparagraphs of Article 17 (3) has not passed since the person departed from the area.
- (2) Procedures and methods for reporting under paragraph (1) and other necessary matters shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 13980, Feb. 3, 2016]

#Article 29-3 Deleted. <by Act No. 17068, Mar. 4, 2020>

<<Enforcement Date: Mar. 5, 2021>>

Article 29-4 (Requests for Passenger Reservation Data)

- (1) The Minister of Health and Welfare may request an operator of a means of transport provided in Article 6 (hereinafter referred to as “forwarder”) to have access to passenger reservation data held by the forwarder via the information and communications network or to submit such passenger reservation data in writing (or in electronic form) without delay, if deemed necessary to perform the following work:
 1. To provide quarantine services for a person who enters, or is suspected of entering, the Republic of Korea, from or via, a country where a quarantinable infectious disease has broken out;
 2. To provide quarantine services for a confirmed or suspected patient when the person enters or departs from the Republic of Korea;
 3. To conduct an quarantine inspection under Article 12;
 4. To take measures for public health under Article 26.
- (2) A forwarder in receipt of a request made under paragraph (1) shall comply with the request unless good cause exists.
- (3) The scope of data that can be accessed or submitted under paragraph (1) shall be limited to:
 1. Name, nationality, date of birth, passport number, and booking reference;
 2. Address and telephone number;
 3. Number of the means of transport and time of arrival;
 4. Time of reservation and time of check-in;
 5. Boarding pass number, seat number, date of issue, and place of issue;
 6. Travel route and travel agency;
 7. Details about accompanying passengers, such as family or tourist group, their seat numbers;
 8. Data about luggage.
- (4) Methods for retaining passenger reservation data submitted under paragraph (1), the retention period, destruction of such data, and other necessary matters shall be prescribed by Presidential Decree.

[This Article Newly Inserted by Act No. 13980, Feb. 3, 2016]

#Article 29-4 (Requests for Passenger Reservation Data)

- (1) The Minister of Health and Welfare may request the head of a means of transport to have access to passenger reservation data held by him or her via the information and communications network or to submit such passenger reservation data in writing (or in electronic form) without delay, if deemed necessary to perform the following work: <Amended by Act No. 17068, Mar. 4, 2020>
 1. To provide quarantine services for a person who enters, or is suspected of entering, the Republic of Korea, from or via, a country where a quarantinable infectious disease has broken out;

2. To provide quarantine services for a confirmed or suspected patient when the patient enters or departs from the Republic of Korea;
 3. To conduct a quarantine inspection under Article 12;
 4. To take measures under Article 12-2 (3).
- (2) The head of a means of transport in receipt of a request under paragraph (1) shall comply with the request unless good cause exists. <Amended by Act No. 17068, Mar. 4, 2020>
- (3) The scope of data that can be accessed or submitted under paragraph (1) shall be limited to the following:
1. Name, nationality, date of birth, passport number, and booking reference;
 2. Address and telephone number;
 3. Number of the means of transport and time of arrival;
 4. Time of reservation and time of check-in;
 5. Boarding pass number, seat number, date of issue, and place of issue;
 6. Travel route and travel agency;
 7. Details about accompanying passengers, such as family or tourist group, their seat numbers;
 8. Data about luggage.
- (4) Methods for retaining passenger reservation data submitted under paragraph (1), the retention period, destruction of such data and other necessary matters shall be prescribed by Presidential Decree.

[This Article Newly Inserted by Act No. 13980, Feb. 3, 2016]

<<Enforcement Date: Mar. 5, 2021>>

Article 29-5 (Cooperation from Related Agencies)

In order to prevent and control a quarantinable infectious disease, the Minister of Health and Welfare may request the heads of the following central administrative agencies to submit the resident registration number, immigration records, baggage declaration, and financial information about a confirmed or suspected patient, and other urgently necessary data and information prescribed by Presidential Decree. In such cases, the head of a central administrative agency in receipt of the request shall comply with such request unless good cause exists: <Amended by Act No. 14839, Jul. 26, 2017>

1. The Minister of Justice;
2. The Minister of the Interior and Safety;
3. The Minister of Land, Infrastructure and Transport;
4. The Chairperson of the Financial Services Commission;
5. The Commissioner of the Korea Customs Service;
6. The head of a central administrative agency prescribed by Presidential Decree.

[This Article Newly Inserted by Act No. 13980, Feb. 3, 2016]

#Article 29-5 (Cooperation from Related Agencies)

In order to prevent and control a quarantinable infectious disease, the Minister of Health and Welfare may request the resident registration number, immigration records, baggage declaration, and financial information about a confirmed or suspected patient, and other urgently necessary data and information prescribed by Presidential Decree, from the heads of the following central administrative agencies (including the heads of agencies under their control and responsible administrative agencies; hereafter the same applies in this Article). In such cases, the head of a central administrative agency in receipt of the request shall comply with such request unless good cause exists: <Amended by Act No. 14839, Jul. 26, 2017; Act No. 17068, Mar. 4, 2020>

1. The Minister of Foreign Affairs;
2. The Minister of Justice;
3. The Minister of the Interior and Safety;

4. The Minister of Land, Infrastructure and Transport;
5. The Chairperson of the Financial Services Commission;
6. The Commissioner of the Korea Customs Service;
7. The head of a central administrative agency prescribed by Presidential Decree.

[This Article Newly Inserted by Act No. 13980, Feb. 3, 2016]

<<Enforcement Date: Mar. 5, 2021>>

Article 29-6 (Notification and Education)

- (1) The manager of a facility, such as an airport defined under subparagraph 3 of Article 2 of the Airport Facilities Act or a harbor defined under subparagraph 1 of Article 2 of the Harbor Act, shall notify the users of the facility about the locations of a contaminated area designated under Article 5 (1) and adjacent areas to the contaminated area designated under Article 5-2, the type of the quarantinable infectious disease that has broken out in the contaminated area and the preventive measures, measures to be taken when a confirmed or suspected case occurs and other matters, as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 15266, Dec. 19, 2017>*
- (2) If necessary to notify a contaminated area designated under Article 5 (1) and adjacent areas to the contaminated area designated under Article 5-2 and provide education for the prevention of a quarantinable infectious disease, the director of the quarantine station may request a forwarder to notify or educate the crew members and passengers about the location of the contaminated area and adjacent areas to the contaminated area, the type of the quarantinable infectious disease that has broken out in the contaminated area and the preventive measures, measures to be taken when a confirmed or suspected case occurs and other matters. In such cases, the director of the quarantine station shall provide the forwarder with contents of notification and education, and the forwarder in receipt of the request shall comply with such request unless good cause exists. *<Amended by Act No. 15266, Dec. 19, 2017>*

[This Article Newly Inserted by Act No. 13980, Feb. 3, 2016]

#Article 29-6 (Notification and Education)

- (1) The manager of a facility, such as an airport defined under subparagraph 3 of Article 2 of the Airport Facilities Act or a harbor defined under subparagraph 1 of Article 2 of the Harbor Act, shall notify the users of the facility about the locations of a quarantine inspection required area or similar area, the type of the quarantinable infectious disease that has broken out in the contaminated area and the preventive measures, measures to be taken when a confirmed or suspected case occurs and other matters, as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 15266, Dec. 19, 2017; Act No. 17068, Mar. 4, 2020>*
- (2) If necessary to notify a quarantine inspection required area or similar area and provide education for the prevention of a quarantinable infectious disease, the director of the quarantine station shall request the head of a means of transport to notify or educate persons entering or departing from the Republic of Korea about the following matters. In such cases, the director of the quarantine station shall provide the head of a means of transport with contents of notification and education in the form of videos and other visual media, and the head of a means of transport in receipt of the request shall comply with such request unless good cause exists: *<Amended by Act No. 15266, Dec. 19, 2017; Act No. 17068, Mar. 4, 2020>*
 1. The location of the quarantine inspection required area or similar area;
 2. Type, dangerousness and preventive measures of the quarantinable infectious disease that has broken out in the quarantine inspection required area or similar area;
 3. Measures to be taken if a confirmed or suspected case occurs;
 4. How to report health conditions and fever checking;
 5. Procedures and methods for reporting under Article 12-2;

6. Other matters notification and education on which is requested by the director of the quarantine station as the director deems to be necessary.

[This Article Newly Inserted by Act No. 13980, Feb. 3, 2016]

<<Enforcement Date: Mar. 5, 2021>>

#Article 29-7 (Establishment of Quarantine Stations)

(1) National quarantine stations (hereinafter referred to as “quarantine stations”) shall be established and operated at airports, ports, railway stations and land-border crossings in order to prevent the spread of quarantinable infectious diseases in the Republic of Korea and overseas and to safely protect the health of citizens.

(2) The Minister of Health and Welfare may operate key quarantine stations by region according to the standards prescribed by Presidential Decree.

[This Article Newly Inserted by Act No. 17068, Mar. 4, 2020]

<<Enforcement Date: Mar. 5, 2021>>

#Article 29-8 (Functions and Duties of Quarantine Stations)

The quarantine stations shall carry out the following functions and duties:

1. To provide quarantine services for the prevention of introduction of quarantinable infectious diseases to the Republic of Korea and the spread thereof overseas;
2. To conduct epidemiological investigations of arriving passengers who have symptoms of quarantinable infectious diseases;
3. To have a patient of a quarantinable infectious disease, etc. or a contact of a patient of a quarantinable infectious disease, etc. isolated or quarantined and to conduct diagnostic tests;
4. To provide health and sanitation control in quarantine areas;
5. To provide preventive education and campaign about quarantinable infectious diseases;
6. Other duties prescribed by Ordinance of Ministry of Health and Welfare in relation to quarantine.

[This Article Newly Inserted by Act No. 17068, Mar. 4, 2020]

<<Enforcement Date: Mar. 5, 2021>>

#Article 29-9 (Facilities and Equipment in Quarantine Stations)

The quarantine stations shall be furnished with facilities, equipment, etc. that comply with the standards prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 17068, Mar. 4, 2020]

<<Enforcement Date: Mar. 5, 2021>>

CHAPTER III Public Officials in Charge of Quarantine

Article 30 (Public Officials in Charge of Quarantine)

(1) Every quarantine station shall have a director, quarantine officers and other public officials (hereinafter referred to as "public officials in charge of quarantine") to perform duties provided in this Act.

(2) Necessary matters concerning qualifications of public officials in charge of quarantine shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 9932, Jan. 18, 2010>*

#Article 30 (Public Officials in Charge of Quarantine)

(1) Every quarantine station shall have a director, quarantine officers and other public officials

(hereinafter referred to as "public officials in charge of quarantine") to perform duties provided in this Act. <Amended by Act No. 17068, Mar. 4, 2020>

- (2) The Minister of Health and Welfare shall regularly provide public officials in charge of quarantine with education and training about the performance of their duties. <Newly Inserted by Act No. 17068, Mar. 4, 2020>
- (3) Necessary matters concerning qualifications of public officials in charge of quarantine shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010>

<<Enforcement Date: Mar. 5, 2021>>

Article 31 (Authority of Public Officials in Charge of Quarantine)

Public officials in charge of quarantine may enter the means of transport subject to quarantine and other necessary places in order to perform duties provided in this Act.

#Article 31 (Authority of Public Officials in Charge of Quarantine)

- (1) Public officials in charge of quarantine may enter the means of transport subject to quarantine and other necessary places in order to perform duties provided in this Act and may inspect and investigate documents, facilities, equipment, etc. related to the operation of the means of transport. <Amended by Act No. 17068, Mar. 4, 2020>
- (2) Public officials in charge of quarantine may ask question to persons and the heads of means of transport entering or departing from the Republic of Korea or may request them to submit or present other necessary materials for quarantine inspections. <Newly Inserted by Act No. 17068, Mar. 4, 2020>

<<Enforcement Date: Mar. 5, 2021>>

Article 32 (Operation of Quarantine Ship)

- (1) The director of the quarantine station may operate a quarantine ship, quarantine vehicle, etc. to perform quarantine-related duties and necessary detailed matters shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010>
- (2) Where it is necessary to take emergency quarantine measures, such as occurrence of patients, the director of the quarantine station may request the head of the relevant agency to provide a quarantine ship, etc. required for the performance of quarantine-related duties and the head of the relevant agency in receipt of the request shall comply with such request unless any good cause exists.

Article 33 (Uniforms of Public Officials in Charge of Quarantine)

- (1) Public officials in charge of quarantine shall wear their uniforms when performing the duties provided for in this Act and carry their certificates indicating their authority and present them to the persons concerned at their request.
- (2) Matters concerning uniforms of public officials in charge of quarantine referred to in paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010>

#Article 33 (Uniforms of Public Officials in Charge of Quarantine)

- (1) Public officials in charge of quarantine shall wear their uniforms when performing the duties provided for in this Act and carry their certificates indicating their authority and present them to the persons concerned at their request.
- (2) Matters concerning uniforms and certificates of public officials in charge of quarantine referred to in paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010; Act No. 17068, Mar. 4, 2020>

<<Enforcement Date: Mar. 5, 2021>>

CHAPTER IV Supplementary Provisions

Article 34 (Collection of Fees)

Where the director of the quarantine station takes a measure falling under any of the following, the director may receive the fees prescribed by Ordinance of the Ministry of Health and Welfare from heads or owners of means of transport, owners or managers of cargo, passengers, crew members, etc.: <Amended by Act No. 9932, Jan. 18, 2010>

1. Where the director takes measures provided for in Article 15 (1) 3 through 5, 7, and 8;
2. Where the director takes measures provided for in Articles 27 and 28 or issues a certificate with regard thereto.

#Article 34 (Collection of Fees)

The Minister of Health and Welfare may receive the fees prescribed by Ordinance of the Ministry of Health and Welfare from the heads of means of transport, owners or managers of cargo, passengers, crew members, etc. in any of the following cases: <Amended by Act No. 9932, Jan. 18, 2010; Act No. 17068, Mar. 4, 2020>

1. Where the Minister takes measures provided for in Article 15 (1) 3, 4, 7, and 8;
- 1-2. Where the Minister takes measure provided for in Article 25 (4);
2. Where the Minister takes measures provided for in Articles 27, 28 and 28-2 or issues a certificate with regard thereto.

<<Enforcement Date: Mar. 5, 2021>>

Article 34-2 (Hearings)

The Minister of Health and Welfare shall hold a hearing to revoke the designation of an internationally certified vaccination center under Article 28-2.

[This Article Newly Inserted by Act No. 12445, Mar. 18, 2014]

#Article 34-2 (Hearings)

The Minister of Health and Welfare shall hold a hearing to revoke the designation of an internationally certified vaccination center under Article 28-3. <Amended by Act No. 17068, Mar. 4, 2020>

[This Article Newly Inserted by Act No. 12445, Mar. 18, 2014] <<Enforcement Date: Mar. 5, 2021>>

Article 35 (Bearing of Expenses)

Expenses incurred in isolation or quarantine and monitoring provided for in Articles 16 and 17 shall be borne by the State.

Article 36 (Establishment and Operation of Disease-Control Organization)

The Minister of Health and Welfare may establish and operate a disease-control organization to entrust quarantine services and other services prescribed by other Acts, as prescribed by Presidential Decree, notwithstanding Articles 3 and 4 of the Government Organization Act. <Amended by Act No. 9932, Jan. 18, 2010>

Article 37 (Delegation of Authority)

Authority of the Minister of Health and Welfare vested under this Act may be partially delegated to the head of an agency under his or her jurisdiction, as prescribed by Presidential Decree. <Amended by Act No. 9932, Jan. 18, 2010>

Article 38 (Duty to Maintain Confidentiality)

No person who has performed or performs the duties related to quarantine, such as quarantine inspections,

shall divulge to another person any confidential information that he or she becomes aware of in the course of performing the duties, such as conducting quarantine inspections under Article 12, taking measures for public health under Article 26, establishing and operating the quarantine information system under Article 29-2, requesting access to passenger reservation data under Article 29-4 or requesting cooperation from related agencies under Article 29-5. <Amended by Act No. 13980, Feb. 3, 2016>

#Article 38 (Duty to Maintain Confidentiality)

No person who has performed or performs the duties related to quarantine, such as quarantine inspections, shall divulge to another person any confidential information that he or she becomes aware of in the course of performing the duties, such as conducting quarantine inspections under Article 12, taking the measures under Article 12-2, conducting aircraft quarantine inspections, ship quarantine inspections and quarantine inspections for persons entering or departing from the Republic of Korea by land under Articles 12-3, 12-4 and 12-5, establishing and operating the quarantine information system under Article 29-2, requesting access to passenger reservation data under Article 29-4 or requesting cooperation from related agencies under Article 29-5. <Amended by Act No. 13980, Feb. 3, 2016; Act No. 17068, Mar. 4, 2020>

<<Enforcement Date: Mar. 5, 2021>>

CHAPTER V Penalty Provisions

Article 39 (Penalty Provisions)

- (1) Any of the following persons shall be punished by imprisonment with labor for not more than one year or by a fine not exceeding ten million won:
1. A person, the head of a means of transport, or the owner or manager of cargo which enters or departs from the Republic of Korea without undergoing a quarantine inspection under Article 6 (1);
 2. A person who refuses, obstructs, and evades a request for documents provided for in Article 12 (3) or submits or presents any falsified document;
 3. A person who fails to take measures ordered by the director of the quarantine station pursuant to Article 15 (1);
 4. A person who fails to comply with the measure taken to isolate or quarantine him or her pursuant to Articles 16 (1) and 17 (1);
 5. A person who divulges to another person any confidential information that he or she has learned in the course of performing business, in violation of Article 38.
- (2) Any of the following persons shall be punished by a fine not exceeding five million won:
1. A person who fails to comply with an order for disinfection, etc., in violation of Article 15 (3) or who fails to be confirmed by the director of the quarantine station regarding the results of performance;
 2. The head of a means of transport who refuses to comply with an instruction to return or move pursuant to Article 15 (4) or 23 (4);
 3. A person who removes goods used or kept from an isolation ward or temporary isolation facility without approval from the director of the quarantine station in violation of Article 18;
 4. A person who fails to follow any of the measures, such as the prohibition of transfer pursuant to Article 19 (1).

#Article 39 (Penalty Provisions)

- (1) Any of the following persons shall be punished by imprisonment with labor for not more than one

year or by a fine not exceeding ten million won: <Amended by Act No. 17068, Mar. 4, 2020>

1. A person, the head of a means of transport, or the owner or manager of cargo which enters or departs from the Republic of Korea without undergoing a quarantine inspection under Article 6 (1);
2. A person who refuses, obstructs, and evades a request for documents provided for in Article 12 (3) or submits or presents any falsified document;
3. A person who fails to take measures ordered by the Minister of the Health and Welfare under Article 15 (1);
4. A person who fails to comply with the measure taken to isolate or quarantine him or her under Articles 16 (1) and 17 (1);
5. A person who divulges to another person any confidential information that he or she has learned in the course of performing business, in violation of Article 38.

(2) Any of the following persons shall be punished by a fine not exceeding five million won: <Amended by Act No. 17068, Mar. 4, 2020>

1. A person who fails to comply with an order for disinfection, etc., in violation of Article 15 (3) or who fails to be confirmed by the director of the quarantine station regarding the results of performance;
2. The head of a means of transport who refuses to follow the instruction to move pursuant to Article 15 (4) or 23 (4);
3. A person who removes goods used or kept from an isolation facility or temporary isolation facility without approval of the director of the quarantine station, in violation of Article 18;
4. A person who fails to follow any of the measures, such as the prohibition of transfer pursuant to Article 19 (1).

<<Enforcement Date: Mar. 5, 2021>>

Article 40 (Joint Penalty Provisions)

If the representative of a juristic person, or an agent, employee, or any other employed person of a juristic person or individual violates Article 39 in connection with the business affairs of the juristic person or individual, such juristic person or individual shall be punished, and the juristic person or the individual shall also be punished by a fine under the relevant provisions: *Provided*, That the same shall not apply where the juristic person or individual is not negligent in paying due attention to or providing supervision of the relevant duties in order to prevent such violation.

Article 41 (Administrative Fines)

(1) Any of the following persons shall be subject to an administrative fine not exceeding ten million won: <Newly Inserted by Act No. 13980, Feb. 3, 2016>

1. A person who fails to submit a report in violation of Article 29-3 or a person who submits a false report;
2. A person who fails to comply with a request for passenger reservation data under Article 29-4 or submits false passenger reservation data.

(2) Any of the following persons shall be subject to an administrative fine not exceeding five million won: <Amended by Act No. 13980, Feb. 3, 2016>

1. The head of a means of transport who fails to file a report pursuant to Article 8 (1) or files a false report;
2. The head of a means of transport who fails to notify quarantine as provided for in Article 9;
3. A person who boards before undergoing a quarantine inspection, in violation of Article 13;
4. A person subject to isolation who has contact with any other person during the isolation period, in violation of Article 16 (5);
5. A person who fails to follow any of the public health measures provided for in Article 26;
6. A person who fails to follow any of the measures taken or directions given under Article 29 (1);

7. A person who fails to comply with a request without good cause, in violation of Article 29-6 (2).
- (3) Administrative fines referred to in paragraphs (1) and (2) shall be imposed and collected by the director of the quarantine station, as prescribed by Presidential Decree. <Amended by Act No. 13980, Feb. 3, 2016>

#Article 41 (Administrative Fines)

- (1) Any of the following persons shall be subject to an administrative fine not exceeding ten million won: <Newly Inserted by Act No. 13980, Feb. 3, 2016; Act No. 17068, Mar. 4, 2020>
1. A person who fails to report in violation of Article 12-2 (1) or a person who falsely reports;
 2. A person who fails to comply with a request for passenger reservation data made under Article 29-4 or a person who submits false passenger reservation data.
- (2) Any of the following persons shall be subject to an administrative fine not exceeding five million won: <Amended by Act No. 13980, Feb. 3, 2016; Act No. 17068, Mar. 4, 2020>
1. Deleted; <by Act No. 17068, Mar. 4, 2020>
 2. The head of a means of transport who fails to notify as provided in Article 9 or who notifies false information;
 - 2-2. A person who fails to follow the measures taken under Article 12-2 (3);
 3. A person who boards a ship or plane before undergoing a quarantine inspection, in violation of Article 13;
 4. A person in isolation who has contact with any other person during the isolation period, in violation of Article 16 (5);
 5. Deleted; <by Act No. 17068, Mar. 4, 2020>
 6. A person who fails to follow any of the measures taken or instructions given under Article 29 (1);
 7. A person who fails to comply with a request without good cause, in violation of Article 29-6 (2).
- (3) Administrative fines referred to in paragraphs (1) and (2) shall be imposed and collected by the director of the quarantine station, as prescribed by Presidential Decree. <Amended by Act No. 13980, Feb. 3, 2016> <<Enforcement Date: Mar. 5, 2021>>

Addenda <Act No. 17068, Mar. 4, 2020>

Article 1 (Enforcement Date)

This Act shall enter into force one year after the date of its promulgation: *Provided*, That amended provisions of subparagraphs 7 and 8 of Article 2 and Articles 5 and 24 shall enter into force on the date of its promulgation.

Article 2 (Transitional Measures concerning Quarantine Inspection Required Areas or Similar Areas)

Contaminated areas or adjacent areas to contaminated areas designated under the previous provisions as at the time this Act enters into force shall be deemed to be quarantine inspection required areas or strict quarantine inspection required areas designated under Article 5 (1).

Article 3 (Transitional Measures)

- (1) Notwithstanding the amended provisions of Article 5 entering into force under the proviso of Article 1 of the Addenda, “a contaminated area and adjacent areas to the contaminated area” under Article 5-2 and Article 29-6 (which are in force before a partial amendment to the Quarantine Act by Act No. 17068) shall be deemed to be a quarantine inspection required area or similar area under the amended provisions of Article 5 until before the enforcement date of this Act.
- (2) Notwithstanding the amended provisions of Article 5 entering into force under the proviso of Article 1 of the Addenda, “a contaminated area” under Article 29-3 shall be deemed to be “a contaminated

area” under Article 5 (which is in force before a partial amendment to the Quarantine Act by Act No. 17068) until before the enforcement date of this Act.

- (3) Notwithstanding the amended provisions of Article 5 entering into force under the proviso of Article 1 of the Addenda, “a contact of a patient of a quarantinable infectious disease, etc.” under the amended provisions of subparagraph 2 of Article 24 shall be deemed to be “a person suspected of contracting a quarantinable infectious disease” as defined in subparagraph 5 of Article 2 (which is in force before a partial amendment to the Quarantine Act by Act No. 17068) until before the enforcement date of this Act.

Article 4 Omitted.

2.4 Enforcement Decree of The Quarantine Act

Presidential Decree No. 28150, Jun. 27, 2017

Article 1 (Purpose)

The purpose of this Decree is to prescribe the matters delegated by the Quarantine Act and matters necessary for the enforcement of the said Act.

Article 2 (Management of Passenger Reservation Data)

- (1) Upon receipt of passenger reservation data submitted under Article 29-4 (1) of the Quarantine Act (hereinafter referred to as the “Act”), the Minister of Health and Welfare shall take the following measures:
1. To specify a person who can access the passenger reservation data and his/her access authority;
 2. To place a physical lock on the passenger reservation data (referring to installing a security program if such passenger reservation data exists in electronic form).
- (2) The Minister of Health and Welfare shall retain passenger reservation data submitted under Article 29-4 (1) of the Act for two months from the date of submission of the passenger reservation data.
- (3) Upon expiration of the retention period of passenger reservation data prescribed under paragraph (2), the Minister of Health and Welfare shall destroy the passenger reservation data by either of the following means within seven days from expiration of the retention period:
1. To permanently delete such passenger reservation data by an irrecoverable or unrestoreable means, if such data exists in electronic form;
 2. To shred or incinerate such passenger reservation data, if it is in any form other than the form referred to in subparagraph 1.

[This Article Newly Inserted by Presidential Decree No. 27430, Aug. 2, 2016]

Article 2-2 (Cooperation from Related Agencies)

- (1) “Data and information prescribed by Presidential Decree” in the forepart of Article 29-5 of the Act means the following data and information: *<Amended by Presidential Decree No. 28150, Jun. 27, 2017>*
1. Information about the entry inspection of an alien under Article 12 (1) of the Immigration Act and alien registration information under Article 32 of the same Act;
 2. Information about the place of residence in the Republic of Korea reported by a foreign nationality Korean under Article 6 of the Act on the Immigration and Legal Status of Overseas Koreans;
 3. Information about the resident registration number issued under Article 7-2 (1) of the Resident Registration Act and address reported under Article 10 (1) or 10-2 (1) of the same Act;
 4. Personal effects or consignments referred to in Article 241 (2) 1 of the Customs Act;
 5. Descriptions in a passport referred to in Article 7 (1) of the Passport Act.
- (2) “Head of a central administrative agency prescribed by Presidential Decree” in subparagraph 6 of Article 29-5 of the Act means the Minister of Foreign Affairs.

[This Article Newly Inserted by Presidential Decree No. 27430, Aug. 2, 2016]

Article 2-3 (Delegation of Authority)

The Minister of Health and Welfare shall delegate his/her authority over the following affairs to the Director of the Korea Centers for Disease Control and Prevention pursuant to Article 37 of the Act: *<Amended by Presidential Decree No. 25600, Sep. 11, 2014; Presidential Decree No. 27430, Aug. 2, 2016>*

1. Designation and cancellation of designation of a contaminated area under Article 5 of the Act;
- 1-2. Selection, cancellation and control of adjacent areas to a contaminated area under Article 5-2 of the Act;

- 1-3. Quarantine measures for a person who has stayed at, or travelled via, an adjacent area to a contaminated area designated under Article 5-2 of the Act;
2. Request to prohibit or suspend entry into and departure from the Republic of Korea under Article 24 of the Act;
3. Designation of an internationally certified vaccination institution, public announcement of designation, and revocation of designation under Article 28-2 of the Act;
- 3-2. Building and operation of the quarantine information system under Article 29-2 (1) and (2) of the Act;
- 3-3. Requests for perusal and submission of passenger reservation data, and management thereof under Article 29-4 (1) and (4) of the Act;
- 3-4. Requests for data and information, and management thereof under Article 29-5 of the Act;
4. Hearings under Article 34-2 of the Act.

Article 2-4 (Management of Sensitive Information and Personally Identifiable Information)

The Minister of Health and Welfare (including the person to whom the authority of the Minister of Health and Welfare is delegated under Article 37 of the Act) and the director of a quarantine station may manage information on health pursuant to Article 23 of the Personal Information Protection Act and data containing resident registration numbers, passport numbers, or alien registration numbers pursuant to subparagraph 1, 2 or 4 of Article 19 of the Enforcement Decree of the same Act, if it is inevitable for conducting the following affairs: *<Amended by Presidential Decree No. 27430, Aug. 2, 2016>*

1. Affairs concerning quarantine measures for a person who has stayed at, or travelled via, an adjacent area to a contaminated area designated under Article 5-2 of the Act;
- 1-2. Affairs concerning quarantine inspections under Article 12 of the Act;
2. Affairs concerning quarantine measures under Article 15 of the Act;
3. Affairs concerning the measures taken to prevent infectious diseases other than quarantinable infectious diseases under Article 20 of the Act;
4. Affairs concerning the shipment and inspection of a dead body, etc. under Article 25 of the Act;
5. Affairs concerning the measures for public health under Article 26 of the Act;
6. Affairs concerning the requests for the issuance of certificates, etc. and the issuance thereof under Article 28 of the Act;
7. Affairs concerning the management of health and sanitation in quarantine areas under Article 29 of the Act;
8. Affairs concerning reporting by a person who has stayed at, or travelled via, a contaminated area under Article 29-3 of the Act;
9. Affairs concerning requests for perusal or submission of passenger reservation data and management thereof under Article 29-4 of the Act;
10. Affairs concerning requests for data and information and management thereof under Article 29-5 of the Act.

[This Article Newly Inserted by Presidential Decree No. 23488, Jan. 6, 2012]

Article 3 (Guidelines for Imposition of Administrative Fines)

The guidelines for imposition of administrative fines under Article 41 of the Act shall be as provided in the attached Table.

[This Article Wholly Amended by Presidential Decree No. 27430, Aug. 2, 2016]

Addenda *<Presidential Decree No. 28150, Jun. 27, 2017>*

Article 1 (Enforcement Date)

This Decree shall enter into force on July 1, 2017: *Provided*, That the amended provisions of Article 3 of the Addenda shall enter into force on the date of its promulgation.

Articles 2 and 3 Omitted.

2.5 Framework Act on Health and Medical Services

Act No. 15883, Dec. 11, 2018

CHAPTER I General Provisions

Article 1 (Purpose)

The purpose of this Act is to prescribe the rights and duties of nationals and the obligations of the State and local governments, with regard to health and medical services, and to provide for basic matters on the supply of and demand for health and medical services, thereby contributing to the development of health and medical services and the improvement of national health and welfare.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 2 (Basic Principles)

The basic principles of this Act are to ensure that all nationals pursue happiness with dignity and value as humans through health and medical services, to create systems and circumstances to help individual nationals lead a healthy life, and to promote balance between the equity and efficiency of health and medical services, thereby improving the quality of life of the nation.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 3 (Definitions)

The terms used in this Act shall be defined as follows:

1. The term "health and medical services" means all activities conducted by the State, local governments, health and medical institutions, health and medical services personnel, etc., with the purposes of protecting and improving national health;
2. The term "health and medical treatment services" means all activities conducted by health and medical services personnel with the purposes of protecting and improving national health;
3. The term "health and medical services personnel" means persons who acquire qualifications, licenses, etc. or are allowed to engage in providing health and medical treatment services under statutes related to health and medical services;
4. The term "health and medical institution" means any health care institution, medical institution, pharmacy or any other institution prescribed by Presidential Decree where health and medical services personnel provide health and medical treatment services to the public or many and specified persons;
5. The term "public health and medical institution" means any health and medical institution established and operated by the State, local governments or other public organizations;
6. The term "information on health and medical services" means knowledge or all kinds of data expressed in the form of code, figure, letter, voice, sound, image, etc., which are related to health and medical services.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 4 (Obligations of State and Local Governments)

- (1) The State and local governments shall endeavor to take legal and institutional measures necessary for protecting and improving national health and to secure financial resources necessary therefor.
- (2) The State and local governments shall endeavor to meet the demand for basic health and medical services of all nationals in an equitable manner.
- (3) The State and local governments shall endeavor to take measures to prevent potential harm from

health-related items, such as foods, medical supplies, medical appliances, and cosmetics, or health-related activities, and to protect national health from various harmful factors.

- (4) The State and local governments may provide administrative and financial support for health and medical services offered by the private sector, when deemed necessary for policies on health and medical services.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 5 (Obligations of Health and Medical Services Personnel)

- (1) Health and medical services personnel shall endeavor to provide patients with high-quality and appropriate health and medical treatment services on the basis of their knowledge, experience and conscience.
- (2) When health and medical services personnel are requested to provide health and medical treatment services, they shall not refuse to comply with such request, unless any justifiable ground exists otherwise.
- (3) Health and medical services personnel shall endeavor to refer persons who receive health and medical treatment services to other health and medical institutions and provide the relevant data on health and medical services to such other health and medical institutions, when necessary for providing appropriate health and medical treatment services.
- (4) When health and medical services personnel discover persons who have or are suspected to have diseases which need to be controlled by the State or local governments, they shall state, report, or notify such fact to the relevant institutions, or take other necessary measures.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 6 (Rights of Patients and Health and Medical Services Personnel)

- (1) All patients shall have the right to receive appropriate health and medical treatment services to protect and improve their own health.
- (2) Health and medical services personnel shall have the right to choose appropriate techniques for health and medical services, treatment materials, etc. based on their knowledge, experience and conscience, in rendering health and medical treatment services, so as to protect the health of patients: Provided, That this shall not apply where this Act or other Acts provide otherwise.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 7 (Correlation between Policies on Health and Medical Services and Social Security Policies)

The State and local governments shall endeavor to ensure correlation between policies on health and medical services and the relevant social security policies.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 8 (Participation of Nationals)

The State and local governments shall gather consensus from nationals, including interested persons, in developing and implementing policies on health and medical services which exert significant influence on the life of nationals, including the rights and duties of nationals.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 9 (Relationship to other Acts)

When Acts on health and medical services are enacted or amended, such enactments or amendments shall comply with this Act.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

CHAPTER II Rights and Duties of Nationals Concerning Health and Medical Services

Article 10 (Right to Health, etc.)

- (1) All nationals shall have the right to live under the protection of the State, as prescribed by this Act or other Acts, with regard to their health and that of their families.
- (2) No rights of nationals with regard to their health and that of their families shall be infringed on the grounds of gender, age, religion, social status, financial circumstances, etc.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 11 (Right to Know about Health and Medical Services)

- (1) All nationals shall have the right to request disclosure of the details of policies on health and medical services of the State and local governments, as prescribed by relevant statutes.
- (2) All nationals may request health and medical services personnel or health and medical institutions to allow them to peruse their own records related to health and medical services or deliver copies thereof to them, as prescribed by relevant statutes: Provided, That when the principals cannot make such requests, their spouses, lineal ascendants, lineal descendants, or the lineal ascendants of the spouses may make such requests, and when the spouses, lineal ascendants, lineal descendants, or the lineal ascendants of such spouses do not exist or cannot make such requests themselves due to diseases or other inevitable grounds, agents designated by such principals may request perusal, etc. of the relevant records.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 12 (Right to Decide on Health and Medical Treatment Services)

All nationals shall have the right to receive full explanations from health and medical services personnel on methods for treating their diseases, whether they are subject to medical research, whether they require organ transplants, etc. and then to decide whether to agree with the aforementioned.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 13 (Guarantee of Confidentiality)

No confidential information about the body, health or private life of nationals shall be revealed, with regard to health and medical services.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 14 (Duties of Nationals concerning Health and Medical Services)

- (1) All nationals shall endeavor to protect and improve their health and that of their families, and shall bear expenses necessary for protecting and improving health, as prescribed by relevant statutes.
- (2) No one shall disseminate or advertise information harmful to health, sell or provide equipment and articles harmful to health, or do other acts which undermine or are likely to undermine the health of others.
- (3) All nationals shall cooperate in justifiable health and medical treatment services and guidance provided by health and medical services personnel.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

CHAPTER III Formulation and Implementation of Plans for Development of Health and Medical Services

Article 15 (Formulation, etc. of Plans for Development of Health and Medical Services)

- (1) The Minister of Health and Welfare shall formulate a plan for the development of health and medical services every five years, after consultation with the heads of related central administrative agencies and deliberation by the Health and Medical Services Policy Deliberation Committee established under Article 20.
- (2) Plans for the development of health and medical services shall include the following matters:
<Amended by Act No. 14216, May 29, 2016>
 1. Basic objectives in the development of health and medical services and the direction for promoting such development;
 2. Major plans for projects for health and medical services and the methods of promoting such plans;
 3. Measures to secure and manage resources for health and medical services;
 4. Policies for managing the total number of sickbeds of each region;
 5. Policies for boosting the efficiency of health and medical services, such as establishment of the system for providing and using health and medical services;
 6. Integration and coordination of duties concerning health and medical services between central administrative agencies;
 7. Plans for projects for health and medical services aimed at disadvantaged classes, such as senior citizens or persons with disabilities;
 8. Measures to manage statistics and information on health and medical services;
 9. Other matters deemed particularly necessary for the development of health and medical services.
- (3) Plans for the development of health and medical services shall be finalized after deliberation by the State Council.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 16 (Formulation and Implementation of Measures to Promote Major Policies)

When a plan for the development of health and medical services is finalized, the Minister of Health and Welfare and the heads of the relevant central administrative agencies shall, based on such plan, formulate and implement measures to promote major policies on health and medical services under their jurisdiction each year.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 17 (Formulation and Implementation of Regional Plans for Health and Medical Services)

When a plan for the development of health and medical services is finalized, the Special Metropolitan City Mayor, a Metropolitan City Mayor, a Do Governor, a Special Self-Governing Province Governor (hereinafter referred to as "Mayor/Do Governor"), and the head of a *Si/Gun/Gu* (referring to an autonomous Gu; hereinafter the same shall apply) shall formulate and implement regional plans for health and medical services, as prescribed by related statutes, taking into account the conditions of the relevant local governments.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 18 (Cooperation in Formulation of Plans)

- (1) The Minister of Health and Welfare, the head of the relevant central administrative agency, a Mayor/Do Governor, and the head of a *Si/Gun/Gu* may request related institutions, organizations, etc. to provide cooperation, such as submission of data, when necessary for formulating and implementing plans for the development of health and medical services, measures to promote major

policies under their jurisdiction, and regional plans for health and medical services.

- (2) The relevant institutions, organizations, etc., upon receipt of a request for cooperation under paragraph (1), shall comply with such request unless any special ground exists otherwise.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 18-2 (Report to National Assembly)

The Minister of Health and Welfare shall each year determine major details of plans for the development of health and medical services, measures to promote major policies of the pertinent year under Article 16, and the promotion performance of the previous year, and shall without delay report the same to the standing committee under the National Assembly's jurisdiction.

[This Article Newly Inserted by Act No. 13649, Dec. 29, 2015]

Article 19 (Reimbursement for Expenses)

The State may, within budgetary limits, provide local governments with subsidy to cover all or part of expenses incurred in implementing regional plans for health and medical services.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 20 (Health and Medical Services Policy Deliberation Committee)

The Health and Medical Services Policy Deliberation Committee (hereinafter referred to as the "Committee") shall be established under the jurisdiction of the Minister of Health and Welfare, with the purpose of deliberating on major policies on health and medical services.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 21 (Organization of Committee)

- (1) The Committee shall be comprised of not more than 20 members, including one chairperson, and the members who are not public officials shall be a majority of the total number of the members.

<Amended by Act No. 15883, Dec. 11, 2018>

- (2) The chairperson shall be the Minister of Health and Welfare.

- (3) Members of the Committee shall be appointed or commissioned by the Minister of Health and Welfare from among the following persons:

1. Public officials of the relevant central administrative agencies prescribed by Presidential Decree;
2. Persons who represent the consumers of health and medical services;
3. Persons who represent the suppliers of health and medical services;
4. Persons with abundant academic knowledge and experience in health and medical services.

- (4) Working committees shall be established under the jurisdiction of the Committee with a view to efficiently managing its meetings, and subcommittees may be established by area with a view to examining matters subject to deliberation by the Committee in a more professional manner.

- (5) The organization and operation of the Committee, working committees, and subcommittees, and other necessary matters shall be prescribed by Presidential Decree, except as otherwise prescribed in this Act.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 22 (Functions of Committee)

The Committee shall deliberate on the following matters:

1. Plans for the development of health and medical services;
2. Improvement of the main systems of health and medical services;
3. Major policies on health and medical services;
4. Roles of the State and local governments with regard to health and medical services;
5. Other matters referred by the chairperson for deliberation.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 23 (Cooperation of Relevant Administrative Agencies)

- (1) The Committee may request the relevant administrative agencies to submit data on health and medical services and to provide necessary cooperation with regard to duties of the Committee.
- (2) The relevant administrative agencies, upon receipt of a request under paragraph (1), shall comply with such request, unless any special ground exists otherwise.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

CHAPTER IV Management, etc. of Resources for Health and Medical Services

Article 24 (Management, etc. of Resources for Health and Medical Services)

- (1) The State and local governments shall formulate comprehensive and systematic policies, in order to develop and secure resources for health and medical services, such as human resources, facilities, goods, knowledge and technology related to health and medical services.
- (2) The State and local governments shall manage resources for health and medical services to ensure that such resources are supplied appropriately, by predicting the short- and long-term demand for resources for health and medical services.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 25 (Fostering, etc. Human Resources for Health and Medical Services)

The State and local governments shall formulate necessary policies to foster excellent human resources for health and medical services and improve the capabilities of such human resources, including education programs.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 26 (Cooperation among Health and Medical Services Personnel)

Health and medical services personnel shall endeavor to cooperate with each other in each specialized field or between specialized fields in providing health and medical services, so as to provide high-quality health and medical services to nationals and contribute to improving national health.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 27 (Sharing Roles, etc. between Public and Private Health and Medical Institutions)

- (1) The State and local governments shall establish a system for sharing roles and promoting cooperation between public health and medical institutions and private health and medical institutions.
- (2) When necessary for meeting demand for basic health and medical services under Article 4 (2), the State and local government may establish and operate public health and medical institutions and provide subsidy to cover all or part of expenses incurred in such establishment or operation.
- (3) The State and local governments shall formulate and implement necessary policies to efficiently operate and manage public health and medical services.
- (4) Basic matters regarding public health and medical services, such as the establishment and operation of public health and medical institutions, shall be separately prescribed by law.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 28 (Knowledge and Technology concerning Health and Medical Services)

- (1) The State and local governments shall formulate and implement necessary policies for the development of knowledge and technology concerning health and medical services.
- (2) The Minister of Health and Welfare shall endeavor to take necessary measures to provide efficient

health and medical treatment services, such as the evaluation of new technology concerning health and medical services.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

CHAPTER V Provision and Use of Health and Medical Services

SECTION 1 System for Providing and Using Health and Medical Services

Article 29 (System for Providing and Using Health and Medical Services)

- (1) The State and local governments shall endeavor to ensure that resources for health and medical services including human resources, facilities and goods are equally distributed across regions and health and medical treatment services are provided in a balanced manner, and to establish a system for providing and using health and medical services for the purposes of efficiently providing high-quality health and medical treatment services.
- (2) The State and local governments may take administrative and financial measures necessary for establishing a system for providing and using health and medical services, and provide other necessary support therefor.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 30 (System for Emergency Medical Services)

The State and local governments shall establish a system for emergency medical services to ensure that all nationals (including foreigners staying in Korea) can receive swift and appropriate emergency medical services in an emergency. <Amended by Act No. 11855, Jun. 4, 2013>

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

SECTION 2 System of Lifelong Health Care for Citizens

Article 31 (Projects for Lifelong Health Care for Citizens)

- (1) The State and local governments shall implement projects for lifelong health care for citizens, taking into account health characteristics of each life cycle and major health risk factors.
- (2) The State and local governments shall develop policies necessary to ensure that public health and medical institutions can play a pivotal role in the projects for lifelong health care for citizens.
- (3) The State and local governments shall nurture specialized human resources to be in charge of health guidance, health education, etc., establish the health care information system, and develop other policies necessary to facilitate implementation of projects for lifelong health care for citizens.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 32 (Improvement of Health of Women and Children)

The State and local governments shall formulate policies necessary to protect and promote the health of women and children. In such cases, the State and local governments shall ensure that policies to promote women's health reflect characteristics of each age group. <Amended by Act No. 13649, Dec. 29, 2015>

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 33 (Improvement of Health of Senior Citizens)

The State and local governments shall formulate policies necessary to protect and improve the health of senior citizens for the purposes of early diagnosing and preventing diseases of senior citizens, and ensuring appropriate treatment and medical care for them, depending on the conditions of diseases.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 34 (Promoting Health of Persons with Disabilities)

The State and local governments shall prevent inborn or acquired disabilities, assist in the treatment and rehabilitation of persons with disabilities, and formulate other policies necessary to protect and promote their health.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 35 (School Health and Medical Services)

The State and local governments shall formulate policies necessary to help the sound growth of students, to protect and promote their health, and to cultivate life habits, emotions, etc. required for students' growth into healthy adults.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 36 (Industrial Health and Medical Services)

The State shall formulate necessary policies to protect and promote the health of workers.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 37 (Environmental Health and Medical Services)

The State and local governments shall formulate policies necessary to maintain a comfortable environment and prevent any harm to health caused by environmental pollution, so as to protect and promote national health.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 37-2 (National Health Impact Assessment, etc. due to Climate Change)

- (1) In order to protect and promote national health, the Minister of Health and Welfare shall examine and assess the impacts of climate change, such as global warming, on national health (hereinafter referred to as "climatic health impact assessment") every five years and publish the results of the examination and assessment, and utilize such results as basic data for the formulation of policies.
- (2) The Minister of Health and Welfare may conduct fact-finding research in order to obtain basic data and prepare statistics necessary for climatic health impact assessment.
- (3) The Minister of Health and Welfare may request the head of a central administrative agency, the head of a local government and the head of an institution or organization related to medical services to provide data necessary for climatic health impact assessment or to cooperate in fact-finding research conducted under paragraph (2). In such cases, the head of a central administrative agency, etc. requested to provide data or cooperate in fact-finding research shall comply with such request unless he/she has a justifiable reason.
- (4) Necessary matters concerning specific details, methods, etc. of climatic health impact assessment and fact-finding research shall be prescribed by Presidential Decree.

[This Article Newly Inserted by Act No. 14558, Feb. 8, 2017]

Article 38 (Food Hygiene and Nutrition)

The State and local governments shall formulate policies necessary to prevent any harm to health caused by food and to improve the nutritional conditions of nationals, so as to protect and promote national health.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

SECTION 3 System for Managing Major Diseases

Article 39 (Establishment of System for Managing Major Diseases)

The Minister of Health and Welfare shall select diseases that particularly need to be managed by the State, from among diseases that may cause considerable harm to national health, and formulate and

implement policies necessary for managing such diseases.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 40 (Prevention and Management of Infectious Diseases)

The State and local governments shall formulate and implement policies necessary for preventing outbreaks and prevalence of infectious diseases, providing appropriate health and medical services to patients with infectious diseases, and managing such diseases.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 41 (Prevention and Management of Chronic Diseases)

The State and local governments shall formulate and implement policies necessary for preventing outbreaks and spread of major chronic diseases, such as cancer and hypertension, providing appropriate health and medical services to patients with chronic diseases, including patients with end-stage diseases, and managing such diseases.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 42 (Mental Health and Medical Services)

The State and local governments shall formulate and implement policies necessary for promoting the mental health of nationals, such as preventing mental diseases, treating patients with mental diseases and helping such patients to reintegrate into society.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 43 (Oral Health and Medical Services)

The State and local governments shall formulate and implement policies necessary for promoting the oral health of nationals, such as preventing and treating oral diseases and managing oral health.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

CHAPTER VI Support, Development, etc. of Health and Medical Services

Article 44 (Pilot Projects for Health and Medical Services)

- (1) The State and local governments may conduct pilot projects, when necessary for implementing a new system of health and medical services.
- (2) When the State and local governments have conducted pilot projects under paragraph (1), they shall evaluate the outcomes thereof and reflect such outcomes in the new system of health and medical services to be implemented.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 45 (Provision of Health and Medical Treatment Services to Disadvantaged Classes)

- (1) The State and local governments shall formulate and implement policies necessary to provide appropriate health and medical treatment services to disadvantaged classes, including senior citizens and persons with disabilities.
- (2) The State and local governments shall formulate and implement policies necessary to protect and promote the health of farmers, fishermen. etc.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 46 (Dispute Resolution, etc.)

- (1) The State and local governments shall formulate policies necessary to settle disputes arising in respect of health and medical treatment services in a swift and fair manner.

(2) The State and local governments shall formulate policies necessary to facilitate relief of any damage or loss caused by health and medical treatment services.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 47 (Expenses Borne by Persons who Cause Harm to National Health)

The State and local governments may require persons who produce or sell goods, etc. which cause or are likely to cause harm to national health, to bear expenses incurred in protecting and promoting national health, as prescribed by relevant statutes.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 48 (Promotion of Industries Related to Health and Medical Services)

The State and local governments shall formulate policies necessary to promote industries related to health and medical services, such as the research and development of health and medical services technology or support therefor.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 49 (Fostering and Development of Oriental Medical Services)

The State and local governments shall endeavor to foster and develop Oriental medical services.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 50 (International Cooperation, etc.)

The State and local governments shall exchange information and technology related to health and medical services through cooperation with foreign governments and international organizations, etc., train specialized human resources, and actively participate in international endeavors for the development of health and medical services.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 51 (Evaluation of Projects for Health and Medical Services)

The State and local governments shall evaluate the outcomes of major projects for health and medical services each year and reflect such outcomes in policies on health and medical services.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 52 (Evaluation of Health and Medical Treatment Services)

The Minister of Health and Welfare shall conduct an evaluation of health and medical treatment services under relevant statutes, so as to improve the quality of health and medical treatment services.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

CHAPTER VII Management of Statistics and Information on Health and Medical Services

Article 53 (Policies on Management of Statistics and Information on Health and Medical Services)

The State and local governments shall formulate and implement necessary policies to collect and manage statistics and information on health and medical services and utilize such statistics and information for policies on health and medical services.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 54 (Facilitation of Informatization of Health and Medical Services)

The State and local governments shall formulate policies necessary to facilitate the informatization of health and medical services.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 55 (Fact-Finding Surveys on Health and Medical Services)

The Minister of Health and Welfare shall conduct nationwide fact-finding surveys on health and medical services, such as the national demand for health and medical services, trends in using such services, or human resources, facilities and materials related to health and medical services.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 56 (Dissemination and Expansion of Information on Health and Medical Services)

The Minister of Health and Welfare shall formulate policies necessary to widely disseminate and expand information on health and medical services held by health and medical institutions and other related institutions and organizations.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Article 57 (Facilitation of Standardization of Information on Health and Medical Services)

The Minister of Health and Welfare shall formulate policies to standardize the information on health and medical services, in order to efficiently manage information on health and medical services and ensure compatibility.

[This Article Wholly Amended by Act No. 10131, Mar. 17, 2010]

Addenda <Act No. 15883, Dec. 11, 2018>

Article 1 (Enforcement Date)

This Act shall enter into force six months after the date of its promulgation.

Article 2 (Applicability to Organization of Committee)

The amended provisions of Article 21 (1) shall begin to apply to the appointment or commission of members of the Committee after this Act enters into force.

2.6 Enforcement Decree of The Framework Act on Health and Medical Services

Presidential Decree No. 28237, Aug. 9, 2017

Article 1 (Purpose)

The purpose of this Decree is to provide for the matters delegated from the Framework Act on Health and Medical Services and those necessary for the enforcement thereof.

[This Article Wholly Amended by Presidential Decree No. 22171, May 27, 2010]

Article 2 (Notification of Plan for Development of Health and Medical Services)

(1) Where a plan for the development of health and medical services is finalized pursuant to Article 15 (3) of the Framework Act on Health and Medical Services (hereinafter referred to as the "Act"), the Minister of Health and Welfare shall without delay notify the heads of relevant central administrative agencies, the Special Metropolitan City Mayor, a Metropolitan City Mayor, a *Do* Governor, and a Special Self-Governing Province Governor (hereinafter referred to as "Mayor/*Do* Governor") of such plan.

(2) A Mayor/*Do* Governor, in receipt of a notice under paragraph (1), shall without delay notify the head of a *Si/Gun/Gu* (referring to the head of an autonomous *Gu*; hereinafter the same shall apply) of such plan.

[This Article Wholly Amended by Presidential Decree No. 22171, May 27, 2010]

Article 3 (Formulation and Implementation of Measures to Promote Major Policies)

The head of a relevant central administrative agency shall submit measures to promote its major policies on health and medical services for the relevant year formulated under Article 16 of the Act and the results of implementing such policies for the preceding year to the Minister of Health and Welfare by the end of every February.

[This Article Wholly Amended by Presidential Decree No. 22171, May 27, 2010]

Article 4 (Formation of Healthcare Policy Deliberative Committee)

"Public officials of the relevant central administrative agencies prescribed by Presidential Decree" in Article 21 (3) 1 of the Act means the following persons. In such cases, an agency which has at least two vice ministers, such person means the vice minister designated by the head of the relevant agency: <Amended by Presidential Decree No. 22269, Jul. 12, 2010; Presidential Decree No. 24454, Mar. 23, 2013; Presidential Decree No. 25751, Nov. 19, 2014; Presidential Decree No. 28211, Jul. 26, 2017>

1. Vice Minister of Strategy and Finance;
2. Vice Minister of Education;
3. Vice Minister of Science and ICT;
4. Vice Minister of the Interior and Safety;
5. Vice Minister of Environment;
6. Vice Minister of Employment and Labor;
7. and 8. Deleted; <Presidential Decree No. 28237, Aug. 9, 2017>
9. Minister of Food and Drug Safety.

[This Article Wholly Amended by Presidential Decree No. 22171, May 27, 2010]

Article 5 (Term of Office of Members)

The term of office of the members (excluding those falling under Article 21 (3) 1 of the Act) of the

Health and Medical Services Policy Deliberation Committee (hereinafter referred to as the "Committee") established under Article 20 of the Act shall be two years, and they may be reappointed to office.

[This Article Wholly Amended by Presidential Decree No. 22171, May 27, 2010]

Article 5-2 (Dismissal of Members)

The Minister of Health and Welfare may dismiss a member of the Committee (excluding a person falling under Article 21 (3) 1 of the Act), where such member falls under any of the following cases:

1. Where he/she is no longer capable of performing duties due to his/her mental disorder;
2. Where he/she has committed a misconduct regarding his/her duties;
3. Where he/she is deemed unsuitable as a member due to neglect of duties, injury to dignity, or other reasons;
4. Where a member expresses his/her difficulty to perform his/her duties.

[This Article Newly Inserted by Presidential Decree No. 14216, May, 10, 2016]

Article 6 (Duties, etc. of Chairperson of the Committee)

- (1) The chairperson of the Committee shall represent the Committee and exercise general supervision over its affairs.
- (2) Where the chairperson of the Committee is unable to perform any of his/her duties due to extenuating circumstances, a member of the Committee designated by him/her shall perform the duties on his/her behalf.

[This Article Wholly Amended by Presidential Decree No. 22171, May 27, 2010]

Article 7 (Meetings and Proceedings)

- (1) The chairperson of the Committee shall convene its meetings.
- (2) A majority of the members of the Committee shall constitute a quorum, any decision thereof shall require the concurring vote of a majority of those present.

[This Article Wholly Amended by Presidential Decree No. 22171, May 27, 2010]

Article 8 (Hearing Opinions)

Where necessary to conduct affairs, the Committee may require relevant public officials or relevant experts to attend its meetings to listen to their opinions.

[This Article Wholly Amended by Presidential Decree No. 22171, May 27, 2010]

Article 9 (Allowances and Travel Expenses)

The Committee may pay allowances, and reimburse travel expenses and other necessary expenses, to its members, relevant public officials or relevant experts who attend meetings of the Committee, within budgetary limits: *Provided*, That the foregoing shall not apply where members who are public officials or relevant public officials attend its meetings in direct relation to their duties.

[This Article Wholly Amended by Presidential Decree No. 22171, May 27, 2010]

Article 10 (Administrative Secretary)

- (1) The Committee shall have one administrative secretary to be in charge of conducting its affairs.
- (2) The Minister of Health and Welfare shall appoint the administrative secretary from among members of the Senior Executive Service under the jurisdiction of the Ministry of Health and Welfare.

[This Article Wholly Amended by Presidential Decree No. 22171, May 27, 2010]

Article 11 (Detailed Rules for Operation of Committee)

In addition to the matters prescribed by this Decree, matters necessary for the operation of the Committee shall be prescribed by the Minister of Health and Welfare upon a resolution passed by the Committee.

[This Article Wholly Amended by Presidential Decree No. 22171, May 27, 2010]

Article 12 (Formation, etc. of Working Committee)

- (1) The working committee established under Article 21 (4) of the Act shall be composed of not more than 25 members, including one chairperson.
- (2) The chairperson of the working committee shall be appointed by the Minister of Health and Welfare from among members of the Senior Executive Service under the jurisdiction of the Ministry of Health and Welfare; and members shall be commissioned by the Minister of Health and Welfare from among public officials in Grade III or IV under the jurisdiction of relevant central administrative agencies under Article 4 and the Ministry of Health and Welfare, and persons who have extensive knowledge of and experience in the field of health and medical services.
- (3) The working committee shall deliberate on the following:
 1. Matters which require prior review, such as consultations with relevant central administrative agencies before deliberation by the Committee;
 2. Matters on which the working committee is requested by the Committee to deliberate;
 3. Other matters referred for deliberation by the chairperson of the Committee.
- (4) Where the chairperson of the working committee is unable to perform any of his/her duties due to extenuating circumstances, a member who is a public official under the jurisdiction of the Ministry of Health and Welfare shall perform the duties on his/her behalf.
- (5) The working committee shall have one administrative secretary, appointed by the Minister of Health and Welfare from among public officials under the jurisdiction of the Ministry of Health and Welfare.
- (6) Articles 5, 5-2, 6 (1), 7 through 9, and 11 shall apply *mutatis mutandis* to meetings, and to the term of office, dismissal, duties, etc. of the members of the working committee. *<Amended by Presidential Decree No. 14216, May, 10, 2016>*

[This Article Wholly Amended by Presidential Decree No. 22171, May 27, 2010]

Article 13 (Formation, etc. of Subcommittees)

The formation of subcommittees for each field and the appointment of the chairperson of each subcommittee under Article 21 (5) of the Act shall be as prescribed by the chairperson of the Committee, and Articles 5, 5-2, 6 (1), 7 through 9, and 11 shall apply *mutatis mutandis* to meetings of subcommittees, and to the term of office, dismissal, duties, etc. of the members of subcommittees. *<Amended by Presidential Decree No. 14216, May, 10, 2016>*

[This Article Wholly Amended by Presidential Decree No. 22171, May 27, 2010]

Article 13-2 (Details, Methods, etc. of Climatic Health Impact Assessment)

- (1) The details of climatic health impact assessment (hereinafter referred to as "climatic health impact assessment") under Article 37-2 (1) of the Act are as follows:
 1. Matters concerning types, details, characteristics, etc. of climate change that has impacts on public health;
 2. Matters concerning the clinical symptoms, trends in outbreaks, progress of treatments, etc. of diseases, illnesses, etc. related to climate change;
 3. Matters concerning the distribution, characteristics, etc. of diseases, illnesses, etc. by gender, age group, and region related to climate change;
 4. Impacts of climate change on the health, life, etc. of vulnerable groups of people less likely to have access to health and medical services, such as senior citizens, persons with disabilities, pregnant women, and children;
 5. Other matters the Minister of Health and Welfare deems especially necessary in consideration of the impacts of climate change on public health, which correspond to the details under subparagraphs 1

through 4.

- (2) Where the Minister of Health and Welfare deems professional review on climatic health impact assessment necessary, he/she may have climatic health impact assessment deliberated by the Committee before he/she publishes the results of climatic health impact assessment pursuant to Article 37-2 (1) of the Act.
- (3) Where the Minister of Health and Welfare deems it necessary to protect and promote national health, he/she shall notify the heads of relevant central administrative agencies, Mayors/*Do* Governors, and the heads of *Sis/Gun/Gus* of the results of climatic health impact assessment.
- (4) Where the Minister of Health and Welfare publishes the results of climatic health impact assessment pursuant to Article 37-2 (1) of the Act, he/she shall publish the results thereof on the website he/she designates.
- (5) Except as otherwise provided for in paragraphs (1) through (4), the Minister of Health and Welfare shall prescribe detailed matters necessary for the details and methods of, and procedures for climatic health impact assessment.

[This Article Newly Inserted by Presidential Decree No. 28237, Aug. 9, 2017]

Article 13-3 (Details, Methods, etc. of Fact-Finding Research)

- (1) The details of fact-finding research (hereinafter referred to as "fact-finding research") under Article 37-2 (2) of the Act are as follows:
 1. Matters concerning the progress of outbreaks and the current status of outbreaks of, and clinical information on diseases, illnesses, etc. due to climate change;
 2. Matters concerning information on the medical diagnosis and treatment, such as diagnoses, examinations, and prescriptions, of diseases, illnesses, etc. due to climate change;
 3. Matters concerning the examination of various kinds of literatures, data, etc. related to analysis and study of diseases, illnesses, etc. due to climate change;
 4. Matters concerning the progress of medical treatments of vulnerable groups of people less likely to have access to health and medical services, such as senior citizens, persons with disabilities, pregnant women, and children, in relation to diseases, illnesses, etc. due to climate change;
 5. Other matters the Minister of Health and Welfare deems specially necessary for fact-finding research, which correspond to the details under subparagraphs 1 through 4.
- (2) Where the Minister of Health and Welfare deems it necessary to conduct fact-finding research, a fact-finding research team may be organized and operated, as prescribed by the Minister of Health and Welfare.
- (3) Where the Minister of Health and Welfare deems it necessary to efficiently conduct fact-finding research, he/she may conduct fact-finding research by entrusting fact-finding research to a health and medical care-related research institution, organization or expert.
- (4) Where the Minister of Health and Welfare deems it necessary to protect and manage national health due to climate change, he/she may disclose the results of fact-finding research.
- (5) Except as otherwise provided for in paragraphs (1) through (4), the Minister of Health and Welfare shall prescribe necessary detailed matters concerning the details and methods of, and procedures for fact-finding research.

[This Article Newly Inserted by Presidential Decree No. 28237, Aug. 9, 2017]

Article 13-4 (Long-Term Epidemiological Investigation of Chronic Diseases)

- (1) The Minister of Health and Welfare shall conduct a long-term epidemiological investigation of chronic diseases, which is aimed at identifying causes and risk factors thereof, in order to prevent and manage chronic diseases under Article 41 of the Act.
- (2) When necessary for conducting an epidemiological investigation under paragraph (1), the Minister of Health and Welfare may request cooperation from the head of a relevant central administrative

agency, a Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* or of a public institution under the Act on the Management of Public Institutions.

[This Article Newly Inserted by Presidential Decree No. 27432, Aug. 2, 2016]

Article 14 (Fact-Finding Surveys on Health and Medical Services)

- (1) The Minister of Health and Welfare shall conduct a fact-finding survey on health and medical services under Article 55 of the Act every five years, and formulate a plan for conducting each fact-finding survey, including the scope, details, date and time, etc. of the survey, through consultation with the heads of relevant central administrative agencies.
- (2) If necessary, the Minister of Health and Welfare may conduct an interim fact-finding survey on health and medical services.
- (3) When the Minister of Health and Welfare conducts a fact-finding survey under paragraphs (1) and (2), he/she may request cooperation from the heads of relevant central administrative agencies, Mayors/*Do* Governors, and the heads of *Sis/Guns/Gus*, if deemed necessary.

[*This Article Wholly Amended by Presidential Decree No. 22171, May 27, 2010*]

Article 15 (Management of Sensitive Information and Personally Identifiable Information)

The Minister of Health and Welfare may, if unavoidable to handle affairs under Article 41 of the Act (affairs related to the long-term epidemiological investigation of chronic diseases under Article 13-4 (1)), manage data containing personal information on health under Article 23 of the Personal Information Protection Act, resident identification numbers or foreigner registration numbers under subparagraph 1 or 4 of Article 19 of the Enforcement Decree of the said Act. <*Amended by Presidential Decree No. 28237, Aug. 9, 2017*>

[*This Article Newly Inserted by Act No. 27432, Aug. 2, 2016*]

Addendum <*Presidential Decree No. 28237, Aug. 9, 2017*>

This Decree shall enter into force on August 9, 2017.

2.7 Public Health and Medical Services Act

Act No. 15440, Mar. 13, 2018

CHAPTER I General Provisions

Article 1 (Purpose)

The purpose of this Act is to effectively provide citizens with high-quality public health and medical services and contribute to the improvement of national health by prescribing basic matters regarding public health and medical services.

Article 2 (Definitions)

The terms used in this Act shall be defined as follows: <Amended by Act No. 13098, Jan. 28, 2015; Act No. 13982, Feb. 3, 2016>

1. The term "public health and medical services" means all activities of the State, local governments, and of public and medical institutions to ensure all citizens equal access to medical services and to protect and promote their health, irrespective of which region they live in and to whatsoever class they belong;
2. The term "public health and medical service programs" means the following programs:
 - (a) Programs for providing medical services to the areas and sectors with difficulties in providing medical services;
 - (b) Programs for providing medical services to underprivileged classes of people who have less opportunities for health and medical services;
 - (c) Programs to prevent and manage infectious diseases and non-infectious diseases that require the State and local governments to take measures considering the scale of outbreaks, seriousness, etc., to manage medical treatment, etc. of patients due to disasters, to promote health, and to administer health education;
 - (d) Other programs specified by Ordinance of the Ministry of Health and Welfare for health and medical services the State needs to manage;
3. The term "public health and medical institutions" means health and medical institutions established and operated by the State, a local government, or a public institution prescribed by Presidential Decree (hereinafter referred to as "public institution") mainly for providing public health and medical services;
4. The term "institutions providing public health and medical services" means the following health and medical institutions:
 - (a) Public health and medical institutions;
 - (b) Central medical institutions for areas lacking medical services, designated under Article 13;
 - (c) Specialized public medical centers designated under Article 14;
 - (d) Medical institutions that enters into an agreement with the Minister of Health and Welfare, the Special Metropolitan City Mayor, a Metropolitan City Mayor, a *Do* Governor, or the Governor of a Special Self-Governing Province (hereinafter referred to as "Mayor/*Do* Governor") or the head of a *Si/Gun/Gu* (the head of a *Gu* means the head of an autonomous *Gu*; the same shall apply hereinafter) under Article 16 (2).
5. The term "public health and medical services delivery system" means building a system of performing roles of the following medical institutions to provide services referred to in each subparagraph of Article 7 (1) by the State or local governments:
 - (a) National Medical Center under the Act on Establishing and Administrating the National Medical Center;

- (b) Seoul National University Hospital under the Establishment of Seoul National University Hospital Act and National University-affiliated hospitals under the Act on the Establishment of National University-Affiliated Hospitals;
- (c) Health and medical institutions designated by the Minister of Health and Welfare, which are established and operated by areas;
- (d) Local medical centers under the Act on the Establishment and Management of Local Medical Centers.

Article 3 (Obligations of State and Local Governments)

- (1) The State and local governments shall implement public health and medical service programs in order to improve public health and medical services.
- (2) The State and local governments shall secure an adequate number of institutions providing public health and medical services in order to smoothly implement public and medical service programs.
- (3) The State and local governments may implement policies necessary to secure medical personnel defined in Article 2 (1) of the Medical Service Act so that public health and medical institutions can provide high quality medical services. *<Newly Inserted by Act No. 15440, Mar. 13, 2018>*
- (4) The State and local governments shall secure funds to implement public health and medical service programs and to promote building and management of the public health and medical service delivery system and may provide financial and administrative support to institutions providing public health and medical services. *<Amended by Act No. 13982, Feb. 3, 2016>*

CHAPTER II Master Plans, Etc. for Public Health and Medical Services

Article 4 (Master Plans for Public Health and Medical Services)

- (1) The Minister of Health and Welfare shall formulate a master plan for public health and medical services every five years in line with the plan to develop health and medical services formulated under Article 15 of the Framework Act on Health and Medical Services in order to provide citizens with high-quality public health and medical services and shall formulate and execute an annual plan to implement major policies.
- (2) A master plan for public health and medical services referred to in paragraph (1) (hereinafter referred to as "master plan for public health and medical services") shall include the following:
 - 1. Targets of, and direction-setting for, public health and medical services;
 - 2. A plan and methods for promoting public health and medical services;
 - 3. Schemes for procuring and managing resources for public health and medical services to expand health and medical services;
 - 4. Other matters specified by Ordinance of the Ministry of Health and Welfare to improve public health and medical services.
- (3) The head of each related central administrative agency, the head of each public institution, and each Mayor/Do Governor shall respectively formulate and execute an annual implementation plan for public health and medical services (hereinafter referred to as "implementation plan") in accordance with the relevant master plan for public health and medical services.
- (4) The head of each related central administrative agency, the head of each public institution, and each Mayor/Do Governor shall respectively submit a report on the results of executing the implementation plan during the preceding year and an implementation plan for the following year, to the Minister of Health and Welfare each year.
- (5) Matters necessary for formulation and execution of implementation plans under paragraphs (3) and (4) and evaluation of the results of executing such plans shall be prescribed by Presidential Decree.

Article 5 (Deliberation on Policies on Public Health and Medical Services)

The following matters concerning public health and medical services shall be deliberated on by the Health and Medical Services Policy Deliberation Committee established under Article 20 of the Framework Act on Health and Medical Services:

1. Formulation of, and amendment to a master plan for public health and medical services;
2. Designation of areas lacking medical services pursuant to Article 12;
3. The necessity and scale of specialized public medical centers pursuant to Article 14;
4. Other matters referred by the chairperson of the Health and Medical Services Policy Deliberation Committee for deliberation.

CHAPTER III Institutions Providing Public Health and Medical Services**Article 6 (Establishment and Operation of Public Health and Medical Institutions)**

- (1) The State and local governments shall establish and operate public health and medical institutions and endeavor to adequately meet citizens' demand for basic health and medical services.
- (2) The State and local governments may subsidize public health and medical institutions for expenses incurred in establishing and operating such institutions.

Article 7 (Obligations of Public Health and Medical Institutions)

- (1) Public health and medical institutions shall prioritize providing the following health and medical services: *<Amended by Act No. 13982, Feb. 3, 2016>*
 1. Health and medical services for the underprivileged, including medical care beneficiaries;
 2. Health and medical services for children, maternity, persons with disabilities, mental diseases, emergency treatment, and health and medical services inadequately provided due to low profitability;
 3. Public health and medical services for disasters, infectious diseases, etc. that require prompt countermeasures;
 4. Health and medical services for preventing diseases and promoting health;
 5. Health and medical services for maintaining equality among regions through education and training and provision of human resources;
 6. Other health and medical services specified by the Minister of Health and Welfare in line with the plan to develop health and medical services pursuant to Article 15 of the Framework Act on Health and Medical Services.
- (2) The Minister of Health and Welfare may request a public health and medical institution to provide other public health and medical service programs in addition to the programs specified in the Acts and subordinate statutes governing the establishment and operation of the relevant public health and medical institutions.
- (3) Upon receipt of a request made under paragraph (1), a public health and medical institution shall comply therewith, except in extenuating circumstances.
- (4) The State and local governments may subsidize public health and medical institutions under paragraphs (1) and (2) or institutions providing public health and medical services under Article 17 (1) within budgetary limits for the expenses necessary for the provision, etc. of health and medical services. *<Newly Inserted by Act No. 13098, Jan. 28, 2015>*

Article 8 (Formulation of Plans for Public Health and Medical Services)

- (1) The head of each public health and medical institution shall formulate an annual plan for public health and medical services and shall submit the plan to the Minister of Health and Welfare, along with a report on the results of executing such plan during the preceding year.

- (2) If the Minister of Health and Welfare finds it necessary with regard to a plan for public health and medical services, submitted under paragraph (1), he/she may recommend the head of the relevant public health and medical institution to amend the plan, as prescribed by Ordinance of the Ministry of Health and Welfare.
- (3) The Minister of Health and Welfare or a Mayor/*Do* Governor may partially subsidize a public health and medical institution for expenses incurred in executing a plan for public health and medical services under paragraph (1).
- (4) Contents of a plan for public health and medical services under paragraph (1) and the procedures for formulating such plan and other necessary matters shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 9 (Evaluation on Outcomes of Plans for Public Health and Medical Services)

- (1) The Minister of Health and Welfare shall evaluate the results of executing a plan for public health and medical services reported under Article 8. In such cases, the Minister of Health and Welfare shall reflect the performance outcomes of public health and medical institutions and institutions providing public health and medical services (excluding those institutions under subparagraph 4 (d) of Article 2; hereafter the same shall apply in this Article) that provided health and medical services, etc. pursuant to Article 7 (1) and (2) or Article 17 (1) in the evaluation. *<Amended by Act No. 13098, Jan. 28, 2015>*
- (2) The Minister of Health and Welfare shall not unfavorably reflect economic losses that occurred while public health and medical institutions and institutions providing public health and medical services provided health and medical services pursuant to Article 7 (1) and (2) or 17 (1) in the evaluation under paragraph (1). *<Newly Inserted by Act No. 13098, Jan. 28, 2015>*
- (3) The Minister of Health and Welfare shall notify the heads of relevant public health and medical institutions and the head of an agency with which the relevant public health and medical institutions are affiliated of the findings from the evaluation conducted pursuant to paragraph (1). *<Amended by Act No. 13098, Jan. 28, 2015>*
- (4) The Minister of Health and Welfare may publicly announce the findings from the evaluation conducted pursuant to or reflect such findings in subsidizing expenses under Article 8. *<Amended by Act No. 13098, Jan. 28, 2015>*
- (5) Standards and procedures for and time and methods of evaluating the performance outcomes of a plan for public health and medical services under paragraph (1) and other necessary matters shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 13098, Jan. 28, 2015>*

Article 10 (Free Lease of State or Public Property)

- (1) If the State or a local government deems it necessary to establish and operate a public health and medical institution, it may lease State or public property to a public health and medical institution free of charge or may permit a public health and medical institution to use or profit from State or public property free of charge, notwithstanding the State Property Act or the Public Property and Commodity Management Act.
- (2) The details, terms, and conditions of the lease and use of or profit from State or public property under paragraph (1) and the procedures therefor shall be prescribed by Presidential Decree.

Article 11 (Special Provisions for Institutions Not Exceeding Specified Scale)

@Articles 8, 9, 13, and 14 shall not apply to public health and medical institutions not exceeding the scale specified by Ordinance of the Ministry of Health and Welfare, such as public health clinics.

Article 12 (Designation and Public Announcement of Areas Lacking Medical Services)

- (1) The Minister of Health and Welfare shall periodically evaluate and analyze citizens' use of medical services and the distribution of resources for medical services.
- (2) The Minister of Health and Welfare may designate and publicly announce an area found substantially lacking medical services as a result of evaluation and analysis conducted under paragraph (1) as an area lacking medical services.
- (3) The Minister of Health and Welfare may designate areas lacking medical services under paragraph (2) upon categorizing such areas based on the targets and types of insufficient medical services.
- (4) The Minister of Health and Welfare may provide the following support to areas designated and publicly announced as an area lacking medical services under paragraph (2) (hereinafter referred to as "area lacking medical services") to facilitate the provision of health and medical services to such areas:
 1. Assistance in providing human resources for health and medical services;
 2. Subsidization for expenses incurred in establishing and operating medical institutions defined in Article 3 of the Medical Service Act (hereinafter referred to as "medical institution").
- (5) Evaluations and analysis conducted under paragraph (1), standards and procedures for, and method of designating areas lacking medical services, and the period for such designation and other necessary matters shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 13 (Designation of Central Medical Institutions for Areas Lacking Medical Services)

- (1) A Mayor/*Do* Governor may designate a medical institution that has, or is deemed capable of having, facilities, personnel, and equipment necessary to provide adequate health and medical services to residents in an area lacking medical services within his/her jurisdiction as a central medical institution for an area lacking medical services (hereinafter referred to as "central medical institution for an area lacking medical services").
- (2) A medical institution that intends to obtain designation as a central medical institution for an area lacking medical services shall file an application therefor with the competent Mayor/*Do* Governor. If a public health and medical institution files an application for such designation, the Mayor/*Do* Governor may give preferential consideration to designation.
- (3) A medical institution designated as a central medical institution for an area lacking medical services shall formulate a plan for providing adequate health and medical services to the area lacking medical services and shall report the results of executing the plan to the competent Mayor/*Do* Governor, as prescribed by Ordinance of the Ministry of Health and Welfare.
- (4) The Minister of Health and Welfare, a Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* may fully or partially subsidize central medical institutions for expenses incurred in expanding and operating facilities and equipment.
- (5) Medical institutions designated as central medical institutions for an area lacking medical services over-bound or are insufficient, the Minister of Health and Welfare may recommend the competent Mayor/*Do* Governor to adjust designation, as prescribed by Ordinance of the Ministry of Health and Welfare.
- (6) Standards and procedures for, and method of designating central medical institutions for an area lacking medical services and other necessary matters shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 14 (Designation of Specialized Public Medical Centers)

- (1) In order to facilitate the provision of following health and medical services, the Minister of Health and Welfare may designate a medical institution that has, or is deemed capable of having, facilities, personnel, and equipment necessary for the fields of specialty as a specialized public medical center

(hereinafter referred to as "specialized public medical center"):

1. A field of specialty inadequately provided due to low profitability;
 2. A field of specialty the State greatly needs to develop for citizens' health;
 3. A field of specialty the State needs to support due to an inter-regional discrepancy in such medical services.
- (2) A medical institution that intends to obtain designation as a specialized public medical center shall file an application therefor with the Minister of Health and Welfare. If a public health and medical institution files an application for such designation, the Minister of Health and Welfare may give preferential consideration to designation.
- (3) A specialized public medical center shall provide citizens with high-quality health and medical services in the designated field of specialty and train human resources therefor, formulate a plan therefor, and report the results of executing such plan to the Minister of Health and Welfare, as prescribed by Ordinance of the Ministry of Health and Welfare.
- (4) The Minister of Health and Welfare or a Mayor/*Do* Governor may fully or partially subsidize specialized public medical centers for expenses incurred in expanding and operating their facilities and equipment.
- (5) Standards and procedures for, and method of designating specialized public medical centers and other necessary matters shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 15 (Evaluation of Results of Executing Public Health and Medical Service Programs)

- (1) The Minister of Health and Welfare may evaluate the results of public health and medical service programs executed by each central medical institution for an area lacking medical services and each specialized public medical center.
- (2) The Minister of Health and Welfare may vary financial and administrative support to each central medical institution for an area lacking medical services or a specialized public medical center, based on the findings from of evaluation conducted under paragraph (1).
- (3) The Minister of Health and Welfare may disclose the findings from evaluation conducted under paragraph (1) to the public, require the relevant central medical institution for an area lacking medical services or a specialized public medical center to rectify defects, or take other necessary measures to efficiently operate such central medical institution for an area lacking medical services or specialized public medical center.
- (4) Detailed standards for, and method of conducting evaluations under paragraph (1) and other necessary matters shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 16 (Cooperation in Services and Conclusion of Agreements with Medical Institutions)

- (1) The State or a local government may cooperate with medical institutions in executing programs for public health and medical services and providing technical support for such programs.
- (2) The Minister of Health and Welfare, a Mayor/*Do* Governor, or the head of a *Si/Gun/Gu*, when it is necessary for the promotion of a public health and medical service program, may enter into an agreement with medical institutions. *<Amended by Act No. 13098, Jan. 28, 2015>*

Article 17 (Matters to Be Observed, etc. by Institutions Providing Public Health and Medical Services)

- (1) Institutions providing public health and medical services shall provide patients with high-quality health and medical services. *<Newly Inserted by Act No. 13098, Jan. 28, 2015>*
- (2) An institution providing public health and medical services (excluding an institution under subparagraph 4 (d) of Article 2; the same shall apply hereafter in this Article) shall comply with the following principles in implementing a public health and medical services program: *<Amended by Act No. 13098, Jan. 28, 2015>*

1. Formulation of a program plan with participation of local residents;
 2. Diligent operation of programs, focusing on public interests;
 3. Transparent financial management and disclosure of accounting.
- (3) If a serious hazard to citizens' health prescribed by Presidential Decree is foreseen, the Minister of Health and Welfare may, first issue an order to institutions providing public health and medical services to take measures necessary to mitigate the occurrence or spread of the hazard. *<Amended by Act No. 13098, Jan. 28, 2015>*
- (4) The head of an institution providing public health and medical services, in receipt of an order to take measures under paragraph (3), shall not refuse such order, except in extenuating circumstances. *<Amended by Act No. 13098, Jan. 28, 2015>*

Article 18 (Revocation of Designation of Central Medical Institutions for Areas Lacking Medical Services)

- (1) If any of the following applies to any central medical institution for an area lacking medical services or a specialized public medical center, the Minister of Health and Welfare or the competent Mayor/*Do* Governor may revoke the designation thereof: *Provided*, That the Minister of Health and Welfare must revoke such designation in cases referred to in subparagraph 1: *<Amended by Act No. 13098, Jan. 28, 2015>*
1. If a central medical institution for an area lacking medical services or a specialized public medical center obtains designation by fraud or other illegal means;
 2. If a central medical institution for an area lacking medical services or a specialized public medical center wrongfully executes the budget provided by the State or a local government or executes such budget for any purpose other than the original purpose;
 3. If a central medical institution for an area lacking medical services or a specialized public medical center fails to report, in violation of Article 13 (3) or 14 (3);
 4. If a central medical institution for an area lacking medical services or a specialized public medical center falls short of the standards for designation referred to in Article 13 (6) or 14 (5);
 5. If a central medical institution for an area lacking medical services or a specialized public medical center fails to comply with an order without justifiable grounds, in violation of Article 17 (4);
 6. If any other ground specified by Ordinance of the Ministry of Health and Welfare exists.
- (2) If a medical institution's designation is revoked under paragraph (1), it shall not be re-designated as a central medical institution for an area lacking medical services or a specialized public medical center within two years from the date the designation is revoked.
- (3) When the Minister of Health and Welfare or a Mayor/*Do* Governor revoke designation under paragraph (1), he/she may fully or partially recoup subsidies paid to the relevant medical institution: *Provided*, That the Minister of Health and Welfare shall fully or partially recoup subsidies in cases referred to in paragraph (1) 1 or 2.

Article 19 (Hearings)

When the Minister of Health and Welfare or a Mayor/*Do* Governor intends to revoke the designation of a central medical institution for an area lacking medical services or a specialized public medical center under Article 18, he/she shall hold a hearing.

CHAPTER IV Education, Training, Etc.

Article 20 (Education, Training, etc.)

- (1) The Minister of Health and Welfare, a Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* may conduct

educational and training programs to improve the quality of persons engaged in public health and medical services.

- (2) The Minister of Health and Welfare or a Mayor/*Do* Governor may establish or operate educational and training centers for education and training under paragraph (1).
- (3) The Minister of Health and Welfare or a Mayor/*Do* Governor may entrust a public health and medical institution with the operation of educational and training centers under paragraph (2) and provide financial and administrative support necessary for operation thereof.
- (4) Methods and details of education and training under paragraphs (1) through (3) and eligible persons, the establishment and operation of educational and training centers, and entrustment of the operation of such centers and other matters shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 21 (Establishment and Operation of Support Centers for Public Health and Medical Services)

- (1) In order to support the following activities for public health and medical services, the Minister of Health and Welfare may establish and operate a support center for public health and medical services: *<Amended by Act No. 13982, Feb. 3, 2016; Act No. 15440, Mar. 13, 2018>*
 1. Technical and managerial improvement support to institutions providing public health and medical services;
 2. Support for development and distribution of guidelines for the public medical sector;
 3. Development and distribution of educational and training programs for human resources for public health and medical services;
 4. Collection and analysis of information and statistics on public health and medical services;
 5. Evaluation of the results of executing plans for public health and medical services under Article 9 (1);
 6. Evaluation of the results of executing public health and medical service programs under Article 15 (1);
 7. Support for exchange and cooperation among task forces to support public health and medical services under Article 22 (1);
 8. Other public health and medical service activities specified by the Minister of Health and Welfare.
- (2) The Minister of Health and Welfare shall entrust the operation of a support center for public health and medical services referred to in paragraph (1) to a corporation or organization providing public health and medical services and may fully or partially subsidize such corporation or organization for expenses incurred in operating such center.
- (3) The establishment and operation of support centers for public health and medical services, entrustment of the operation of such support centers, and other necessary matters under paragraphs (1) and (2) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 22 (Establishment and Operation of Task Force to Support Public Health and Medical Services)

- (1) In order to support activities for public health and medical services, a Mayor/*Do* Governor may organize and operate a task force to support public health and medical services.
- (2) A Mayor/*Do* Governor may entrust a public health and medical institution with the operation of a task force to support public health and medical services. In such cases, the competent Mayor/*Do* Governor may fully or partially subsidize a public health and medical institution for expenses incurred in operating such task force.
- (3) The State may provide financial and administrative support necessary to establish and operate a task force to support public health and medical services under paragraphs (1) and (2).
- (4) The establishment and operation of a task force to support public health and medical services under paragraphs (1) through (3), entrustment of the operation of such task force and other necessary matters shall be prescribed by Ordinance of the Ministry of Health and Welfare.

CHAPTER V Supplementary Provisions

Article 23 (Requests to Provide Data)

- (1) The Minister of Health and Welfare, a Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* may request an institution providing public health and medical services or a public institution to provide him/her with data necessary to formulate and execute a master plan or an implementation plan for public health and medical services and manage and evaluate public health and medical service programs.
- (2) Upon receipt of a request made under paragraph (1), the head of an institution providing public health and medical services or the head of a public institution shall comply with such request, except in extenuating circumstances.

Article 24 (Investigations and Inspections)

- (1) If the Minister of Health and Welfare, a Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* deems it necessary to issue instructions to, or supervise an institution providing public health and medical services (excluding cases referred to in subparagraph 4 (d) of Article 2; the same shall apply hereafter in this Article) with regard to a public health and medical service program, he/she may authorize any affiliated public official to investigate its operations, accounts, and property or to inspect relevant accounting books, documents, etc.
- (2) A public official who conducts an investigation or inspection under paragraph (1) shall carry an identification certificate indicating his/her authority and produce it to persons involved.

CHAPTER VI Penal Provisions

Article 25 (Fines for Negligence)

- (1) Any person who evades, refuses, or interferes with an investigation or inspection conducted under Article 24 (1) shall be punished by a fine for negligence not exceeding three million won.
- (2) Fines for negligence referred to in paragraph (1) shall be imposed and collected by the Minister of Health and Welfare or the head of each local government, as prescribed by Presidential Decree.

Addendum <Act No. 15440, Mar. 13, 2018>

This Act shall enter into force three months after the date of its promulgation.

2.8 Regional Public Health Act

Act No. 16262, Jan. 15, 2019

CHAPTER I General Provisions

Article 1 (Purpose)

The purpose of this Act is to contribute to promoting the health of local residents through effective implementation of health policies, by prescribing matters relating to the establishment and operation of regional healthcare institutions, such as public health centers, and matters necessary for the regional healthcare institutions to perform their functions effectively in alliance and cooperation with healthcare-related institutions and organizations.

Article 2 (Definitions)

The terms used in this Act are defined as follows:

1. The term “regional healthcare institution” means a public health center, a public health clinic, a public health unit, and a center for supporting healthy living established pursuant to this Act to promote the health of local residents and to prevent and control diseases;
2. The term “regional healthcare services” means services provided directly by regional healthcare institutions or via healthcare-related institutions and organizations, which include all activities conducted by health and medical services personnel (referring to health and medical services personnel as defined in subparagraph 3 of Article 3 of the Framework Act on Health and Medical Services) to promote the health of local residents and to prevent and control diseases;
3. The term “healthcare-related institution or organization” means a medical institution, a pharmacy, an organization of health and medical services personnel, and an entity that provides regional healthcare services to the general public and many specified persons in communities.

Article 3 (Responsibilities of State and Local Governments)

- (1) The State and local governments shall endeavor to conduct surveys and research into regional healthcare; to collect, manage, utilize, and protect information on regional healthcare; to train and secure regional healthcare professionals; to guarantee their employment; and to improve their quality. *<Amended by Act No. 14009, Feb. 3, 2016>*
- (2) The State and local governments shall provide technical and financial support to perform regional healthcare functions efficiently.
- (3) The State and local governments shall establish a plan to prevent disparities in the health conditions of local residents.

Article 4 (Community Health Status Surveys)

- (1) The State and local governments shall conduct a community health status survey annually to ascertain the health conditions of local residents and to identify the causes of health problems.
- (2) Methods and details of community health status surveys referred to in paragraph (1), and other necessary matters, shall be prescribed by Presidential Decree.

Article 5 (Digitalization of Regional Healthcare Affairs)

- (1) The Minister of Health and Welfare may establish and operate a regional healthcare information system in order to efficiently process various data and information necessary for regional healthcare institutions (including public health clinics as defined in subparagraph 4 of Article 2 of the Act on the Special Measures for Public Health and Medical Services in Agricultural and Fishing Villages,

Etc.; the same shall apply hereafter in this Article) to perform their functions and to digitalize the recordkeeping and management thereof.

- (2) The Minister of Health and Welfare may collect, manage, retain, and utilize (meaning performance reporting and compilation of statistics) any of the following data, which is necessary to establish and operate the regional healthcare information system pursuant to paragraph (1); and may request necessary data from related institutions and organizations. In such cases, any institution or organization in receipt of such request shall comply therewith, except in extenuating circumstances:
 1. Data about provision of regional healthcare services referred to in Article 11 (5) 5;
 2. Data about the applications for regional healthcare services, investigations, and provision of such services pursuant to Articles 19 through 21;
 3. Other data prescribed by Presidential Decree, necessary for regional healthcare institutions in performing their functions.
- (3) No one shall damage, destroy, alter, forge, leak, search, or copy any data in any regional healthcare information system without access authority or beyond the scope of authorized access.

Article 6 (Regional Healthcare Deliberative Committees)

- (1) A regional healthcare deliberative committee (hereinafter referred to as “committee”) shall be established in each Special Metropolitan City, Metropolitan City, *Do* (hereinafter referred to as “City/ *Do*”), Special Self-Governing City, Special Self-Governing Province, and *Si/Gun/Gu* (a *Gu* means an autonomous *Gu*; hereinafter referred to as “*Si/Gun/ Gu*”) to deliberate on the following matters relating to regional healthcare:
 1. Matters relating to regional healthcare status surveys, including community health status surveys;
 2. Matters relating to the formulation, implementation, and evaluations of regional healthcare plans and annual action plans;
 3. Matters that require cooperation with healthcare-related institutions and organizations, schools, workplaces, etc., to implement regional healthcare plans efficiently;
 4. Other matters necessary for promoting regional healthcare policies.
- (2) Each committee shall be comprised of no more than 20 members, including one chairperson; and the vice-head of a local government (or the vice-head prescribed by Presidential Decree if the local government has at least two vice-heads) shall serve as the chairperson: *Provided*, That the chairperson shall be prescribed by municipal ordinance, if any other committee functions as the committee pursuant to paragraph (4).
- (3) Members of a committee shall be appointed or commissioned by the head of the local government with which the committee is affiliated, from among representatives of the local residents, school health officials, occupational safety and health officials, executive officers or employees of healthcare-related institutions and organizations, and relevant public officials.
- (4) The committee may integrate with another committee, as prescribed by ordinance of a City/*Do* or a *Si/Gun/Gu*, if such other committee exists; it can adequately perform its functions; and it has members qualified as required in paragraph (3).
- (5) Except as otherwise expressly provided for in paragraphs (1) through (4), the composition and operation of committees, and other necessary matters, shall be prescribed by Presidential Decree.

CHAPTER II Formulation and Implementation of Regional Healthcare Plans

Article 7 (Formulation of Regional Healthcare Plans)

- (1) To promote the health of local residents, the Special Metropolitan City Mayor, each Metropolitan City Mayor or *Do* Governor (hereinafter referred to as “Mayor/*Do* Governor”), the Special

Self-Governing City Mayor, the Special Self-Governing Province Governor, or the head of each *Si/Gun/Gu* (the head of a *Gu* means the head of an autonomous *Gu*; hereinafter referred to as “head of a *Si/Gun/ Gu*”) shall formulate a regional healthcare plan containing the following matters every four years pursuant to paragraphs (3) and (4):

1. Measurement of demand for healthcare;
 2. A short- and long-term plan for the supply of regional healthcare services;
 3. Procurement and management of healthcare resources, including human resources, organizations, and finances;
 4. A plan to organize a system for delivery of regional healthcare services;
 5. Collection and compilation of statistics on regional healthcare.
- (2) Each Mayor/*Do* Governor or the head of a *Si/Gun/Gu* shall formulate an annual action plan each year pursuant to the regional healthcare plan formulated under paragraph (1).
- (3) The head of a *Si/Gun/Gu* (excluding the Special Self-Governing City Mayor and the Special Self-Governing Province Governor; the same shall apply hereafter in this Article) shall formulate a regional healthcare plan (including an annual action plan; the same shall apply hereafter in this Article), following deliberation thereon by the committee of the *Si/Gun/Gu* (excluding the Special Self-Governing City and the Special Self-Governing Province; the same shall apply hereafter in this Article); report the plan to the competent *Si/Gun/Gu* Council; and submit it to the competent Mayor/*Do* Governor.
- (4) The Special Self-Governing City Mayor, the Special Self-Governing Province Governor, or the Mayor/*Do* Governor who has received regional healthcare plans submitted by the heads of *Sis/Guns/Gus* under his/her jurisdiction pursuant to paragraph (3) shall formulate a regional healthcare plan of the *City/Do* (including the Special Self-Governing City and the Special Self-Governing Province; the same shall apply hereafter in this Article), following deliberation thereon by the relevant committee; report the plan to the competent *City/Do* Council; and submit it to the Minister of Health and Welfare.
- (5) Regional healthcare plans formulated under paragraphs (3) and (4) shall be correlated with the social security master plans formulated under Article 16 of the Framework Act on Social Security, the regional social security plans formulated under the Act on the Use and Provision of Social Security Benefits and Search for Eligible Beneficiaries, and the comprehensive plans for promoting national health formulated under Article 4 of the National Health Promotion Act. <Amended by Act No. 16262, Jan. 15, 2019>
- (6) The Special Self-Governing City Mayor, the Special Self-Governing Province Governor, each Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* may seek opinions about the adjustment of redundant or similar programs from healthcare-related institutions and organizations, schools, workplaces and related entities or may request information and cooperation therefrom, if deemed necessary to formulate the regional healthcare plan pursuant to paragraph (3) or (4). In such cases, any related institution in receipt of such request shall comply therewith, unless there is any compelling reason not to do so.
- (7) If deemed necessary, the Minister of Health and Welfare may recommend the Special Self-Governing City Mayor, the Special Self-Governing Province Governor, or the relevant Mayor/*Do* Governor to adjust the contents of a regional healthcare plan; and the Mayor/*Do* Governor may recommend the head of a *Si/Gun/Gu* to adjust the contents of a regional healthcare plan, respectively, as prescribed by Ordinance of the Ministry of Health and Welfare.
- (8) Except as provided in paragraphs (1) through (7), details of regional healthcare plans, methods and timing for formulating such plans, and other necessary matters shall be prescribed by Presidential Decree.

Article 8 (Implementation of Regional Healthcare Plans)

- (1) Each Mayor/*Do* Governor or the head of a *Si/Gun/Gu* shall implement a regional healthcare plan pursuant to an annual action plan formulated under Article 7 (2).
- (2) Each Mayor/*Do* Governor or the head of a *Si/Gun/Gu* may provide healthcare-related institutions and organizations, etc., with human resources, technical and financial support, if deemed necessary in implementing the regional healthcare plan.

Article 9 (Evaluation of Outcomes of Regional Healthcare Plans)

- (1) Upon the implementation of the regional healthcare plan pursuant to Article 8 (1), the Minister of Health and Welfare may evaluate the outcomes of the regional healthcare plan implemented by the Special Self-Governing City, the Special Self-Governing Province or each City/*Do*; and each Mayor/*Do* Governor may evaluate the outcomes of the regional healthcare plan implemented by each *Si/Gun/Gu* (excluding the Special Self-Governing City and the Special Self-Governing Province), respectively, as prescribed by Presidential Decree.
- (2) If necessary, the Minister of Health and Welfare or each Mayor/*Do* Governor may reflect the results of evaluations under paragraph (1) in the provision of subsidies under Article 24.

CHAPTER III Establishment and Operation of Regional Healthcare Institutions

Article 10 (Establishment of Public Health Centers)

- (1) To promote the health of local residents and to prevent and control diseases, a public health center (including a public health clinic; the same shall apply hereinafter) shall be established in each *Si/Gun/Gu* in compliance with the standard prescribed by Presidential Decree, pursuant to the ordinance of the relevant local government.
- (2) Where at least two public health centers exist in the same *Si/Gun/Gu*, one public health center may be designated to exercise general supervision over their affairs, pursuant to the ordinance of the relevant local government.

Article 11 (Functions and Services of Public Health Centers)

- (1) The functions and services of public health centers in the jurisdiction of the relevant local government are: *<Amended by Act No. 14009, Feb. 3, 2016; Act No. 16262, Jan. 15, 2019>*
 1. To create a health-oriented environment in the community;
 2. To plan for, to conduct surveys and research into, and to evaluate regional healthcare policies;
 3. To instruct, manage, and foster health and medical services personnel, health and medical institutions defined in subparagraph 4 of Article 3 of the Framework Act on Health and Medical Services, etc.; and to instruct and manage, in order to improve national health;
 4. To build a cooperative system with healthcare-related institutions, organizations, schools, workplaces, etc.;
 5. To provide the following regional healthcare services to promote the health of local residents and to prevent and control diseases:
 - (a) Promotion of national health, oral health care services, nutrition control programs, and health education;
 - (b) Prevention and control of infectious diseases;
 - (c) Maintenance and promotion of the health of mothers and infants;
 - (d) Maintenance and promotion of the medically underserved individuals, including women, senior citizens, and persons with disabilities;

- (e) Services for promoting mental health and respect for life;
 - (f) Medical diagnosis and treatment, and health check-ups for local residents and control of diseases, including chronic illnesses;
 - (g) A healthcare and health management program conducted upon visiting home, social welfare facilities, etc.
- (2) The functions and services of public health centers referred to in paragraph (1), and other necessary details, shall be prescribed by Presidential Decree.

Article 12 (Public Health Clinics)

A public health center that meets the requirements for hospitals referred to in Article 3 (2) 3 (a) of the Medical Service Act, may use “public health clinic” in its title.

Article 13 (Establishment of Public Health Units)

A local government may establish a branch of a public health center (hereinafter referred to as “public health unit”) in compliance with the standard prescribed by Presidential Decree, pursuant to the ordinance of the local government, if necessary for the public health center to provide its services.

Article 14 (Establishment of Centers for Supporting Healthy Living)

A local government may establish a center for supporting healthy living, which is focused on helping local residents prevent chronic illnesses and lead healthy lifestyles, in compliance with the standard prescribed by Presidential Decree, pursuant to the ordinance of the local government.

Article 15 (Organization of Regional Healthcare Institutions)

@Article 112 of the Local Autonomy Act shall apply to the organization of regional healthcare institutions, except as otherwise expressly prescribed by Presidential Decree.

Article 16 (Proper Placement, etc. of Professionals)

- (1) Each regional healthcare institution shall have a chief officer and human resources having licenses, qualifications, or expertise necessary for providing the services of that institution (hereinafter referred to as “professionals”).
- (2) A Mayor/*Do* Governor (including the Special Self-Governing City Mayor and the Special Self-Governing Province Governor) may permit the exchange of professionals among regional healthcare institutions pursuant to Article 30-2 (2) of the Local Public Officials Act, if necessary to place such professionals properly with the regional healthcare institutions.
- (3) The Minister of Health and Welfare and each Mayor/*Do* Governor (including the Special Self-Governing City Mayor and the Special Self-Governing Province Governor) shall conduct training and education necessary for improving the capability of professionals working at the regional healthcare institutions.
- (4) The Minister of Health and Welfare may investigate the status of placement and management of professionals working at the regional healthcare institutions; and may recommend a Mayor/*Do* Governor or the head of a *Si/Gun/Gu* to make a correction, if the placement and/or management of any professional is found improper.
- (5) Criteria for placement of, and qualification criteria for appointment of, professionals referred to in paragraph (1); professionals who should receive the training and education under paragraph (3), durations, evaluations, and handling of evaluation outcomes; and other necessary matters, shall be prescribed by Presidential Decree.

Article 16-2 (Public Officials in Exclusive Charge of Visiting Health Management)

- (1) To handle visiting health management programs prescribed in Article 11 (1) 5 (g), a regional

healthcare institution may have professional personnel prescribed by Ordinance of the Ministry of Health and Welfare, as public officials in exclusive charge of visiting health management.

- (2) The State may fully or partially subsidize the placement of public officials in exclusive charge of visiting health management under paragraph (1).

[This Article Newly Inserted by Act No. 16262, Jan. 15, 2019]

Article 17 (Facilities, Equipment, etc. at Regional Health and Medical Institutions)

- (1) A regional healthcare institution shall be equipped with facilities, apparatus, etc. that comply with the standards prescribed by Ordinance of the Ministry of Health and Welfare.
- (2) The head of a regional healthcare institution shall display the mark prescribed by Ordinance of the Ministry of Health and Welfare to assist the local residents to easily identify and conveniently use the institution.

Article 18 (Use of Facilities)

A regional healthcare institution may permit a doctor, a dentist, an oriental medical doctor, a pharmacist, etc. to use its facilities to conduct a healthcare-related experiment or testing, or may conduct an experiment or testing at the request of other individuals.

CHAPTER IV Provision of Regional Healthcare Services

Article 19 (Filing Applications for Regional Healthcare Services)

- (1) A person who needs a service prescribed by Ordinance of the Ministry of Health and Welfare (hereinafter referred to as “individual eligible for services”) among regional healthcare services, any of his/her relatives, or any person related to him/her, may file an application for the provision of regional healthcare services (hereinafter referred to as “provision of services”) with the competent head of the *Si/Gun/Gu*.
- (2) Upon receipt of an application filed under paragraph (1), the competent head of the *Si/Gun/Gu* shall give notice to the individual eligible for services, any of his/her lineal relatives within the first degree of consanguinity, and his/her spouse (hereinafter referred to as “person who has a legal duty to support”) of the following matters relating to data or information he/she intends to investigate or accept pursuant to Article 20, and obtain such individual’s and person’s consent to the collection of the data and information:
1. Legal basis, purposes, and scope of use;
 2. Methods of use;
 3. Retention period and method of destruction.
- (3) An applicant for services may request the competent head of the *Si/Gun/Gu* to return or delete the data or information that such head has investigated or the applicant has submitted, when withdrawing his/her application for services. In such cases, the competent head of the *Si/Gun/Gu* in receipt of such request shall comply therewith, except in extenuating circumstances.
- (4) Filing applications for services, withdrawing applications, methods of giving notice, methods of obtaining consent under paragraphs (1) through (3), and other necessary matters, shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 20 (Investigations Based upon Applications)

- (1) Upon receipt of an application for the provision of services under Article 19 (1), the head of a *Si/Gun/Gu* shall investigate the earnings, assets, etc. of the individual eligible for services and the person who has a legal duty to support such individual.

- (2) To obtain data necessary to conduct an investigation under paragraph (1), the head of a *Si/Gun/Gu* may request the individual eligible for services or the person who has a legal duty to support such individual to submit necessary data or information.
- (3) Investigations under paragraph (1) shall be conducted in accordance with Article 33-3 of the Social Welfare Services Act.

Article 21 (Decision to Provide Services and Provision thereof)

- (1) After conducting an investigation under Article 20, the head of a *Si/Gun/Gu* shall determine whether to provide services, considering the status of budgets and other factors, and shall give written or electronic notice of his/her decision to the applicant.
- (2) The head of a *Si/Gun/Gu* who has determined to provide services for an individual eligible for services shall formulate a plan including the duration for the provision of such services, and provide regional healthcare services according to such plan.

Article 22 (Destruction of Information)

- (1) No head of a *Si/Gun/Gu* shall retain information about any person, other than individuals eligible for services, which he/she has investigated or accepted pursuant to Article 20, for more than five years. In such cases, the head of a *Si/Gun/Gu* shall, without delay, destroy such information upon the expiration of its retention period.
- (2) Where information referred to in paragraph (1) is collected in the regional healthcare information system or the information system established under Article 6-2 of the Social Welfare Services Act, the head of a *Si/Gun/Gu* may request the Minister of Health and Welfare to destroy such information. In such cases, the Minister of Health and Welfare shall, without delay, destroy the relevant information.

Article 23 (Reporting Health Checkups)

- (1) Any of the persons referred to in the subparagraphs of Article 27 (1) of the Medical Service Act, who intends to engage in activities affecting the local residents' health, such as health checkups or medical outreach services for many local residents (hereinafter referred to as "health checkups, etc."), shall file a report with the head of the public health center having jurisdiction over the area in which he/she intends to conduct health checkups, etc., as prescribed by Ordinance of the Ministry of Health and Welfare.
- (2) A medical institution shall file a report pursuant to paragraph (1) if it intends to conduct health checkups, etc. for many local residents at a place other than the premises of the medical institution, on any of the grounds provided for in the subparagraphs of Article 33 (1) of the Medical Service Act.
- (3) Upon receipt of a report under paragraph (1) or (2), the head of a public health center shall accept such report after reviewing the details thereof, if it conforms to this Act. <Newly Inserted by Act No. 16262, Jan. 15, 2019>

CHAPTER V Supplementary Provisions

Article 24 (Subsidization)

- (1) The State and a *City/Do* may provide subsidies to cover part of the expenses incurred in establishing and operating regional healthcare institutions and in implementing regional healthcare plans.
- (2) When subsidies are provided under paragraph (1), expenses incurred in establishing regional healthcare institutions and incidental expenses shall be covered by up to 2/3 thereof; and expenses incurred in implementing regional healthcare plans shall be covered by up to 1/2 thereof.

Article 25 (Charges, etc.)

- (1) Regional healthcare institutions may collect charges or medical fees from persons who use their facilities, who request experiments or testing, or who receive medical examinations and treatment.
- (2) The charges and medical fees collected under paragraph (1) shall be set by ordinance of the relevant local government, in compliance with the standards prescribed by Ordinance of the Ministry of Health and Welfare.

Article 26 (Accounting of Regional Health and Medical Institutions)

Regional healthcare institutions may use the income from the charges and medical fees they collect, directly for revenue-substitute expenses provided for in Article 26 of the Local Accounting Act; and may simplify their accounting affairs, as prescribed by the rules of the relevant local government.
<Amended by Act No. 14197, May 29, 2016>

Article 27 (Reporting, etc.)

The Minister of Health and Welfare may require local governments to report matters relating to the establishment and operation of regional healthcare institutions; or may require subordinate public officials to guide and supervise the regional healthcare institutions, by conducting fact-finding surveys, as prescribed by Ordinance of the Ministry of Health and Welfare.

Article 28 (Prohibition against Disclosure of Personal Information)

No person who is performing or has ever performed the affairs related to the functions of regional healthcare institutions (including public health clinics as defined in subparagraph 4 of Article 2 of the Act on the Special Measures for Public Health and Medical Services in Agricultural and Fishing Villages, Etc.), nor any person who is establishing and operating or has ever established and operated the regional healthcare information system (including a person who is performing or has ever performed the official duties under entrustment or as an agent pursuant to Article 30 (2) or (4)), shall use any of the following information that has come to his/her knowledge in the course of performing the affairs, for any purpose other than the performance of such affairs; nor provide or divulge it to any third person:

1. Medical information on an individual or family that has come to the knowledge of health and medical services personnel in the course of medical treatment (including health checkups);
2. The following information investigated or submitted pursuant to Article 20:
 - (a) Financial information (referring to financial information as defined in Article 21 (3) 1 of the National Basic Living Security Act; the same shall apply hereinafter);
 - (b) Credit information or insurance information (referring to credit information and insurance information as defined in Article 21 (3) 2 and 3 of the National Basic Living Security Act; the same shall apply hereinafter);
3. Personal information (referring to personal information as defined in subparagraph 1 of Article 2 of the Personal Information Protection Act; the same shall apply hereinafter), other than the information referred to in subparagraphs 1 and 2.

Article 29 (Prohibition against Use of Same Titles)

No entity, other than a public health center, public health clinic, public health unit, and a center for supporting healthy living established under this Act, shall use any of the phrases “public health center,” “public health clinic,” “public health unit,” or “center for supporting healthy living,” in its title.

Article 30 (Delegation, etc. of Authority)

- (1) The Minister of Health and Welfare may delegate part of his/her authority under this Act to each Mayor/Do Governor or the head of a *Si/Gun/Gu*, as prescribed by Presidential Decree.
- (2) Each Mayor/Do Governor or the head of a *Si/Gun/Gu* may partially entrust the official duties

necessary to perform the functions of regional healthcare institutions under this Act to a healthcare-related institution or organization; or may authorize medical personnel as defined in Article 2 of the Medical Service Act, to perform some official duties as an agent, as prescribed by Presidential Decree.

- (3) Each Mayor/*Do* Governor or the head of a *Si/Gun/Gu* may provide subsidies to cover part of the expenses incurred in performing the official duties entrusted under paragraph (2); and may reimburse actual expenses incurred by medical personnel performing some official duties as an agent as authorized under paragraph (2).
- (4) The Minister of Health and Welfare may authorize the exclusive organization established under Article 6-3 of the Social Welfare Services Act, to perform the official duties relating to the establishment and operation of the regional healthcare information system as an agent.
- (5) The Minister of Health and Welfare may provide a subsidy for the exclusive organization authorized to perform the official duties as an agent under paragraph (4), to cover expenses incurred therein, within budgetary limits.

Article 31 (Special Cases concerning the Medical Service Act)

“Public health clinic” established under Article 12 shall be construed as “hospital” referred to in Article 3 (2) 3 (a) of the Medical Service Act, “dental clinic” referred to in Article 3 (2) 1 (b), or “oriental medical clinic” referred to in Article 3 (2) 1 (c); and “public health center”, “public health unit”, or “center for supporting healthy living”, as “medical clinic”, “dental clinic”, or “oriental medical clinic” referred to in Article 3 (2) 3, respectively.

CHAPTER VI Penalty Provisions

Article 32 (Penalty Provisions)

- (1) Any of the following persons shall be punished by imprisonment with labor for not more than five years, or by a fine not exceeding fifty million won: *<Amended by Act No. 14895, Sep. 19, 2017>*
 1. A person who damages, destroys, alters, forges, or divulges any data in the regional healthcare information system without access authority or beyond the scope of authorized access in violation of Article 5 (3);
 2. A person who uses, provides, or divulges information prescribed in subparagraphs 1, 2, or 3 of Article 28 in violation of the same Article, or a person who receives such information in bad faith, for profit or for any wrongful purpose.
- (2) Deleted. *<by Act No. 14895, Sep. 19, 2017>*
- (3) Any person who searches or copies any data in the regional healthcare information system without access authority or beyond the scope of authorized access in violation of Article 5 (3) shall be punished by imprisonment with labor for not more than three years, or by a fine not exceeding thirty million won. *<Amended by Act No. 14895, Sep. 19, 2017>*
 1. and 2. Deleted. *<by Act No. 14895, Sep. 19, 2017>*

Article 33 (Joint Penalty Provisions)

Where the representative of a corporation, or an agent, employee, or other servant of the corporation or an individual commits any of the violations described in Article 32 in conducting the business affairs of the corporation or individual, the corporation or individual shall, in addition to punishment of the violators accordingly, be subject to a fine prescribed in the relevant Article: *Provided*, That the foregoing shall not apply where the corporation or individual has not been negligent in giving due attention and supervision over the business affairs to prevent such violations.

Article 34 (Administrative Fines)

- (1) Any of the following persons shall be subject to an administrative fine not exceeding three million won:
1. A person who conducts a health checkup, etc. without filing a report required under Article 23, or upon filing a false report;
 2. A person who uses any of the titles listed in Article 29.
- (2) The head of a *Si/Gun/Gu* shall impose and levy administrative fines provided for in paragraph (1), as prescribed by ordinance of the *Si/Gun/Gu*.

Addendum <Act No. 16262, Jan. 15, 2019>

This Act shall enter into force six months after the date of its promulgation.

2.9 Act on The Special Measures for Public Health and Medical Services in Agricultural and Fishing Villages

Act No. 14183, May 29, 2016

CHAPTER I General Provisions

Article 1 (Purpose)

The purpose of this Act is to ensure that the people receive uniform medical care services and to contribute to improving the health of the people by providing efficient public health care services to residents in medically underserved areas, such as agricultural and fishing villages.

[This Article Wholly Amended by Act No. 11514, Oct. 22, 2012]

Article 2 (Definitions)

The terms used in this Act shall be defined as follows:

1. The term "public health doctor" means a person who is a doctor, dentist or traditional Korean medicine doctor enlisted as a public health doctor pursuant to Article 34 (1) of the Military Service Act to be engaged in providing public health services, who is ordered by the Minister of Health and Welfare to provide public health services;
2. The term "public health services" means public health and medical services provided by any institution or facility under the subparagraphs of Article 5-2 (1);
3. The term "public official exclusively responsible for public health care services" means a person who works with a public health clinic to conduct medical practice under Article 19;
4. The term "public health clinic" means a public health and medical care facility established and operated by the head of a *Si/Gun* to require a public official exclusively responsible for public health care services to conduct medical practice in a medically underserved area where no doctor is assigned and it is expected to be difficult to continuously assign doctors.

[This Article Wholly Amended by Act No. 11514, Oct. 22, 2012]

CHAPTER II Public Health Doctors

Article 3 (Status of Public Health Doctors)

(1) A public health doctor shall be a public official in a fixed term position pursuant to Article 26-5 of the State Public Officials Act. *<Amended by Act No. 11530, Dec. 11, 2012>*

(2) Where a public health doctor is ordered by the Minister of Health and Welfare to be engaged in providing public health services pursuant to Article 5 (1), he/she shall be deemed appointed as a public official in a fixed term position pursuant to Article 26-5 of the State Public Officials Act. *<Amended by Act No. 11530, Dec. 11, 2012>*

[This Article Wholly Amended by Act No. 11514, Oct. 22, 2012]

Article 3-2 (Grounds for Disqualification)

No person who falls under any of the subparagraphs of Article 33 of the State Public Officials Act shall be appointed as a public health doctor.

[This Article Wholly Amended by Act No. 11514, Oct. 22, 2012]

Article 4 (Notification of List of Public Health Doctors)

The Commissioner of the Military Manpower Administration shall notify the Minister of Health and Welfare of a list of doctors, dentists or traditional Korean medicine doctors enlisted pursuant to Article 34 (1) of the Military Service Act.

[This Article Wholly Amended by Act No. 11514, Oct. 22, 2012]

Article 5 (Orders to Be Engaged in Public Health Services, etc.)

- (1) When the Minister of Health and Welfare receives a list of doctors, dentists or traditional Korean medicine doctors under Article 4, he/she shall, without delay, order the relevant doctors, dentists or traditional Korean medicine doctors to be engaged in providing public health care services, specifying an area, institution or facility where they are to provide health care services, and notify the Mayor of the relevant Metropolitan City, the Mayor of the relevant Special Self-Governing City, the Governor of the relevant *Do*, the Governor of the relevant Special Self-Governing Province (hereinafter referred to as the "Mayor/*Do* Governor"), or the head of the relevant institution to which they are to be assigned (referring to the head of the institution to which the Minister of Health and Welfare has assigned directly; hereinafter the same shall apply) and the Commissioner of the Military Manpower Administration of such assignment.
- (2) Where the Mayor/*Do* Governor receives a list of public health doctors under paragraph (1), he/she shall, without delay, call up the relevant public health doctors and conduct on-the-job training necessary for the performance of public health services, and then designate a place, institution or facility where they are to provide health care services, and report the results thereof to the Minister of Health and Welfare without delay.
- (3) If deemed especially necessary for public health and medical services, the Minister of Health and Welfare may conduct on-the-job training directly.
- (4) The period of on-the-job training under paragraphs (2) and (3) shall be included in the period of compulsory service under Article 7 (1).
- (5) Where the Mayor/*Do* Governor designates a place, institution or facility where public health doctors are to provide health care services pursuant to paragraph (2), he/she shall have public health doctors assigned to public health clinics in *Guns* or branches of public health clinics in *Eups/Myeons* in preference to other areas.
- (6) Matters necessary for orders to be engaged in public health care services under paragraph (1) and on-the-job training under paragraphs (2) and (3) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Wholly Amended by Act No. 11514, Oct. 22, 2012]

Article 5-2 (Institutions and Facilities to Which Public Health Doctors are Assigned)

- (1) Institutions or facilities to which the Minister of Health and Welfare or the Mayor/*Do* Governor may assign public health doctors pursuant to Article 5 (1) and (2) shall be as follows:
 1. A public health clinic or a branch thereof;
 2. A hospital established and operated by the State, a local government or public institution, which is designated by the Minister of Health and Welfare (hereafter in this Article referred to as "public hospital");
 3. A research institute for public health and medical service;
 4. An institution or organization that provides entrusted public health services;
 5. An institution or facility prescribed by Presidential Decree, which is required to assign public health doctors in the execution of policies on public health and medical services.
- (2) A public health clinic and public hospital under paragraph (1) shall be limited to an institution or facility in an area other than a Special Metropolitan City or a Metropolitan City (excluding an area of

Gun in the jurisdiction of a Metropolitan City).

[This Article Wholly Amended by Act No. 11514, Oct. 22, 2012]

Article 6 (Change of Place of Work, etc.)

- (1) If deemed necessary, the Minister of Health and Welfare may change a place, institution or facility in which a public health doctor is to provide public health care services: *Provided*, That in cases of the change of a place of work within the same Metropolitan City, Special Self-Governing City, *Do*, or Special Self-Governing Province (hereinafter referred to as "City/*Do*") or in the same *Si/Gun/Gu* (referring to an autonomous *Gu*; hereinafter the same shall apply), the relevant Mayor/*Do* Governor or the head of the relevant *Si/Gun/Gu* (referring to the head of an autonomous *Gu*: hereinafter the same shall apply) may change a place of work.
- (2) The Mayor/*Do* Governor or the head of a *Si/Gun/Gu* who changes a place, institution or facility in which a public health doctor is to provide public health care services pursuant to the proviso to paragraph (1) shall report the result thereof to the Minister of Health and Welfare without delay.

[This Article Wholly Amended by Act No. 11514, Oct. 22, 2012]

Article 6-2 (Dispatched Service)

- (1) Where the Minister of Health and Welfare deems human resources for medical service are urgently required due to the outbreak of a contagious disease or the occurrence of a disaster, he/she may dispatch public health doctors to another place, institution or facility to have them provide medical care services therein: *Provided*, That dispatching within the same City/*Do* or the same *Si/Gun/Gu* shall be conducted by the relevant Mayor/*Do* Governor or the head of the relevant *Si/Gun/Gu*.
- (2) The Mayor/*Do* Governor or the head of a *Si/Gun/Gu* who orders the dispatch of public health doctors in accordance with the proviso to paragraph (1) shall report the result to the Minister of Health and Welfare without delay.
- (3) Dispatched service under paragraph (1) may also be ordered for a place of work other than an assigned institution or facility under Article 5-2. In such cases, the Mayor/*Do* Governor or the head of a *Si/Gun/Gu* shall obtain approval therefor from the Minister of Health and Welfare.

[This Article Wholly Amended by Act No. 11514, Oct. 22, 2012]

Article 7 (Period of Compulsory Service)

- (1) The mandatory service period of a public health doctor shall be three years in addition to the period of call-up for military education that he/she receives pursuant to Article 55 of the Military Service Act. *<Amended by Act No. 14183, May 29, 2016>*
- (2) A public health doctor who has completed the mandatory service period under paragraph (1) shall be deemed to have completed his/her service as social work personnel in accordance with Article 34 (2) of the Military Service Act. *<Amended by Act No. 11849, Jun. 4, 2013>*
- (3) The Minister of Health and Welfare shall notify the Commissioner of the Military Manpower Administration of a list of public health doctors who have completed the mandatory service period under paragraph (1).

[This Article Wholly Amended by Act No. 11514, Oct. 22, 2012]

Article 8 (Prohibition of Absence from Post without Leave)

- (1) No public health doctor shall be absent from his/her post during office hours without leave of the Mayor of the relevant Special Self-Governing City, the Governor of the relevant Special Self-Governing Province, the head of the relevant *Si/Gun/Gu* or the head of the relevant institution to which he/she is assigned.
- (2) In any of the following cases, the Minister of Health and Welfare, the Mayor/*Do* Governor or the head of a *Si/Gun/Gu* may order public health doctors in his/her jurisdiction not to be absent from

their place of work without leave:

1. Where they are needed to treat emergency patients in the relevant jurisdiction;
 2. Where they are needed to protect the health of residents in the following areas where there is no medical institution under Article 3 of the Medical Service Act (hereinafter referred to as "medical institution") or no medical institution that provides medical services at night or on holidays:
 - (a) Islands under Article 2 of the Islands Development Promotion Act;
 - (b) A border area under subparagraph 1 of Article 2 of the Border Area Support Act;
 3. Where many cases of disease have occurred due to a contagious disease, disasters, etc., and any other reason corresponding thereto has arisen.
- (3) The bounds of a place of work under paragraph (2) shall be prescribed by Ordinance of the Ministry of Health and Welfare.
- (4) Where the Mayor/*Do* Governor or the head of a *Si/Gun/Gu* orders public health doctors not to be absent from their place of work without leave pursuant to paragraph (2), he/she shall report such action to the Minister of Health and Welfare without delay.

[This Article Wholly Amended by Act No. 11514, Oct. 22, 2012]

Article 9 (Service of Public Health Doctors)

- (1) A public health doctor shall engage in providing public health services in good faith during the period of his/her compulsory service and shall not engage in any business other than public health services assigned pursuant to Article 5 (1).
- (2) Where a public health doctor is absent from his/her post or his/her place of work without leave for not more than seven days in total during the period of his/her service, in violation of orders under Article 8 (1) and (2), the Minister of Health and Welfare may order him/her to serve for the period extended by five times the number of days of such absence.
- (3) Where a public health doctor engages in any business other than public health services, in violation of paragraph (1), the Minister of Health and Welfare may order him/her to serve for the period extended by five times the number of days during which he/she engages in such business.
- (4) Where a public health doctor fails to serve for at least one month for reasons other than his/her duties, such as a long-term hospitalization or medical treatment, the Minister of Health and Welfare may order him/her to serve for the period extended to the extent of such period.
- (5) Where the Minister of Health and Welfare orders a public health doctor to serve for the extended period of compulsory service in accordance with paragraphs (2) through (4), he/she shall first give the relevant public health doctor the opportunity to state his/her opinion.
- (6) Where a public health doctor receives an order to serve for the extended period of his/her service from the Minister of Health and Welfare in accordance with paragraphs (2) through (4), the period of a contract of employment shall be deemed extended.
- (7) Where the enlistment of a public health doctor has been revoked pursuant to Article 35 (2) and (4) of the Military Service Act or his/her residency training has been permitted pursuant to Article 12 (1), a contract of employment shall be deemed cancelled.
- (8) Except as provided for in this Act, the State Public Officials Act shall apply to the service of public health doctors.

[This Article Wholly Amended by Act No. 11514, Oct. 22, 2012]

Article 9-2 (Loss and Deprivation of Status)

- (1) Where a public health doctor falls under any of the following, he/she shall lose his/her status of public health doctor:
 1. Where he/she falls under any subparagraph of Article 33 of the State Public Officials Act: *Provided*, That where he/she falls under subparagraph 5 of Article 33 of the said Act, the proviso to Article 69 of the said Act shall apply;

2. Where he/she is disqualified for a doctor, dentist or traditional Korean medicine doctor, or his/her qualification is suspended.
- (2) Where a public health doctor falls under any of the following, the Minister of Health and Welfare may deprive him/her of his/her status by his/her official authority: *Provided*, That where he/she falls under subparagraph 1 or 2, he/she shall deprive him/her of his/her status:
 1. Where he/she fails to receive on-the-job training under Article 5 (2) and (3) without justifiable grounds;
 2. Where he/she is absent from his/her post without leave for at least eight days in total without justifiable grounds during the period of his/her compulsory service, in violation of Article 8 (1), or absent from his/her place of work without leave for at least eight days in total without justifiable grounds during the period of his/her compulsory service, in violation of an order under Article 8 (2);
 3. Where he/she is unable to return to his/her duties or to fulfill his/her duties within one year due to mental or physical disabilities.

[This Article Wholly Amended by Act No. 11514, Oct. 22, 2012]

Article 10 (Notification of Action on Status)

Where a public health doctor loses or is deprived of his/her status in accordance with Article 9-2, the Minister of Health and Welfare shall notify the Commissioner of the Military Manpower Administration of the list thereof without delay.

[This Article Wholly Amended by Act No. 11514, Oct. 22, 2012]

Article 11 (Remuneration, etc.)

- (1) A public health doctor shall be remunerated for his/her service within the limits of remuneration to military personnel: *Provided*, That a public health doctor assigned to a privately-operated medical institution established pursuant to Article 3 of the Medical Service Act among institutions or facilities referred to in Article 5-2 (1) 5 shall be remunerated for his/her service by the head of the relevant privately-operated medical institution.
- (2) The head of an institution or facility to which a public health doctor is assigned shall grant allowances and pay travel expenses, etc. incurred for the performance of his/her duties, as prescribed by the Minister of Health and Welfare: *Provided*, That he/she may restrict allowances to a public health doctor who does not work in good faith, as prescribed by the Minister of Health and Welfare.
<Amended by Act No. 13989, Feb. 3, 2016>
- (3) The standards for remuneration under paragraph (1) shall be prescribed by Presidential Decree.

[This Article Wholly Amended by Act No. 11514, Oct. 22, 2012]

Article 12 (Residency Training of Public Health Doctors)

- (1) The Minister of Health and Welfare may permit a public health doctor to undergo residency training within the extent of one year.
- (2) The period of residency training under paragraph (1) shall not be included in the period of compulsory service under Article 7 (1).
- (3) Matters necessary for public health doctors' application for permission to undergo residency training shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Wholly Amended by Act No. 11514, Oct. 22, 2012]

Article 13 Deleted. <by Act No. 6156, Jan. 12, 2000>

Article 14 (Supervision of Service)

Regarding the service of public health doctors, the Mayor of a Special Self-Governing City, the

Governor of a Special Self-Governing Province, the head of a *Si/Gun/Gu* or the head of an institution to which public health doctors are assigned shall direct and supervise the public health doctors serving in his/her jurisdiction or the relevant institution.

[This Article Wholly Amended by Act No. 11514, Oct. 22, 2012]

Article 14-2 Deleted. *<by Act No. 12359, Jan. 28, 2014>*

Article 14-3 (Assessment of Appropriateness of Assignment of Public Health Doctors)

- (1) The Minister of Health and Welfare may assess the appropriateness of assignment of public health doctors to ensure the effective utilization thereof, and reflect the result thereof in their assignment in the following year.
- (2) The Minister of Health and Welfare may entrust assessment referred to in paragraph (1) to related specialized institutions. *<Amended by Act No. 12359, Jan. 28, 2014>*
- (3) Where necessary for the assessment of appropriateness of assignment of public health doctors under paragraph (1), the Minister of Health and Welfare may conduct a field examination or hear opinions from relevant persons.

[This Article Wholly Amended by Act No. 11514, Oct. 22, 2012]

CHAPTER III Public Health Clinics and Public Officials Exclusively Responsible for Public Health Care Services

Article 15 (Establishment and Operation of Public Health Clinics)

- (1) The head of a *Si* (referring to the head of a *Si* in the composite urban-rural community form, and limited to where he/she establishes and operates a public health clinic in an *Eup/Myeon* area) or the head of a *Gun* shall establish and operate public health clinics to provide public health care services for residents in medically underserved areas: *Provided*, That in islands in the jurisdiction of the *Si/Gu*, the head of the relevant *Si/Gu* may establish and operate a public health clinic, and where the administrative district of a public health clinic in a *Gun* area is included in a *Si/Gu* area due to a change of the administrative district, etc., the head of the relevant *Si/Gu* may continue to operate such public health clinic, as determined by the Minister of Health and Welfare.
- (2) The head of a public health clinic and necessary employees shall be assigned to any public health clinic, and a public official exclusively responsible for public health care services shall be appointed as the head of the public health clinic.
- (3) The standards for the establishment of public health clinics shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Wholly Amended by Act No. 11514, Oct. 22, 2012]

Article 16 (Qualification for Public Officials Exclusively Responsible for Public Health Care Services)

- (1) A public official exclusively responsible for public health care services shall be a person who is a licensed nurse or midwife who has received on-the-job training for at least 24 weeks conducted by the Minister of Health and Welfare.
- (2) Matters necessary for on-the-job training under paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Wholly Amended by Act No. 11514, Oct. 22, 2012]

Article 17 (Status and Employment of Public Officials Exclusively Responsible for Public Health Care Services)

- (1) A public official exclusively responsible for public health care services shall be a local public official, and the Mayor of a Special Self-Governing City, the Governor of a Special Self-Governing Province, or the head of a *Si/Gun/Gu* shall employ him/her and designate his/her place of work.
- (2) Where a public official exclusively responsible for public health care services falls under any of the following, the Mayor of a Special Self-Governing City, the Governor of a Special Self-Governing Province, or the head of a *Si/Gun/Gu* may discipline such public official exclusively responsible for public health care services:
 1. Where he/she conducts medical practice outside his/her designated place of work without justifiable grounds;
 2. Where he/she conducts medical practice beyond the scope under Article 19;
 3. Where he/she is absent from the jurisdiction without leave for at least seven days, in violation of an order not to be absent from the jurisdiction without leave under Article 20.
- (3) The Local Public Officials Act shall apply to procedures for and methods of discipline under paragraph (2) and other necessary matters.

[This Article Wholly Amended by Act No. 11514, Oct. 22, 2012]

Article 18 (Refresher Training of Public Officials Exclusively Responsible for Public Health Care Services)

- (1) Where the Minister of Health and Welfare deems it necessary for the improvement of the quality of public officials exclusively responsible for public health care services, he/she may order them to receive refresher training.
- (2) The period and details of refresher training under paragraph (1) and other necessary matters shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Wholly Amended by Act No. 11514, Oct. 22, 2012]

Article 19 (Scope of Medical Practice of Public Officials Exclusively Responsible for Public Health Care Services)

Notwithstanding Article 27 of the Medical Service Act, a public official for exclusively responsible for public health care services may conduct a slight medical practice prescribed by Presidential Decree in a medically underserved area designated as his/her place of work.

[This Article Wholly Amended by Act No. 11514, Oct. 22, 2012]

Article 20 (Prohibition of Public Officials Exclusively Responsible for Public Health Care Services from Being Absent from Jurisdiction without Leave)

- (1) In any of the following cases, the Mayor of a Special Self-Governing City, the Governor of a Special Self-Governing Province, or the head of a *Si/Gun/Gu* may order public officials exclusively responsible for public health care services in his/her jurisdiction not to be absent from the relevant jurisdiction without leave:
 1. Where they are needed to treat emergency patients in the relevant jurisdiction;
 2. Where they are needed to protect the health of residents in the following areas where there is no medical institution under Article 3 of the Medical Service Act in the relevant jurisdiction:
 - (a) Islands under Article 2 of the Island Development Promotion Act;
 - (b) A border area under subparagraph 1 of Article 2 of the Special Act on Support for Border Area;
 3. Where many cases of disease have occurred due to a contagious disease, accident, etc., or any other reason corresponding thereto has arisen.

- (2) The bounds of jurisdiction under paragraph (1) shall be prescribed by Municipal Ordinance, and detailed matters concerning the prohibition of absence from the jurisdiction without leave shall be prescribed by Ordinance of the Ministry of Health and Welfare.
- (3) Where a public official resides in an official residence of the relevant public health clinic, the Mayor of a Special Self-Governing City, the Governor of a Special Self-Governing Province, or the head of a *Si/Gun/Gu* may subsidize administrative expenses for the official residence within budgetary limits.

[This Article Wholly Amended by Act No. 11514, Oct. 22, 2012]

Article 21 (Public Health Clinic Operation Council)

- (1) In order to operate a public health clinic effectively, a public health clinic operation council formed by residents shall be established in each area where a public health clinic is established.
- (2) A public health clinic operation council shall conduct the following affairs:
 1. Assistance in the operation of a public health clinic;
 2. Proposals concerning the operation of a public health clinic.
- (3) Matters necessary for the organization and operation of a public health clinic operation council shall be prescribed by municipal ordinance of the relevant local government.

[This Article Wholly Amended by Act No. 11514, Oct. 22, 2012]

Article 22 (Subsidization and Reduction of and Exemption from Taxes)

- (1) The State, a *Do*, and a Special Self-Governing Province shall subsidize some of expenses incurred in the establishment of a public health clinic and incidental expenses thereto to a *Si* (referring to a *Si* in the composite urban-rural community form, and limited to where the head of a *Si* establishes and operates a public health clinic in an *Eup/Myeon* area)/*Gun*. In such cases, government subsidies shall not exceed 2/3 of expenses incurred in the establishment of a public health clinic and incidental expenses thereto, and *Do* subsidies shall not exceed 1/3 of expenses incurred in the establishment thereof and incidental expenses thereto.
- (2) The State or a local government may subsidize some of expenses incurred in the operation of a privately-operated health and medical institution entrusted with part of public health services in accordance with Article 26 (2). In such cases, the limits of subsidization shall be prescribed by Ordinance of the Ministry of Health and Welfare.
- (3) The State or a local government may provide taxation support to institutions under paragraph (2), as prescribed by statutes related to taxation, such as the Restriction of Special Taxation Act and the Local Tax Act.

[This Article Wholly Amended by Act No. 11514, Oct. 22, 2012]

Article 23 (Direction and Supervision)

- (1) The Mayor of a Special Self-Governing City, the Governor of a Special Self-governing Province, or the head of a *Si/Gun/Gu* shall direct and supervise public health care services of public health clinics under his/her jurisdiction.
- (2) The Mayor of a Special Self-Governing City, the Governor of a Special Self-Governing Province, or the head of a *Si/Gun/Gu* may have the head of the relevant public health clinic or the head of a branch thereof direct and supervise medical practice of public officials exclusively responsible for public health care services.

[This Article Wholly Amended by Act No. 11514, Oct. 22, 2012]

Article 24 (Service of Public Officials Exclusively Responsible for Public Health Care Services)

Except as provided for in this Act, the Local Public Officials Act shall apply to the service of public officials exclusively responsible for public health care services.

[This Article Wholly Amended by Act No. 11514, Oct. 22, 2012]

Article 25 (Medical Fees)

The standards for medical fees of a public health clinic shall be as determined by the Minister of Health and Welfare.

[This Article Wholly Amended by Act No. 11514, Oct. 22, 2012]

CHAPTER IV Supplementary Provisions

Article 26 (Delegation of Authority or Entrustment of Affairs)

- (1) The Minister of Health and Welfare, the Mayor/*Do* Governor or the head of a *Si/Gun/Gu* may delegate or entrust part of his/her authority under this Act to the Mayor/*Do* Governor, the head of a *Si/Gun/Gu*, the head of an institution to which a public health doctor is assigned or the head of a public health clinic, as prescribed by Presidential Decree.
- (2) The Minister of Health and Welfare may entrust some of public health services to a privately-operated health care facility, as prescribed by Presidential Decree.

[This Article Wholly Amended by Act No. 11514, Oct. 22, 2012]

Addenda <Act No. 14183, May 29, 2016>

Article 1 (Enforcement Date)

This Act shall enter into force six months after its promulgation. (Proviso Omitted.)

Articles 2 through 5 Omitted.

2.10 Medical Service Act

Act No. 17069, Mar. 4, 2020

CHAPTER I General Provisions

Article 1 (Purpose)

The purpose of this Act is to provide for the matters necessary for medical services to people in order to ensure that people can enjoy benefits of high-quality medical treatment, thereby protecting and improving public health.

Article 2 (Medical Personnel)

- (1) The term "medical personnel" in this Act refers to a physician, a dentist, an oriental medical doctor, a midwife or a nurse who holds a license granted by the Minister of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*
- (2) Medical personnel has the mission to improve public health and help people enjoy healthy life by performing any of the following missions by type: *<Amended by Act No. 13658, Dec. 29, 2015; Act No. 16375, Apr. 23, 2019>*
 1. A physician's mission is to administer medical treatment and provide guidance for health;
 2. A dentist's mission is to administer dental treatment and provide guidance for oral hygiene;
 3. An oriental medical doctor's mission is to administer oriental medical treatment and provide guidance for health based on oriental medicine;
 4. A midwife's mission is to assist childbirth, take care of pregnant women and newborn babies and provide guidance for their health;
 5. A nurse has the mission to perform the following duties:
 - (a) Observation of a patient at his/her request for nursing, collection of data, making judgment on nursing, and nursing for convalescence;
 - (b) Provision of assistance in medical treatment under the guidance of a physician, dentist, or oriental medical doctor;
 - (c) Provision of education and consultation to a person in need of nursing, planning of health promotion activities and implementation thereof, and other health services prescribed by Presidential Decree;
 - (d) Guidance on the assistance in the duties referred to in items (a) through (c) performed by an assistant nurse referred to in Article 80.

Article 3 (Medical Institutions)

- (1) The term "medical institution" in this Act means a place where medical personnel provide medical services or midwifery services (hereinafter referred to as "medical service") to the general public or multiple specific people.
- (2) Medical institutions shall be classified as follows: *<Amended by Act No. 9386, Jan. 30, 2009; Act No. 10785, Jun. 7, 2011; Act No. 14224, May 29, 2016; Act No. 16375, Apr. 23, 2019>*
 1. A clinic-level medical institution: A medical institution in which a doctor, dentist or oriental medical doctor provides medical services primarily to outpatients and which are classified as follows:
 - (a) A medical clinic;
 - (b) A dental clinic;
 - (c) An oriental medical clinic;

2. A midwifery clinic: A medical institution in which a midwife assists childbirth and provides health services, education and consultation to pregnant women and newborn babies;

3. A hospital-level medical institution: A medical institution in which doctors, dentists or oriental medical doctors provide medical services primarily to inpatients and which are classified as follows:

(a) A hospital;

(b) A dental hospital;

(c) An oriental medical hospital;

(d) A long-term care hospital (including a mental hospital among mental medical institutions referred to in subparagraph 5 of Article 3 of the Act on the Improvement of Mental Health and the Support for Welfare Services for Mental Patients, and a medical institution meeting the requirements prescribed in Article 3-2 among medical rehabilitation facilities referred to in Article 58 (1) 4 of the Act on Welfare of Persons with Disabilities; hereinafter the same shall apply);

(e) A general hospital.

(3) The Minister of Health and Welfare may determine and publicly notify standard services to be rendered by each type of medical institutions as set forth in paragraph (2) 1 through 3, when deemed necessary for health and medical policies. <Amended by Act No. 9386, Jan. 30, 2009; Act No. 9932, Jan. 18, 2010>

(4) through (8) Deleted. <by Act No. 9386, Jan. 30, 2009>

#Article 3 (Medical Institutions)

(1) The term "medical institution" in this Act means a place where medical personnel provide medical services or midwifery services (hereinafter referred to as "medical service") to the general public or multiple specific people.

(2) Medical institutions shall be classified as follows: <Amended by Act No. 9386, Jan. 30, 2009; Act No. 10785, Jun. 7, 2011; Act No. 14224, May 29, 2016; Act No. 16375, Apr. 23, 2019; Act No. 17069, Mar. 4, 2020>

1. A clinic-level medical institution: A medical institution in which a doctor, dentist or oriental medical doctor provides medical services primarily to outpatients and which are classified as follows:

(a) A medical clinic;

(b) A dental clinic;

(c) An oriental medical clinic;

2. A midwifery clinic: A medical institution in which a midwife assists childbirth and provides health services, education and consultation to pregnant women and newborn babies;

3. A hospital-level medical institution: A medical institution in which doctors, dentists or oriental medical doctors provide medical services primarily to inpatients and which are classified as follows:

(a) A hospital;

(b) A dental hospital;

(c) An oriental medical hospital;

(d) A long-term care hospital (including a medical institution meeting the requirements prescribed in Article 3-2 among medical rehabilitation facilities referred to in Article 58 (1) 4 of the Act on Welfare of Persons with Disabilities; hereinafter the same shall apply);

(e) A mental health hospital;

(f) A general hospital.

(3) The Minister of Health and Welfare may determine and publicly notify standard services to be rendered by each type of medical institutions as set forth in paragraph (2) 1 through 3, when deemed

necessary for health and medical policies. *<Amended by Act No. 9386, Jan. 30, 2009; Act No. 9932, Jan. 18, 2010>*

(4) through (8) Deleted. *<by Act No. 9386, Jan. 30, 2009>*

<<Enforcement Date: Mar. 5, 2021>>

Article 3-2 (Hospitals)

A hospital, dental hospital, oriental medical hospital and long-term care hospital (hereinafter referred to as "hospital, etc") shall have at least 30 beds (only applicable to a hospital and oriental medical hospital) or beds for long-term care (only applicable to a long-term care hospital, and refer to the beds for providing medical services to inpatients in need of long-term care).

[This Article Newly Inserted by Act No. 9386, Jan. 30, 2009]

Article 3-3 (General Hospitals)

(1) A general hospital shall satisfy the following requirements: *<Amended by Act No. 11005, Aug. 4, 2011>*

1. A general hospital shall have at least 100 beds;
2. A general hospital with at least 100, but not more than 300 beds shall have at least seven specialized departments including three specialized departments among internal medicine, general surgery, pediatrics, and obstetrics and gynecology, plus diagnostic radiology, anesthesia and pain medicine, and diagnostic laboratory medicine or pathology, and shall have medical specialists exclusively dedicated to each and every specialized department;
3. A general hospital with more than 300 beds shall have at least nine specialized departments including internal medicine, general surgery, pediatrics, obstetrics and gynecology, diagnostic radiology, anesthesia and pain medicine, diagnostic laboratory medicine or pathology, neuropsychiatry, and dental surgery, and shall have medical specialists exclusively dedicated to each and every specialized department.

(2) A general hospital may establish and operate other specialized departments, if necessary, in addition to the specialized departments under paragraph (1) 2 or 3 (hereafter referred to as "essential specialized departments" in this paragraph). In such cases, medical specialists not exclusively dedicated to the relevant medical institution may be assigned to the specialized departments, other than the essential specialized departments.

[This Article Newly Inserted by Act No. 9386, Jan. 30, 2009]

Article 3-4 (Designation of Tertiary Hospitals)

(1) The Minister of Health and Welfare may designate a general hospital providing highly specialized medical services for treating serious diseases as a tertiary hospital among general hospitals satisfying the following requirements: *<Amended by Act No. 9932, Jan. 18, 2010>*

1. To have at least 20 specialized departments prescribed by Ordinance of the Ministry of Health and Welfare, and have medical specialists exclusively dedicated to each and every specialized department;
2. To be an institution which trains a person who intends to become a medical specialist under Article 77 (1);
3. To have human resources, facilities, equipment, etc. prescribed by Ordinance of the Ministry of Health and Welfare;
4. To meet the standards prescribed by Ordinance of the Ministry of Health and Welfare for the patient distribution in each diagnosis-related group.

(2) When designating a tertiary hospital under paragraph (1), the Minister of Health and Welfare shall evaluate whether the requirements under each subparagraph of paragraph (1) are satisfied, expertise and any other relevant factors. *<Amended by Act No. 9932, Jan. 18, 2010>*

- (3) The Minister of Health and Welfare may make re-designation or revoke the designation of a tertiary hospital under paragraph (1) after conducting an evaluation under paragraph (2) every three years. *<Amended by Act No. 9932, Jan. 18, 2010>*
- (4) The Minister of Health and Welfare may entrust a relevant specialized institution or association with evaluation work under paragraphs (2) and (3). *<Amended by Act No. 9932, Jan. 18, 2010>*
- (5) Necessary matters concerning standards for and procedures of designating or re-designating tertiary hospitals, procedures of entrusting evaluation work, etc. shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 9932, Jan. 18, 2010>*
[This Article Newly Inserted by Act No. 9386, Jan. 30, 2009]

Article 3-5 (Designation of Specialized Hospitals)

- (1) The Minister of Health and Welfare may designate a hospital providing highly specialized medical services in a specific medical department for treating specific diseases as a specialized hospital among hospital-level medical institutions. *<Amended by Act No. 9932, Jan. 18, 2010>*
- (2) A specialized hospital prescribed in paragraph (1) shall satisfy the following requirements: *<Amended by Act No. 9932, Jan. 18, 2010>*
 - 1. The proportion, etc. of patients with each specific disease and of each medical department shall meet the standards prescribed by Ordinance of the Ministry of Health and Welfare;
 - 2. A specialized hospital shall have medical departments, the number of which is at least that prescribed by Ordinance of the Ministry of Health and Welfare, and have medical specialists exclusively dedicated to each specialized department.
- (3) When designating a specialized hospital under paragraph (1), the Minister of Health and Welfare shall evaluate whether the requirements under each subparagraph of paragraph (2) are satisfied, difficulty of medical treatment and any other relevant factors. *<Amended by Act No. 9932, Jan. 18, 2010>*
- (4) Where a medical institution has been designated as a specialized hospital prescribed in paragraph (1), the Minister of Health and Welfare may evaluate the medical institution pursuant to paragraph (3) every three years, and then re-designate the medical institution as a specialized hospital. *<Amended by Act No. 9932, Jan. 18, 2010; Act No. 13107, Jan. 28, 2015>*
- (5) Where a specialized hospital designated or re-designated under paragraph (1) or (4) falls under any of the following cases, the Minister of Health and Welfare may revoke the designation or re-designation: *Provided*, That in cases falling under subparagraph 1, the designation or re-designation shall be revoked: *<Newly Inserted by Act No. 13107, Jan. 28, 2015>*
 - 1. Where a specialized hospital has been designated or re-designated by fraud or other unlawful means;
 - 2. Where a specialized hospital seeks the revocation of the designation or re-designation;
 - 3. Where a specialized hospital has failed to meet the requirements set forth in the subparagraphs of paragraph (2) through evaluation under paragraph (4).
- (6) The Minister of Health and Welfare may entrust a relevant specialized institution or organization with evaluation duties prescribed in paragraphs (3) and (4). *<Amended by Act No. 9932, Jan. 18, 2010; Act No. 13107, Jan. 28, 2015>*
- (7) Matters necessary for the designation of specialized hospitals, standards and procedures for re-designation thereof, procedures for entrusting evaluation duties, etc. shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 9932, Jan. 18, 2010; Act No. 13107, Jan. 28, 2015>*

[This Article Newly Inserted by Act No. 9386, Jan. 30, 2009]

CHAPTER II Medical Personnel

SECTION 1 Qualification and Licenses

Article 4 (Responsibilities of Medical Personnel and Heads of Medical Institutions)

- (1) Medical personnel or the head of a medical institution shall endeavor to provide patients with the best medical services by improving the quality of medical treatment, preventing hazards of hospital infections and developing medical technology. *<Amended by Act No. 11252, Feb. 1, 2012>*
- (2) No medical personnel shall establish nor operate a medical institution under the name of another medical personnel or another medical corporation, etc. *<Newly Inserted by Act No. 11252, Feb. 1, 2012; Act No. 16555, Aug. 27, 2019>*
- (3) The head of a medical institution shall post a notice of matters prescribed by Ordinance of the Ministry of Health and Welfare, such as a patient's rights referred to in Articles 6, 12 and 13 of the Framework Act on Health and Medical Services in the medical institution in a patient-friendly manner. In such cases, methods and places for posting the notice and other matters necessary therefor shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Newly Inserted by Act No. 11252, Feb. 1, 2012>*
- (4) No medical personnel shall lease his/her license certificate issued under Article 5 (referring to a physician, dentist, or oriental medical doctor), Article 6 (referring to a midwife) or Article 7 (referring to a nurse) to other persons. *<Newly Inserted by Act No. 13658, Dec. 29, 2015>*
- (5) The head of a medical institution shall instruct and supervise medical personnel, students prescribed in Article 27 (1) 3 who perform medical practices under the proviso, with the exception of the subparagraphs to Article 27 (1), assistant nurses prescribed in Article 80, and medical service technologists prescribed in Article 2 of the Medical Service Technologists Act to wear their name tags when they are inside a medical institution as prescribed by Presidential Decree so that patients and their guardians can identify persons in charge of medical practices: *Provided*, That they may be allowed not to wear their name tags when they are in medical emergency situation or in an operating room or they are not providing medical practices, or in other cases prescribed by Presidential Decree. *<Newly Inserted by Act No. 14220, May 29, 2016>*
- (6) No medical personnel shall reuse any disposable medical supplies for injection (referring to a fluid injection set including an injection needle, a syringe, a tube for connection with fluid container, which are used for the injection of medicine, blood, fat, etc. to or for collection of them from a human body as medical supplies that are manufactured for a single usage or that should be used for a single patient for a single medical practice, and other medical supplies corresponding thereto; hereinafter the same shall apply) after using them once. *<Newly Inserted by Act No. 14220, May 29, 2016>*

#Article 4 (Duties of Medical Personnel and Heads of Medical Institutions)

- (1) Medical personnel or the head of a medical institution shall endeavor to provide patients with the best medical services by improving the quality of medical treatment, preventing hazards of medical care-related infections (referring to infections that develop in patients, guardians of patients, medical personnel, persons working for medical institutions, etc. within medical institutions; hereinafter the same shall apply) and developing medical technology. *<Amended by Act No. 11252, Feb. 1, 2012; Act No. 17069, Mar. 4, 2020>*
- (2) No medical personnel shall establish nor operate a medical institution under the name of another medical personnel or another medical corporation, etc. *<Newly Inserted by Act No. 11252, Feb. 1, 2012; Act No. 16555, Aug. 27, 2019>*
- (3) The head of a medical institution shall post a notice of matters prescribed by Ordinance of the Ministry of Health and Welfare, such as a patient's rights referred to in Articles 6, 12, and 13 of the

Framework Act on Health and Medical Services in the medical institution in a patient-friendly manner. In such cases, methods and places for posting the notice and other matters necessary therefor shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Newly Inserted by Act No. 11252, Feb. 1, 2012>

- (4) Deleted. <by Act No. 17069, Mar. 4, 2020>
- (5) The head of a medical institution shall instruct and supervise medical personnel, students prescribed in Article 27 (1) 3 who perform medical practices under the proviso, with the exception of the subparagraphs, to Article 27 (1), assistant nurses prescribed in Article 80, and medical service technologists prescribed in Article 2 of the Medical Service Technologists Act to wear their name tags when they are inside a medical institution, as prescribed by Presidential Decree so that patients and their guardians can identify persons in charge of medical practices: *Provided*, That they may be allowed not to wear their name tags when they are in medical emergency situation or in an operating room or they are not providing medical practices, or in other cases prescribed by Presidential Decree. <Newly Inserted by Act No. 14220, May 29, 2016>
- (6) No medical personnel shall reuse any disposable medical instruments (referring to medical instruments manufactured for a single usage or that should be used for a single patient for a single medical practice, which are prescribed by Ordinance of the Ministry of Health and Welfare; hereinafter the same shall apply) after using them once. <Newly Inserted by Act No. 14220, May 29, 2016; Act No. 17069, Mar. 4, 2020>

Article 4-2 (Provision of Integrated Nursing and Caring Service)

- (1) Integrated nursing and caring services are hospitalization services provided comprehensively by nurses, assistant nurses referred to in Article 80 and other care-supporting personnel (hereafter referred to as "personnel for integrated nursing and caring services" in this Article) to inpatients prescribed by Ordinance of the Ministry of Health and Welfare without requiring their guardians, etc. to stay in patients' rooms.
- (2) Each hospital-level medical institution prescribed by Ordinance of the Ministry of Health and Welfare shall endeavor to provide integrated nursing and caring services.
- (3) Each hospital-level medical institution that provides integrated nursing and caring services prescribed in paragraph (2) (hereafter referred to as "institution providing integrate nursing and caring services" in this Article) shall comply with the standards prescribed by Ordinance of the Ministry of Health and Welfare for human resources, facilities, operation, etc.
- (4) Each hospital-level medical institution prescribed by Ordinance of the Ministry of Health and Welfare among public health and medical institutions defined in subparagraph 3 of Article 2 of the Public Health and Medical Services Act shall provide integrated nursing and caring services. In such cases, the State and local governments may subsidize all or part of the required expenses.
- (5) Each institution providing integrated nursing and caring services shall strive for safety management, such as restrictions on stay of guardians, etc. in patients' rooms and preparation of standards for visit to patients.
- (6) Each institution providing integrated nursing and caring services shall provide necessary support for better working environments and working conditions to personnel for integrated nursing and caring services.
- (7) The State and local governments shall formulate policies necessary for the provision and expansion of integrated nursing and caring services, the smooth supply and demand of personnel for integrated nursing and caring services and the improvement of working environments; and provide support required therefor.

[This Article Newly Inserted by Act No. 13658, Dec. 29, 2015]

Article 4-3 (Prohibition of Medical Personnel from Lending Licenses)

- (1) No medical personnel shall lend his/her license obtained pursuant to Articles 5 (referring to physicians, dentists and oriental medical doctors), 6 (referring to midwives) and 7 (referring to nurses) to other persons.
- (2) No person shall borrow a license granted pursuant to Articles 5 through 7 nor arrange the borrowing of such license.

[This Article Newly Inserted by Act No. 17069, Mar. 4, 2020]

Article 5 (Licenses for Physicians, Dentists or Oriental Medical Doctors)

- (1) A person who intends to become a physician, dentist or oriental medical doctor shall meet any of the following qualifications and be licensed by the Minister of Health and Welfare after passing the relevant national examination under Article 9: *<Amended by Act No. 9932, Jan. 18, 2010; Act No. 11252, Feb. 1, 2012; Act No. 16555, Aug. 27, 2019>*
 1. A bachelor's degree holder who has graduated from a university or college with a major in medical science, dentistry or oriental medical science which is certified by an accrediting institution (hereinafter referred to as "accrediting institution") under Article 11-2 of the Higher Education Act (hereinafter referred to as "certification by an accrediting institution");
 2. A master's or a doctor's degree holder who has graduated from a professional graduate school with a major in medical science, dentistry or oriental medical science which is certified by an accrediting institution;
 3. A person who has graduated from a foreign school equivalent to any one set forth in subparagraph 1 or 2 (referring to schools that meet the accreditation standards determined and publicly notified by the Minister of Health and Welfare); has been licensed as a physician, dentist or oriental medical doctor from the competent foreign authority; and has passed the relevant preliminary exam under Article 9.
- (2) A person who is expected to receive the relevant degree within six months from a university, college or professional graduate school with a major in medical science, dentistry or oriental medical science which is certified by an accrediting institution shall be deemed qualified as prescribed by paragraph (1) 1 and 2: *Provided*, That a license shall be granted only after graduating and receiving such degree at the expected date of graduation.
- (3) Notwithstanding paragraph (1), a person who entered a university, college, or professional graduate school with a major in medical science, dentistry, or oriental medical science which is certified by an accrediting institution as at the time of admission; has graduated from the relevant university, college, or professional graduate school; and has received the relevant degree therefrom, shall be deemed a person falling under subparagraph 1 or 2 of the same paragraph. *<Newly Inserted by Act No. 11252, Feb. 1, 2012>*

[This Article Wholly Amended by Act No. 9135, Oct. 14, 2008]

Article 6 (Licenses for Midwives)

A person who intends to become a midwife shall meet the following qualifications and be licensed by the Minister of Health and Welfare after passing the national examination for midwife under Article 9: *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 16555, Aug. 27, 2019>*

1. A holder of a nurse license, who has finished one-year midwifery training course at a medical institution recognized by the Minister of Health and Welfare;
2. A holder of a midwife license issued by the competent foreign authority (referring to licenses that meet the accreditation standards determined and publicly notified by the Minister of Health and Welfare).

Article 7 (Licenses for Nurses)

- (1) A person who intends to become a nurse shall meet any of the following qualifications and be licensed by the Minister of Health and Welfare after passing the national examination for nurses prescribed in Article 9: *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11252, Feb. 1, 2012; Act No. 16555, Aug. 27, 2019>*
1. A person who has graduated from a university, college, or junior college (including a former vocational school or nursing school under the old system) with a major in nursing which is certified by an accrediting institution;
 2. A person who has graduate from a foreign school which falls under subparagraph 1 (referring to schools that meet the accreditation standards determined and publicly notified by the Minister of Health and Welfare) and has been licensed by the competent foreign authority.
- (2) Notwithstanding paragraph (1), a person who entered a university, college, or junior college with a major in nursing science which is certified by an accrediting institution as at the time of admission; has graduated from the relevant university, college, or junior college; and has received the relevant degree therefrom, shall be deemed a person falling under subparagraph 1 of the same paragraph. *<Newly Inserted by Act No. 11252, Feb. 1, 2012>*

Article 8 (Grounds for Disqualification)

None of the following persons shall be qualified as medical personnel: *<Amended by Act No. 8651, Oct. 17, 2007; Act No. 15540, Mar. 27, 2018; Act No. 15716, Aug. 14, 2018>*

1. A mentally ill person under subparagraph 1 of Article 3 of the Act on the Improvement of Mental Health and the Support for Welfare Services for Mental Patients: *Provided*, That this shall not apply to a person who is recognized by a medical specialist as qualified as medical personnel;
2. An addict to narcotics, marijuana or any psychotropic drugs;
3. A person under adult guardianship or person under limited guardianship;
4. A person in whose case his/her imprisonment without labor or greater punishment declared by a court for violation of this Act, or Articles 233, 234, 269, 270, 317 (1), or 347 (applicable only to cases of deceiving a patient or an institution or organization responsible for payment of medical expenses by claiming medical expenses by false) of the Criminal Act, the Act on Special Measures for the Control of Public Health Crimes, the Regional Public Health Act, the Prevention of Acquired Immunodeficiency Syndrome Act, the Emergency Medical Service Act, the Act on the Special Measures for Health and Medical Services in Agricultural and Fishing Villages, the Anatomy and Preservation of Corpses Act, the Blood Management Act, the Narcotics Control Act, the Pharmaceutical Affairs Act, the Mother and Child Health Act, or any other statutes or regulations governing medical affairs specified by Presidential Decree was not completely executed or the none-execution of such sentence has not become final.

Article 9 (National Examinations)

- (1) The Minister of Health and Welfare shall annually hold national examinations for physicians, dentists, oriental medical doctors, midwives or nurses and preliminary examinations for physicians, dentists or oriental medical doctors (hereinafter referred to as "national examinations, etc"). *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*
- (2) The Minister of Health and Welfare may entrust the management of national examinations, etc. to the Korea Health Personnel Licensing Examination Institute established under the Korea Health Personnel Licensing Examination Institute Act, as prescribed by Presidential Decree. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 13367, Jun. 22, 2015>*
- (3) The Minister of Health and Welfare may, when entrusting the management of the national examinations, etc. pursuant to paragraph (2), subsidize the budget necessary for such management.

<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

(4) Matters necessary for the national examinations, etc. shall be prescribed by Presidential Decree.

Article 10 (Restrictions on Eligibility for Examinations)

- (1) No person who falls under any of the subparagraphs of Article 8 shall be eligible for taking any national examination, etc. *<Amended by Act No. 9386, Jan. 30, 2009>*
- (2) A person who takes any national examination, etc. by wrongful means or who commits cheating shall be suspended from taking the examination, or his/her passing the examination shall be declared null and void.
- (3) The Minister of Health and Welfare may restrict a person who has been suspended from taking an examination, or whose passing an examination has been declared null and void pursuant to paragraph (2) from taking the national examination, etc. administered under this Act three times consecutively thereafter as prescribed by Presidential Decree, taking into account the grounds for the restriction, severity of the violation, etc. *<Amended by Act No. 14438, Dec. 20, 2016>*

Article 11 (Conditions and Registration of Licenses)

- (1) If deemed necessary for policies on public health and medical services, the Minister of Health and Welfare may grant a license under any of Articles 5 through 7 on condition that the successful applicant work in specially designated areas or engage in specially designated duties for a predetermined period for up to three years. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*
- (2) The Minister of Health and Welfare shall, whenever granting a license under Articles 5 through 7, enter the details of the license in a register and then issue a license certificate. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*
- (3) A register referred to in paragraph (2) shall be prepared and kept by each type of medical personnel.
- (4) Necessary matters concerning the registration of licenses and license certificates shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

Article 12 (Protection of Medical Technology)

- (1) Except as otherwise provided for in this Act or any other statutes or regulations, no one may interfere with medical practices, including medical treatment, midwifery and nursing (hereinafter referred to as "medical practices").
- (2) No person may destroy or damage, or aid or abet a third party to destroy or damage any medical facility, instrument, medicine or any other equipment in a medical institution, or occupy a medical institution to interfere with its medical services.
- (3) No person may attack or threaten any medical personnel, assistant nurse referred to in Article 80, medical technician defined in Article 2 of the Medical Technicians, etc. Act or any person who receives medical treatment at a place where medical practices are performed. *<Newly Inserted by Act No. 14220, May 29, 2016>*

Article 13 (Prohibition of Seizure of Medical Instruments or Materials)

No instruments, medicines and other facilities and materials necessary for medical services provided by medical personnel shall be subject to seizure.

Article 14 (Preferential Supply of Instruments)

- (1) Each medical personnel shall be preferentially supplied with instruments, medicines and other facilities and materials necessary for medical practices.
- (2) Each medical personnel shall be preferentially supplied with all materials, efforts or means of

transportation incidental to the rights set forth in paragraph (1).

Article 15 (Prohibition against Refusal to Provide Medical Services)

- (1) Medical personnel or the founder of a medical institution shall not, upon receiving a request for medical treatment or assistance in childbirth, refuse such request without good causes. *<Amended by Act No. 14438, Dec. 20, 2016>*
- (2) Medical personnel shall give the best treatment to any emergency patient, in compliance with the Emergency Medical Service Act.

Article 16 (Handling of Medical Laundry)

- (1) No person, other than medical personnel, medical institutions or persons who have reported their services to a Special Self-Governing City Mayor, a Special Self-Governing Province Governor or the head of a *Si/Gun/Gu*, (referring to the head of an autonomous *Gu*; hereinafter the same shall apply), is allowed to handle laundry from any medical institution. *<Amended by Act No. 13107, Jan. 28, 2015>*
- (2) Each person who handles laundry prescribed in paragraph (1) shall keep, carry and dispose of it in good sanitary conditions, as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*
- (3) The founder of a medical institution and a person who has reported medical laundry services prescribed in paragraph (1) (hereafter referred to as "medical laundry service provider" in this Article) shall educate persons engaged in medical laundry services prescribed in paragraph (1) to prevent infection as prescribed by Ordinance of the Ministry of Health and Welfare and shall record and maintain the results of such education. *<Newly Inserted by Act No. 13107, Jan. 28, 2015>*
- (4) A medial laundry service provider who intends to change any reported matters prescribed by Ordinance of the Ministry of Health and Welfare, or to suspend (for at least one month), discontinue or resume his/her services shall file a report thereon with a Special Self-Governing City Mayor, a Special Self-Governing Province Governor, or the head of a *Si/Gun/Gu*, as prescribed by Ordinance of the Ministry of Health and Welfare. *<Newly Inserted by Act No. 13107, Jan. 28, 2015>*
- (5) Matters necessary for the standards for facilities and equipment for handling medical laundry prescribed in paragraph (1), procedures for reporting medical laundry services, guidance and supervision and other matters necessary for management and control shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

Article 17 (Medical Certificates)

- (1) No person shall prepare and issue a medical certificate, postmortem examination report or certificate to a patient (where a patient has died or fallen into unconsciousness, referring to one of his/her lineal ascendants or descendants, his/her spouse, or one of his/her spouse's lineal ascendants; and where a patient has died or fallen into unconsciousness and none of his/her ascendants or descendants, his/her spouse, or lineal ascendants of his/her spouse exist, referring to one of his/her brothers or sisters) or to a public prosecutor in a district public prosecutors' office (limited to a postmortem examination report) who administers an autopsy pursuant to Article 222 (1) of the Criminal Procedure Act, unless he/she is a physician, dentist or oriental medical doctor in medical services who has directly conducted diagnosis or postmortem examination of the patient (hereafter only in cases of a postmortem examination report, including physicians who work for any government agency responsible for autopsies in this paragraph): *Provided*, That such certificate or report may be issued for a patient without any other medical treatment, if the patient has died within 48 hours after his/her last medical treatment, while if the physician, dentist or oriental medical doctor who has directly diagnosed a patient or conducted a postmortem examination of the dead patient is unable to

issue such certificate or report due to extenuating circumstances, another physician, dentist, or oriental medical doctor who works for the same medical institution may issue such certificate or report based on the medical records of the patient. *<Amended by Act No. 9386, Jan. 30, 2009; Act No. 14220, May 29, 2016; Act No. 16555, Aug. 27, 2019>*

- (2) No person shall issue a certificate of birth, death or stillbirth unless he/she is a physician, oriental medical doctor or midwife in medical services who has directly assisted the childbirth: *Provided*, That if a physician, oriental medical doctor or midwife who has assisted childbirth is unable to issue such certificate due to extenuating circumstances, another physician, oriental medical doctor or midwife who works for the same medical institution may issue the certificate based on medical records, etc.
- (3) No physician, dentist or oriental medical doctor shall, upon receiving a request for issuing a medical certificate, a report of postmortem examination or a certificate concerning the person whom he/she examined, refuse such request without good causes.
- (4) No physician, oriental medical doctor or midwife shall, upon receiving a request for issuing a certificate of birth, death or stillbirth in relation to his/her assistance in childbirth, refuse such request without good causes.
- (5) The forms of a medical certificate or certificate prescribed in paragraphs (1) through (4), matters to be stated therein, and other necessary matters shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Newly Inserted by Act No. 8559, Jul. 27, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

Article 17-2 (Prescriptions)

- (1) No person shall prepare a prescription (including prescriptions prepared by physicians or dentists in form of electronic documents with digital signatures prescribed by the Digital Signature Act (hereinafter referred to as "online prescription"); hereinafter the same shall apply) and shall issue or send such prescription (limited to online prescriptions; hereafter the same shall apply in this Article) to a patient unless he/she is a physician, dentist, or oriental medical doctor in medical services who has directly diagnosed the patient; and no person shall receive a prescription prepared by a physician, dentist or oriental medical doctor unless he/she is a patient directly diagnosed by the physician, dentist, or oriental medical doctor.
- (2) Notwithstanding paragraph (1), if a physician, dentist or oriental medical doctor falls under any of the following cases and recognizes the safety of the relevant patient and medicines, he/she may issue or send a prescription to a patient's lineal ascendant or descendant, spouse, spouse's lineal ascendant, siblings, or person prescribed by Presidential Decree, such as a person working for a medical and welfare institution for senior citizens prescribed in Article 34 of the Welfare of Senior Citizens Act (hereafter referred to as "vicarious recipient" in this Article), and a vicarious recipient may receive the prescription on behalf of the patient:
 1. Where a patient falls into unconsciousness;
 2. Where a patient has a substantial difficulty in moving and the same prescription is made for the same disease for a long time.
- (3) Matters necessary for methods, procedures, etc. for issuing a prescription shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 16555, Aug. 27, 2019]

Article 18 (Preparation and Issuance of Prescriptions)

- (1) Each physician or dentist shall, if considered necessary to administer medicine to a patient, issue a prescription or send an online prescription to a patient, as prescribed by Ordinance of the Ministry of Health and Welfare, except in cases where he/she is permitted to directly prepare medicine pursuant to the Pharmaceutical Affairs Act. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

- (2) A form of prescription prescribed in paragraph (1), mandatory descriptions therein, the preservation thereof and other necessary matters shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>
- (3) No person may trace, divulge, alter or mutilate personal information stored in an online prescription without good causes.
- (4) A physician or dentist who has issued a prescription (including an oriental medical doctor who has issued a medical prescription) prescribed in paragraph (1) shall promptly respond to an inquiry from a pharmacist or oriental pharmacist prescribed in Article 26 (2) of the Pharmaceutical Affairs Act: *Provided*, That where he/she is unable to respond to the inquiry from the pharmacist or oriental pharmacist due to any of the following causes, he/she shall respond to the inquiry immediately after such cause ceases to exist: <Newly Inserted by Act No. 8559, Jul. 27, 2007>
1. Where he/she is treating an emergency patient under subparagraph 1 of Article 2 of the Emergency Medical Service Act;
 2. Where he/she is performing a surgery or treating a patient;
 3. Where he/she is unable to respond to the inquiry due to extenuating circumstances.
- (5) Where a physician, dentist or oriental medical doctor directly prepares medicine pursuant to the Pharmaceutical Affairs Act and delivers the medicine to a patient, he/she shall state the name of the patent, usage, dosage, and other matters prescribed by Ordinance of the Ministry of Health and Welfare on the container or package of the medicine: *Provided*, That this shall not apply to cases prescribed by Ordinance of the Ministry of Health and Welfare as cases where it is difficult to state such matters on the container or package of the medicine taking into account the status of medical treatment, such as medical emergency situation, or the nature of the medicine. <Newly Inserted by Act No. 14220, May 29, 2016>

Article 18-2 (Verification of Drug Information)

- (1) Where a physician or dentist issues a prescription prescribed in Article 18 or directly prepares medicine prescribed in Article 23 (4) of the Pharmaceutical Affairs Act, he/she shall verify the following information (hereinafter referred to as "drug information") in advance:
1. Whether the medicine contains the same ingredients with the medicine that has been prescribed or administered to a patient;
 2. Whether the medicine contains any ingredients publicly notified by the Minister of Food and Drug Safety to prohibit joint use or use by a specific age group, pregnant women, etc.;
 3. Other information prescribed by Ordinance of the Ministry of Health and Welfare.
- (2) Notwithstanding paragraph (1), a physician or dentist need not verify drug information where there is any justifiable ground which makes it impracticable to verify it, such as in a medical emergency situation.
- (3) Methods and procedures for verifying drug information prescribed in paragraph (1), justifiable grounds which make it impracticable to verify drug information prescribed in paragraph (2), etc. shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 13658, Dec. 29, 2015]

Article 19 (Prohibition against Divulgence of Confidential Information)

- (1) Except as otherwise expressly provided for in this Act or other statutes or regulations, no medical personnel nor person working for a medical institution shall divulge or disclose personal information he/she becomes aware of in the course of performing medical treatment, assistance in childbirth, nursing; preparing and issuing medical certificates, reports on postmortem examination or certificates prescribed in Article 17; preparing and issuing prescriptions prescribed in Article 18; inspecting medical records and issuing transcripts thereof prescribed in Article 21; keeping medical records, etc. prescribed in Article 22 (2); and preparing, keeping and managing electronic medical

records prescribed in Article 23. <Amended by Act No. 14220, May 29, 2016>

- (2) No person who engages or has engaged in affairs pertaining to the accreditation of a medical institution prescribed in Article 58 (2) shall divulge any information learned in the course of performing such affairs to any other person or use it for a wrongful purpose. <Newly Inserted by Act No. 14220, May 29, 2016>

Article 20 (Prohibition of Fetal Gender Prediction, etc.)

- (1) No medical personnel shall diagnose or examine a pregnant woman for the purpose of predicting the gender of a fetus nor help any other person to commit such act for the same purpose.
- (2) No medical personnel shall inform any pregnant woman, her family member or any other person of the gender of a fetus he/she becomes aware of in the course of diagnosing or examining the fetus or pregnant woman before 32 weeks of pregnancy. <Amended by Act No. 9906, Dec. 31, 2009>

Article 21 (Inspection of Records)

- (1) A patient may request medical personnel, the head of a medical institution or a person working for a medical institution to inspect or copy all or part of records on the patient (where there is any addition or revision to the records, including all of the records added or revised as well as the original records; hereinafter the same shall apply) for confirmation. In such cases, no medical personnel, head of the medical institution nor person working for the medical institution shall refuse such request, except in extenuating circumstances. <Newly Inserted by Act No. 14438, Dec. 20, 2016; No. 15540, Mar. 27, 2018>
- (2) No medical personnel, the head of a medical institution nor a person working for a medical institution shall allow a third party to a patient to inspect or copy the details of the patient's record for confirmation. <Amended by Act No. 9386, Jan. 30, 2009; Act No. 14438, Dec. 20, 2016>
- (3) Notwithstanding paragraph (2), a medical personnel, the head of a medical institution or a person working for a medical institution shall allow the inspection or copy of the details of a patient's record for confirmation in any of the following cases: *Provided*, That where a physician, dentist or oriental medical doctor deems it necessary to treat a patient, this shall not apply: <Amended by Act No. 9386, Jan. 30, 2009; Act No. 9932, Jan. 18, 2010; Act No. 10565, Apr. 7, 2011; Act No. 11141, Dec. 31, 2011; Act No. 11252, Feb. 1, 2012; Act No. 13605, Dec. 22, 2015; Act No. 13658, Dec. 29, 2015; Act No. 14183, May 29, 2016; Act No. 14220, May 29, 2016; Act No. 14438, Dec. 20, 2016; Act No. 15522, Mar. 20, 2018; Act No. 15716, Aug. 14, 2018>
1. Where a spouse, lineal ascendant or descendant, or brother or sister (limited to cases where none of the spouse, ascendants or descendants of a patient, or lineal ascendants of his/her spouse exist) of a patient or a lineal ascendant of the spouse makes a request after satisfying the requirements prescribed by Ordinance of the Ministry of Health and Welfare, such as presenting the consent of the patient in question, a certificate proving kinship and any other documents;
 2. Where the agent designated by a patient makes a request after satisfying the requirements prescribed by Ordinance of the Ministry of Health and Welfare, such as presenting the consent of the patient in question and a certificate proving that the agent has the representative power;
 3. Where a spouse, lineal ascendant or descendant, or brother or sister (limited to cases where none of the spouse, ascendants or descendants of a patient, or lineal ascendants of his/her spouse exist) of a patient or a lineal ascendant of the spouse makes a request after satisfying the requirements prescribed by Ordinance of the Ministry of Health and Welfare, such as presenting a certificate proving that each individual has kinship with the patient as it becomes impracticable to obtain the patient's consent due to his/her death, unconsciousness, etc.;
 4. Where the details of a patient's record are provided to the National Health Insurance Corporation or the Health Insurance Review and Assessment Service for the purposes of the assessment of, payment of, verification of entitlement to, and post-management of insurance benefits; and the

- evaluation of the appropriateness of and increased/reduced payment, etc. of medical care benefits, pursuant to Articles 14, 47, 48 and 63 of the National Health Insurance Act;
5. Where the details of a patient's record are provided to a guarantee agency (each *Si/Gun/Gu*), the National Health Insurance Corporation or the Health Insurance Review and Assessment Service for the affairs concerning medical benefits, such as the verification of recipients of medical benefits and the assessment, payment, post-management, etc. of expenses for benefits, pursuant to Articles 5, 11, 11-3 and 33 of the Medical Care Assistance Act;
 6. Where the details of a patient's record are provided pursuant to Article 106, 215 or 218 of the Criminal Procedure Act;
 - 6-2. Where the details of a patient's record are provided pursuant to Article 146, 254 or 257 of the Military Court Act;
 7. Where the details of a patient's record are provided in writing upon an order pursuant to Article 347 of the Civil Procedure Act;
 8. Where the Korea Workers' Compensation and Welfare Service requests a medical institution (including a doctor) specialized in industrial accidents which has examined and treated an insured worker to submit a report or document concerning the treatment of the worker; or investigates such medical institution pursuant to Article 118 of the Industrial Accident Compensation Insurance Act;
 9. Where an insurance company, etc., which has received a claim for car insurance from a medical institution pursuant to Articles 12 (2) and 14 of the Guarantee of Automobile Accident Compensation Act, requests the medical institution to inspect the relevant medical records;
 10. Where the director of a regional military manpower office requests the head of a medical institution to submit the medical records and details of treatment of a person subject to draft physical examination as it is deemed necessary to verify any illness or mental or physical disability in connection with the draft physical examination, pursuant to Article 11-2 of the Military Service Act;
 11. Where a mutual-aid association requests a medical care institution prescribed in Article 42 of the National Health Insurance Act to inspect relevant medical records or to submit necessary data as it is deemed necessary to determine whether to pay the mutual-aid benefits pursuant to Article 42 of the Act on the Prevention of and Compensation for Accidents at School;
 12. Where the head of a medical institution provides medical records and clinical opinions to the head of a veterans hospital pursuant to Article 7 (3) of the Act on Assistance to Patients Suffering from Actual or Potential Aftereffects of Defoliants and Establishment of Related Organizations;
 13. Where the details of a patient's record are provided pursuant to Article 28 (1) or (3) of the Act on Remedies for Injuries from Medical Malpractice and Mediation of Medical Dispute;
 14. Where the National Pension Service requests a medical institution which treated a person who is or was its member to inspect or copy matters concerning the relevant medical treatment in connection with the examination of payment of a dependent pension, disability pension, survivor pension, etc. prescribed in Article 123 of the National Pension Act;
 - 14-2. Where a medical institution which has treated a person who is or was a public official is requested to allow the inspection or copy of matters concerning the relevant medical treatment in the following cases:
 - (a) Where the Minister of Personnel Management requests the inspection or copy in connection with survivors' benefits and disability benefits for reasons other than official duties pursuant to Article 92 of the Public Officials Pension Act;
 - (b) Where the Government Employees Pension Service requests the inspection or copy in connection with survivors' benefits and disability benefits for reasons other than official duties pursuant to Article 93 of the Public Officials Pension Act;

- (c) Where the Minister of Personnel Management (including persons entrusted pursuant to Article 61 of the Public Officials' Accident Compensation Act) requests the inspection or copy in connection with health care benefits, rehabilitation benefits, disability benefits, nursing benefits and disaster survivors' benefits pursuant to Articles 57 and 58 of the same Act;
- 14-3. Where the Korea Teachers Pension requests a medical institution which has treated a person who is or was a school teacher or staff member to inspect or copy matters concerning the relevant medical treatment in connection with the examination of payment of health care benefits, disability benefits and survivors' benefits, pursuant to Article 19 (4) 4-2 of the Pension for Private School Teachers and Staff Act;
15. Where the head of a public institution prescribed by Presidential Decree requests a medical institution which treated a person who has applied for the registration of or is registered as a person with disabilities in connection with examinations on the degree of disabilities prescribed in Article 32 (7) of the Act on Welfare of Persons with Disabilities to inspect or copy matters concerning the relevant medical treatment;
16. Where the Minister of Health and Welfare, the Director of the Korea Centers for Disease Control and Prevention, a Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* requests, under Articles 18-4 and 29 of the Infectious Disease Control and Prevention Act, the head of a medical institution to submit records of medical treatment of patients, etc. of an infectious disease or records of medical treatment on adverse reactions to vaccinations of persons who have been vaccinated, as it is deemed necessary for the epidemiological investigation of an infectious disease or epidemiological investigation on vaccination;
17. Where the Patriots and Veterans Entitlement Commission requests a medical institution that treated a person subject to a patriot and veteran entitlement examination to inspect or copy matters concerning the relevant medical treatment pursuant to Article 74-8 (1) 7 of the Act on the Honorable Treatment of and Support for Persons of Distinguished Service to the State.
- (4) Each physician, dentist, or oriental medical doctor working at a medical institution which keeps medical records or at a public health clinic to which medical records are transferred shall confirm the fact based on the medical records, when he/she is requested to confirm the details of the past medical treatment of a patient not examined or treated by himself/herself. <Newly Inserted by Act No. 9386, Jan. 30, 2009>
- (5) Deleted. <by Act No. 14438, Dec. 20, 2016>

#Article 21 (Inspection of Records)

- (1) A patient may request medical personnel, the head of a medical institution or a person working for a medical institution to inspect or copy all or part of records on the patient (where there is any addition or revision to the records, including all of the records added or revised as well as the original records before the addition and revision; hereinafter the same shall apply) for confirmation. In such cases, no medical personnel, head of the medical institution nor person working for the medical institution shall refuse such request, except in extenuating circumstances. <Newly Inserted by Act No. 14438, Dec. 20, 2016; No. 15540, Mar. 27, 2018>
- (2) No medical personnel, the head of a medical institution nor any person working for a medical institution may allow a third party to a patient to inspect or copy the details of the patient's record for confirmation. <Amended by Act No. 9386, Jan. 30, 2009; Act No. 14438, Dec. 20, 2016>
- (3) Notwithstanding paragraph (2), each medical personnel, the head of a medical institution, or any person working for a medical institution shall allow the inspection or copy of the details of a patient's record in any of the following cases: *Provided*, That where a physician, dentist, or oriental medical doctor deems it necessary to treat the patient, this shall not apply: <Amended by Act No. 9386, Jan. 30, 2009; Act No. 9932, Jan. 18, 2010; Act No. 10565, Apr. 7, 2011; Act No. 11141, Dec. 31, 2011;

Act No. 11252, Feb. 1, 2012; Act No. 13605, Dec. 22, 2015; Act No. 13658, Dec. 29, 2015; Act No. 14183, May 29, 2016; Act No. 14220, May 29, 2016; Act No. 14438, Dec. 20, 2016; Act No. 15522, Mar. 20, 2018; Act No. 15716, Aug. 14, 2018; Act No. 17069, Mar. 4, 2020>

1. Where a spouse, lineal ascendant or descendant, or brother or sister (limited to cases where none of the spouse, ascendants or descendants of a patient, or lineal ascendants of his/her spouse exist) of a patient or a lineal ascendant of the spouse makes a request after satisfying the requirements prescribed by Ordinance of the Ministry of Health and Welfare, such as presenting the consent of the patient in question, a certificate proving kinship, and any other documents;
2. Where the agent designated by a patient makes a request after satisfying the requirements prescribed by Ordinance of the Ministry of Health and Welfare, such as presenting the consent of the patient in question and a certificate proving that the agent has the representative power;
3. Where a spouse, lineal ascendant or descendant, or brother or sister (limited to cases where none of the spouse, ascendants or descendants of a patient, or lineal ascendants of his/her spouse exist) of a patient or a lineal ascendant of the spouse makes a request after satisfying the requirements prescribed by Ordinance of the Ministry of Health and Welfare, such as presenting a certificate proving that each individual has kinship with the patient as it becomes impracticable to obtain the patient's consent due to his/her death, unconsciousness, etc.;
4. Where the details of a patient's record are provided to the National Health Insurance Corporation or the Health Insurance Review and Assessment Service for the purposes of the assessment of, payment of, verification of entitlement to, and post-management of insurance benefits; and the evaluation of the appropriateness of and increased/reduced payment, etc. of medical care benefits, pursuant to Articles 14, 47, 48 and 63 of the National Health Insurance Act;
5. Where the details of a patient's record are provided to a guarantee agency (each *Si/Gun/Gu*), the National Health Insurance Corporation, or the Health Insurance Review and Assessment Service for the affairs concerning medical benefits, such as the verification of the recipients of medical benefits and the assessment, payment, post-management, etc. of expenses for medical benefits, pursuant to Articles 5, 11, 11-3 and 33 of the Medical Care Assistance Act;
6. Where the details of a patient's record are provided pursuant to Article 106, 215, or 218 of the Criminal Procedure Act;
- 6-2. Where the details of a patient's record are provided pursuant to Article 146, 254 or 257 of the Military Court Act;
7. Where the details of a patient's record are provided in writing upon an order pursuant to Article 347 of the Civil Procedure Act;
8. Where the Korea Workers' Compensation and Welfare Service requests a medical institution (including a doctor) specialized in industrial accidents which has examined and treated an insured worker to submit a report or document concerning the treatment of the worker; or investigates such medical institution, pursuant to Article 118 of the Industrial Accident Compensation Insurance Act;
9. Where an insurance company, etc., which has received a claim for car insurance from a medical institution pursuant to Articles 12 (2) and 14 of the Guarantee of Automobile Accident Compensation Act, requests the medical institution to inspect the relevant medical records;
10. Where the director of a regional military manpower office requests the head of a medical institution to submit the medical records and details of treatment of a person subject to draft physical examination as it is deemed necessary to verify any illness or mental or physical disability in connection with the draft physical examination, pursuant to Article 11-2 of the Military Service Act;
11. Where a mutual-aid association requests a medical care institution prescribed in Article 42 of the National Health Insurance Act to inspect relevant medical records or to submit necessary data as it is deemed necessary to determine whether to pay the mutual-aid benefits pursuant to Article

- 42 of the Act on the Prevention of and Compensation for Accidents at School;
12. Where the head of a medical institution provides medical records and clinical opinions to the head of a veterans hospital, pursuant to Article 7 (3) of the Act on Assistance to Patients Suffering from Actual or Potential Aftereffects of Defoliants and Establishment of Related Organizations;
 13. Where the details of a patient's record are provided pursuant to Article 28 (1) or (3) of the Act on Remedies for Injuries from Medical Malpractice and Mediation of Medical Dispute;
 14. Where the National Pension Service requests a medical institution which treated a person who is or was its member to inspect or copy matters concerning the relevant medical treatment in connection with the examination of payment of a dependent pension, disability pension, survivor pension, etc. prescribed in Article 123 of the National Pension Act;
 - 14-2. Where a medical institution which has treated a person who is or was a public official is requested to allow the inspection or copy of matters concerning the relevant medical treatment in the following cases:
 - (a) Where the Minister of Personnel Management requests the inspection or copy in connection with survivors' benefits and disability benefits for reasons other than official duties pursuant to Article 92 of the Public Officials Pension Act;
 - (b) Where the Government Employees Pension Service requests the inspection or copy in connection with survivors' benefits and disability benefits for reasons other than official duties pursuant to Article 93 of the Public Officials Pension Act;
 - (c) Where the Minister of Personnel Management (including persons to whom business affairs are entrusted pursuant to Article 61 of the Public Officials' Accident Compensation Act) requests the inspection or copy in connection with health care benefits, rehabilitation benefits, disability benefits, nursing benefits and disaster survivors' benefits pursuant to Articles 57 and 58 of the same Act;
 - 14-3. Where the Korea Teachers Pension requests a medical institution which has treated a person who is or was a school teacher or staff member to inspect or copy matters concerning the relevant medical treatment in connection with the examination of payment of medical care benefits, disability benefits and survivors' benefits, pursuant to Article 19 (4) 4-2 of the Pension for Private School Teachers and Staff Act;
 15. Where the head of a public institution prescribed by Presidential Decree requests a medical institution which treated a person who has applied for the registration of or is registered as a person with disabilities in connection with examinations on the degree of disabilities prescribed in Article 32 (7) of the Act on Welfare of Persons with Disabilities to inspect or copy matters concerning the relevant medical treatment;
 16. Where the Minister of Health and Welfare, the Director of the Korea Centers for Disease Control and Prevention, a Mayor/Do Governor, or the head of a *Si/Gun/Gu* requests, under Articles 18-4 and 29 of the Infectious Disease Control and Prevention Act, the head of a medical institution to submit records of medical treatment of patients, etc. of an infectious disease or records of medical treatment on adverse reactions to vaccinations of persons who have been vaccinated, as it is deemed necessary for the epidemiological investigation of an infectious disease or epidemiological investigation on vaccination;
 17. Where the Patriots and Veterans Entitlement Commission requests a medical institution that treated a person subject to a patriot and veteran entitlement examination to inspect or copy matters concerning the relevant medical treatment pursuant to Article 74-8 (1) 7 of the Act on the Honorable Treatment of and Support for Persons of Distinguished Service to the State.
- (4) Each physician, dentist or oriental medical doctor working for a medical institution which keeps medical records or for a public health clinic to which medical records are transferred shall confirm the fact based on the medical records, when he/she is requested to confirm the details of the past

medical treatment of a patient not examined or treated by himself/herself. <Newly Inserted by Act No. 9386, Jan. 30, 2009>

- (5) In cases of paragraph (1), (3) or (4), the medical personnel, the heads of medical institutions and persons working for medical institutions may have patients or third parties to patients confirm recorded matters by means of providing them with electronic documents with digital signatures prescribed by the Digital Signature Act. <Newly Inserted by Act No. 17069, Mar. 4, 2020>

Article 21-2 (Sending of Medical Records)

- (1) Where medical personnel or the head of a medical institution receive a request from another medical personnel or the head of another medical institution to confirm the details of medical records referred to in Article 22 or 23 or to send or transmit his/her clinical opinion on the progress of medical treatment of a patient, he/she shall comply with such request with consent of the relevant patient or his/her guardian: *Provided*, That where the relevant patient has fallen into unconsciousness or is in emergency, or where it is impracticable to obtain the consent due to the absence of the patient's guardian, they can be submitted or transmitted without consent of the patient or his/her guardian.
- (2) Where medical personnel or the head of a medical institution transfers an emergency patient to another medical institution, he/she shall send without delay copies of medical records, etc. prepared as at the time the patient visited the relevant hospital.
- (3) In order to support the affairs related to the transmission of copies of medical records, clinical opinions on the progress of medical treatment, etc. pursuant to paragraphs (1) and (2), the Minister of Health and Welfare may establish and operate an electronic information system (hereafter referred to as "medical record transmission support system" in this Article).
- (4) The Minister of Health and Welfare may entrust the establishment and operation of a medical record transmission support system to a related specialized institution, as prescribed by Presidential Decree. In such cases, the Minister of Health and Welfare may subsidize all or part of the necessary expenses.
- (5) A specialized institution entrusted with the affairs pursuant to paragraph (4) shall observe the following matters:
1. It shall take technical and managerial measures necessary to secure safety, such as designation of persons with right to access, installation of a firewall, use of encryption software and storage of access records, to prevent divulgence, falsification, damage, etc. of information stored in the medical record transmission support system, as prescribed by Presidential Decree;
 2. It shall not re-entrust the affairs related to the operation of the medical record transmission support system to another institution;
 3. It shall not provide on its own discretion or divulge information stored in the medical record transmission support system to a third person.
- (6) The Minister of Health and Welfare may request medical personnel or the head of a medical institution to submit data necessary to establish and operate a medical record transmission support system, such as the data related to the consent of patients or patient's guardians referred to in the main sentence of paragraph (1), as prescribed by Ordinance of the Ministry of Health and Welfare, and store and use them within the scope of the purpose of the receipt thereof. In such cases, a person, in receipt of a request to submit data, shall comply with the request, except in extenuating circumstances.
- (7) Other necessary matters for the establishment, operation, etc. of a medical record transmission support system shall be prescribed by Ordinance of the Ministry of Health and Welfare.
- (8) No one shall divulge, falsify or damage information stored in a medical record transmission support system without good cause.
- (9) Except as expressly provided for in this Act, matters necessary for the establishment and operation of a medical record transmission support system shall be governed by the Personal Information Protection Act.

[This Article Newly Inserted by Act No. 14438, Dec. 20, 2016]

SECTION 2 Rights and Duties

Article 22 (Medical Records)

- (1) Medical personnel shall keep books for recording medical treatment, assistance in childbirth, nursing or other documents concerning medical treatment (hereinafter referred to as "medical records, etc") and record in detail matters concerning medical services prescribed by Ordinance of the Ministry of Health and Welfare, such as a patient's primary symptoms, diagnosis, treatment and opinions and sign his/her name thereon. *<Amended by Act No. 11748, Apr. 5, 2013>*
- (2) Medical personnel and the founder of a medical institution shall keep medical records, etc. (including electronic medical records under Article 23 (1), and where there is any addition or revision, including all of the added or revised medical records, etc. and the original records; hereinafter the same shall apply), as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 15540, Mar. 27, 2018>*
- (3) No medical personnel shall falsely prepare medical records, etc. nor intentionally make additional indications or modifications different from the fact. *<Newly Inserted by Act No. 10565, Apr. 7, 2011>*
- (4) The Minister of Health and Welfare may prepare and publicly notify medical terminology that medical personnel uses for medical records, etc., such as the names of diseases, names of tests and names of medicines, and standards for forms and details of medical records, etc., and may recommend that medical personnel or founders of medical institutions comply therewith. *<Newly Inserted by Act No. 16555, Aug. 27, 2019>*

Article 23 (Electronic Medical Records)

- (1) Medical personnel and the founder of each medical institution may, notwithstanding Article 22, prepare and keep medical records, etc. in the form of an electronic document with a digital signature under the Digital Signature Act (hereinafter referred to as "electronic medical records").
- (2) Medical personnel and the founder of each medical institution shall have facilities and equipment necessary for managing and storing electronic medical records safely, as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*
- (3) No person shall divulge, alter or destroy personal information stored in an electronic medical record without good cause.
- (4) Where any medical personnel or the founder of a medical institution makes an addition or revision to electronic medical records, he/she shall separately store the access records, as prescribed by Ordinance of the Ministry of Health and Welfare. *<Newly Inserted by Act No. 15540, Mar. 27, 2018>*

Article 23-2 (Standardization of Electronic Medical Record System)

- (1) For the purpose of the efficient and unified management and use of electronic medical records, the Minister of Health and Welfare may determine and publicly notify the standards concerning a computerized information processing system (hereafter referred to as "electronic medical record system" in this Article), facilities, equipment, forms of records, etc. necessary to prepare, manage and preserve records, and recommend manufacturers and suppliers of the electronic medical record system, medical personnel or founders of medical institutions to comply with such standards.
- (2) The Minister of Health and Welfare may certify an electronic medical record system, if it meets the criteria for certification prescribed by Presidential Decree, such as the standards referred to in paragraph (1), compatibility among electronic medical record systems and security of data.
- (3) A person who has been certified pursuant to paragraph (2) may mark the details of certification, as

prescribed by Presidential Decree. In such cases, no person who has not been certified shall mark the certification or use any mark similar thereto.

- (4) The Minister of Health and Welfare may revoke certification granted under paragraph (2) in any of the following cases: *Provided*, That in cases falling under subparagraph 1, the certification shall be revoked:
1. Where the certification was obtained by fraudulent or other illegal means;
 2. Where the relevant system fails to meet the criteria for certification referred to in paragraph (2).
- (5) The Minister of Health and Welfare may perform projects to facilitate the development of technology and the use of electronic medical record systems.
- (6) Matters necessary for the objects of standardization prescribed in paragraph (1), methods, procedures, etc. of certification prescribed in paragraph (2) shall be prescribed by Presidential Decree.

[This Article Newly Inserted by Act No. 14438, Dec. 20, 2016]

Article 23-3 (Notification of Medical Treatment Information Breach Incidents)

- (1) Where an incident prescribed by Presidential Decree, such as divulgence of medical treatment information or disruption in business of a medical institution by electronic breach of electronic medical records (hereinafter referred to as "medical treatment information breach incident") occurs, the medical personnel or the founder of the medical institution shall notify the Minister of Health and Welfare of such incident immediately.
- (2) Where the Minister of Health and Welfare is notified of a medical treatment information breach incident pursuant to paragraph (1) or comes to know the occurrence of a medical treatment information breach incident, he/she shall notify the relevant administrative agencies.

[This Article Newly Inserted by Act No. 16555, Aug. 27, 2019]

Article 23-4 (Prevention of and Response to Medical Treatment Information Breach Incidents)

- (1) For the prevention of and response to medical treatment information breach incidents, the Minister of Health and Welfare shall take the following measures:
1. Collecting and disseminating information on medical treatment information breach incidents;
 2. Forecasting and warning medical treatment information breach incidents;
 3. Emergency measures for medical treatment information breach incidents;
 4. Detecting and analyzing electronic breach of electronic medical records;
 5. Other measures prescribed by Presidential Decree to prevent and respond to medical treatment information breach incidents.
- (2) The Minister of Health and Welfare may entrust all or part of the measures prescribed in paragraph (1) to specialized institutions.
- (3) Procedures and methods for taking measures pursuant to paragraph (1), procedures for entrusting measures pursuant to paragraph (2) and other necessary matters shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 16555, Aug. 27, 2019]

Article 23-5 (Prohibition from Gaining Improper Economic Benefits)

- (1) No medical personnel, founder of a medical institution (including a representative of a corporation, director or other person who engages therein; hereafter the same shall apply in this Article), and person working for a medical institution shall receive money, goods, advantages, labor, entertainment and other economic benefits (hereinafter referred to as "economic benefits, etc") which a drug supplier referred to in Article 47 (2) of the Pharmaceutical Affairs Act provides for the promotion of sale, such as selection of drugs, induction to prescribe drugs and maintenance of transactions; or cause the medical institution to receive them: *Provided*, That this shall not apply to

economic benefits, etc. within the extent prescribed by Ordinance of Ministry of Health and Welfare, including the provision of a sample, support for a conference, support for a clinical trial, product showcase, price discount according to price settlement methods, and post market surveillance (hereinafter referred to as "provision of a sample, etc."). <Amended by Act No. 13658, Dec. 29, 2015>

- (2) No medical personnel, founder of a medical institution and person working for a medical institution shall receive economic benefits, etc. which a manufacturer of medical devices prescribed in Article 6 of the Medical Devices Act, an importer of medical devices prescribed in Article 15 of the same Act or any person who sells or leases medical devices prescribed in Article 17 of the same Act provides for the promotion of sale, such as induction to select and use medical devices and maintenance of transactions; or cause the medical institution to receive them: *Provided*, That this shall not apply to economic benefits, etc. within the extent prescribed by Ordinance of Ministry of Health and Welfare, including provision of a sample, etc. <Amended by Act No. 10564, Apr. 7, 2011; Act No. 13658, Dec. 29, 2015>

[This Article Newly Inserted by Act No. 10325, May 27, 2010]

Article 24 (Guidance for Methods of Convalescence)

Medical personnel shall provide patients or their guardians with guidance for the method of convalescence or other matters necessary for health care.

Article 24-2 (Explanation about Medical Practices)

- (1) Where a physician, dentist or oriental medical doctor performs a surgery, blood transfusion or general anesthesia (hereafter referred to as "surgery, etc." in this Article) that might cause serious harm to a life or body, he/she shall explain the matters set forth in paragraph (2) to the patient (referring to a legal representative, where the patient lacks decision-making capacity; hereafter the same shall apply in this Article) and obtain a written consent (including an electronic document; hereafter the same shall apply in this Article) from the patient: *Provided*, That this shall not apply where the patient's life might fall into danger or the patient might fall into serious mental incapacity due to the delay of surgery, etc. caused by taking the procedures for explanation and obtaining consent.
- (2) Matters requiring the explanation to and consent from a patient pursuant to paragraph (1) shall be as follows:
1. Diagnosis of the symptom which has occurred to or which might occur to the patient;
 2. Necessity, methods, and details of the surgery, etc.;
 3. The name of the physician, dentist or oriental medical doctor who gives explanation to the patient, or the name of principal physician, dentist or oriental medical doctor who participates in the surgery, etc.;
 4. Sequelae or side effects expected to occur typically following the surgery, etc.;
 5. Matters to be observed by the patient before and after the surgery, etc.
- (3) A patient may request a physician, dentist or oriental medical doctor to issue a copy of the consent referred to in paragraph (1). In such cases, the physician, dentist or oriental medical doctor in receipt of such request, shall comply with the request, except in extenuating circumstances.
- (4) Where the methods and details of surgery, etc. or the principal physician, dentist or oriental medical doctor who will participate in the surgery, etc. are changed among the matters on which consent is obtained, the ground for and details of the change shall be informed to the patient in writing.
- (5) Matters necessary for methods, procedures, etc. of explanation, consent, and notification prescribed in paragraphs (1) through (4), shall be prescribed by Presidential Decree.

[This Article Newly Inserted by Act No. 14438, Dec. 20, 2016]

Article 25 (Reports)

- (1) Medical personnel shall report his/her actual status and current employment status, etc. to the Minister of Health and Welfare every three years from the date he/she obtains the license for the first time, as prescribed by Presidential Decree. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10609, Apr. 28, 2011>
- (2) With respect to medical personnel who fails to complete refresher training referred to in Article 30 (3), the Minister of Health and Welfare may refuse to accept reports by the medical personnel referred to in paragraph (1). <Newly Inserted by Act No. 10609, Apr. 28, 2011>
- (3) The Minister of Health and Welfare may entrust the duty to receive reports referred to in paragraph (1) to a relevant organization, etc., as prescribed by Presidential Decree. <Newly Inserted by Act No. 10609, Apr. 28, 2011>

Article 26 (Report on Unnatural Death)

A physician, dentist, oriental medical doctor or midwife who is suspicious of unnatural death upon a postmortem examination on a dead body, shall report to the chief of police station having jurisdiction over the place where the dead body was found or located.

SECTION 3 Restrictions on Medical Practices**Article 27 (Prohibition against Unlicensed Medical Practices)**

- (1) Any non-medical personnel shall not perform medical practices; and even medical personnel shall not perform any medical practice other than those licensed: *Provided*, That any of the following persons can perform medical practices to the extent prescribed by Ordinance of the Ministry of Health and Welfare: <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9386, Jan. 30, 2009; Act No. 9932, Jan. 18, 2010>
 1. A person who holds a foreign medical license and stays in Korea for a certain period of time;
 2. A person who performs medical practices for medical volunteer or a research and pilot project at a medical college, dental college, college of oriental medicine, graduate medical school, graduate school for dentistry, graduate school for oriental medicine, general hospital, or foreign medical aid institution;
 3. A student majoring in medical science, dentistry, oriental medical science or nursing.
- (2) Any non-medical personnel shall not use a title of a physician, dentist, oriental medical doctor, midwife, nurse or any other title similar thereto.
- (3) No person may introduce, arrange or solicit a patient to a medical institution or medical personnel for profits, by exempting or discounting medical expenses to be paid by a patient under the National Health Insurance Act or the Medical Care Assistance Act, offering money, etc. or providing means of transportation to the general public; or instigate any person to do so: *Provided*, That any of the following acts may be permitted: <Amended by Act No. 9386, Jan. 30, 2009; Act No. 9932, Jan. 18, 2010; Act No. 11141, Dec. 31, 2011>
 1. Attracting a patient through prior individual approval from the head of the competent *Si/Gun/Gu* by reason of economic conditions, etc. of the patient;
 2. Attracting a foreign patient who is neither a policyholder nor dependent pursuant to Article 109 of the National Health Insurance Act (excluding a foreigner who resides in the Republic of Korea, as prescribed by Ordinance of the Ministry of Health and Welfare).
- (4) Notwithstanding paragraph (3) 2, an insurance company, mutual company, insurance solicitor, insurance agency or certified insurance broker defined in Article 2 of the Insurance Business Act shall be prohibited from attracting foreign patients. <Newly Inserted by Act No. 9386, Jan. 30, 2009>

- (5) No medical personnel, founders of medical institutions, and persons working for medical institutions shall have unlicensed persons provide medical services or have medical personnel provide unlicensed medical practices. <Newly Inserted by Act No. 16375, Apr. 23, 2019>

Article 27-2 Deleted. <by Act No. 13599, Dec. 22, 2015>

SECTION 4 Organizations of Medical Personnel

Article 28 (Central Association and Branches)

- (1) Physicians, dentists, oriental medical doctors, midwives or nurses shall establish the physicians' association, dentists' association, oriental medical doctors' association, midwives' association, and nurses' association, respectively (hereinafter referred to as "central association") that has nationwide organizations, as prescribed by Presidential Decree.
- (2) Each central association shall be a corporate entity.
- (3) When a central association is established and existing pursuant to paragraph (1), medical personnel shall become a member of the corresponding central association, and thus shall comply with the articles of association thereof.
- (4) Except as otherwise expressly provided for in this Act, the provisions of the Civil Act governing the incorporated associations shall apply *mutatis mutandis* to matters concerning central associations.
- (5) Each central association shall establish branches in a Special Metropolitan City, Metropolitan City, *Do* and Special Self-Governing Province (hereinafter referred to as a "City/Do"); and may establish sub-branches in each *Si/Gun/Gu* (referring only to an autonomous *Gu*; hereinafter the same shall apply), as prescribed by Presidential Decree: *Provided*, That the establishment of a branch in addition to those specified above, or a branch of the physicians' association in a foreign country shall require approval from the Minister of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>
- (6) Each central association shall submit a report to a Special Metropolitan City Mayor, Metropolitan City Mayor, *Do* Governor or Special Self-Governing Province Governor (hereinafter referred to as "Mayor/*Do* Governor"), or the head of a *Si/Gun/Gu* immediately after the establishment of a branch or sub-branch.
- (7) Each central association shall have an ethics committee to deliberate, and pass a resolution, on claims, etc. for suspension of qualification referred to in Article 66-2. <Newly Inserted by Act No. 10609, Apr. 28, 2011>
- (8) Matters necessary for the organization, operation, etc. of ethics committees shall be prescribed by Presidential Decree. <Newly Inserted by Act No. 10609, Apr. 28, 2011>

Article 29 (Permission for Establishment)

- (1) When planning to establish a central association, a representative of the central association shall submit its articles of association and other necessary documents to the Minister of Health and Welfare, as prescribed by Presidential Decree and obtain permission for the establishment from the Minister. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>
- (2) Matters to be included in the articles of association of each central association shall be prescribed by Presidential Decree.
- (3) Where a central association intends to amend its articles of association, it shall obtain permission for such amendment from the Minister of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

Article 30 (Duty to Cooperate)

- (1) Where a central association receives a request from the Minister of Health and Welfare for

cooperation to improve medical services and public health, it shall comply with such request. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

- (2) Each central association shall implement refresher training to improve the quality of its members, as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*
- (3) Medical personnel shall attend refresher training referred to in paragraph (2).

Article 31 Deleted. *<by Act No. 10565, Apr. 7, 2011>*

Article 32 (Supervision)

When a central association or its branch engages in any business, other than those stipulated in its articles of association, or commits any act that impedes public health, or if it fails to properly respond to a request for cooperation under Article 30 (1), the Minister of Health and Welfare may issue an order to amend its articles of association or re-elect its officers. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

CHAPTER III Medical Institutions

SECTION 1 Establishment of Medical Institutions

Article 33 (Establishment)

- (1) Medical personnel shall not provide medical services unless and until he/she establishes a medical institution in accordance with this Act; and shall provide medical services within the medical institution, except in any of the following cases: *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*
 1. When medical treatment is given to an emergency patient prescribed in subparagraph 1 of Article 2 of the Emergency Medical Service Act;
 2. When medical treatment is given upon a request from a patient or his/her guardian;
 3. When medical services outside of the medical institution are requested by the State or the head of a local government as deemed necessary for public interest;
 4. When home nursing services are provided, as prescribed by Ordinance of the Ministry of Health and Welfare;
 5. When a cause or event specifically prescribed by this Act or any other statutes or regulations occurs, or when it is inevitable to give medical treatment at a place where a patient is located.
- (2) No person, other than any of the following persons, may establish a medical institution. In such cases, a physician may establish a general hospital, hospital, long-term care hospital or medical clinic, a dentist may establish a dental hospital or dental clinic, an oriental medical doctor may establish an oriental medical hospital, long-term care hospital or oriental medical clinic, and a midwife may establish only a midwifery clinic, respectively: *<Amended by Act No. 9386, Jan. 30, 2009>*
 1. A physician, a dentist, an oriental medical doctor, or a midwife;
 2. The State or a local government;
 3. A corporation established for the purpose of rendering medical services (hereinafter referred to as "medical corporation");
 4. A nonprofit corporation established pursuant to the Civil Act or any special Act;
 5. A quasi-government agency prescribed in the Act on the Management of Public Institutions, a local medical center prescribed in the Act on the Establishment and Management of Local Medical Centers or the Korea Veterans Health Service prescribed in the Korea Veterans Health

Service Act.

- (3) Any person who intends to establish a medical clinic, dental clinic, oriental medical clinic or midwifery clinic prescribed in paragraph (2), shall submit a report to the head of the competent *Si/Gun/Gu*, as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>
- (4) Any person who intends to establish a general hospital, hospital, dental hospital, oriental medical hospital or long-term care hospital prescribed in paragraph (2) shall obtain permission from the competent Mayor/Do Governor, as prescribed by Ordinance of the Ministry of Health and Welfare. In such cases, where a medical institution to be established falls under any of the following cases, the Mayor/Do Governor shall not grant permission for establishment: <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 16555, Aug. 27, 2019>
1. Where a medical institution to be established fails to meet facility standards prescribed in Article 36;
 2. Where a medical institution to be established is non-compliant with the basic implementation policy prescribed in Article 60 (1) and the plan for supply and management prescribed in paragraph (2) of the same Article.
- (5) The provisions of paragraphs (3) and (4) shall apply, when a medical institution established pursuant to paragraphs (3) or (4) intends to relocate its place of business or revise an important matter prescribed by Ordinance of the Ministry of Health and Welfare among those reported or permitted as to its establishment. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>
- (6) A person who intends to establish a midwifery clinic shall appoint a physician as an advisor with no exception.
- (7) No medical institution may be established in any of the following cases: <Amended by Act No. 16555, Aug. 27, 2019>
1. Within the premises of a pharmacy or its facility;
 2. Where the part of a pharmacy's facility or premises is partitioned, altered, or repaired to establish a medical institution;
 3. Where there is a passage between a medical institution and a pharmacy, such as an exclusive hallway, stairway, elevator or overpass, or where such facility is installed to establish a medical institution;
 4. Where a medical institution is established in a building built, expanded or rebuilt without obtaining permission or filing a report in accordance with the relevant statutes or regulations, such as the Building Act.
- (8) No medical personnel referred to in paragraph (2) 1 shall establish nor operate at least two medical institutions under any pretext: *Provided*, That where a person with at least two medical licenses intends to establish a clinic-level medical institution, he/she may open medical institutions together at one location only by type of his/her licenses. <Newly Inserted by Act No. 9386, Jan. 30, 2009; Act No. 11252, Feb. 1, 2012>
- (9) A medical corporation or nonprofit corporation referred to in paragraph (2) 4 (hereafter referred to as "medical corporation, etc." in this Article) that intends to establish a medical institution shall obtain permission for the modification of its articles of incorporation (when establishing a medical corporation, etc., referring to the permission for the establishment thereof; hereafter the same shall apply in this paragraph), as prescribed by Presidential Decree, after specifying in its articles of incorporation the place in which the medical institution is located. In such cases, the administrative agency having jurisdiction over the relevant corporation shall consult with the Mayor/Do Governor or the head of the *Si/Gun/Gu* having jurisdiction over the place where the medical institution that the corporation intends to establish is located, before granting permission for modification of the articles of incorporation. <Newly Inserted by Act No. 13658, Dec. 29, 2015>
- (10) No medical corporation, etc. that has established and operates a medical institution shall lend the name of the corporation to a third party. <Newly Inserted by Act No. 13658, Dec. 29, 2015>

[Paragraph (2) of this Article, which was determined to be inconsistent with the Constitution by the Constitutional Court on Dec. 27, 2007, is amended by Act No. 9386, Jan. 30, 2009.]

#Article 33 (Establishment)

- (1) A medical personnel shall not provide medical services, unless and until he/she establishes a medical institution in accordance with this Act; and shall provide medical services within the medical institution, except in any of the following cases: *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*
 1. When medical treatment is provided to an emergency patient prescribed in subparagraph 1 of Article 2 of the Emergency Medical Service Act;
 2. When medical treatment is provided upon a request from a patient or his/her guardian;
 3. When medical services outside of the medical institution are requested by the State or the head of a local government as deemed necessary for public interests;
 4. When home nursing services are provided as prescribed by Ordinance of the Ministry of Health and Welfare;
 5. When a cause or event specifically prescribed by this Act or any other statutes or regulations occurs, or when it is inevitable to give medical treatment at a place where a patient is located.
- (2) No person, other than any of the following persons, may establish a medical institution. In such cases, a physician may establish a general hospital, hospital, long-term care hospital, mental health hospital or medical clinic, a dentist may establish a dental hospital or dental clinic, an oriental medical doctor may establish an oriental medical hospital, long-term care hospital or oriental medical clinic, and a midwife may establish only a midwifery clinic, respectively: *<Amended by Act No. 9386, Jan. 30, 2009; Act No. 17069, Mar. 4, 2020>*
 1. A physician, a dentist, an oriental medical doctor or a midwife;
 2. The State or a local government;
 3. A corporation established for the purpose of rendering medical services (hereinafter referred to as "medical corporation");
 4. A nonprofit corporation established pursuant to the Civil Act or any special Act;
 5. A quasi-government agency prescribed in the Act on the Management of Public Institutions, a local medical center prescribed in the Act on the Establishment and Management of Local Medical Centers, or the Korea Veterans Health Service prescribed in the Korea Veterans Health Service Act.
- (3) Any person who intends to establish a medical clinic, dental clinic, oriental medical clinic, or midwifery clinic prescribed in paragraph (2), shall submit a report to the head of the competent *Si/Gun/Gu*, as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*
- (4) Any person who intends to establish a general hospital, hospital, dental hospital, oriental medical hospital, long-term care hospital or mental health hospital prescribed in paragraph (2), shall obtain permission from the competent Mayor/*Do* Governor, as prescribed by Ordinance of the Ministry of Health and Welfare following deliberation by the City/*Do* Medical Institution Establishment Committee prescribed in Article 33-2. In such cases, where the medical institution to be established falls under any of the following cases, the Mayor/*Do* Governor shall not grant permission for establishment: *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 16555, Aug. 27, 2019; Act No. 17069, Mar. 4, 2020>*
 1. Where a medical institution to be established fails to meet facility standards prescribed in Article 36;
 2. Where a medical institution to be established is non-compatible with the basic implementation policy prescribed in Article 60 (1) and the plan for supply and management prescribed in paragraph (2) of the same Article.
- (5) The provisions of paragraphs (3) and (4) shall apply, when a medical institution established pursuant

- to paragraphs (3) or (4) intends to relocate its place of business or revise an important matter prescribed by Ordinance of the Ministry of Health and Welfare among those reported or permitted as to its establishment. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>
- (6) A person who intends to establish a midwifery clinic shall appoint a physician as an adviser with no exception.
- (7) No medical institution may be established in any of the following cases: <Amended by Act No. 16555, Aug. 27, 2019>
1. Within the premises of a pharmacy or its facility;
 2. Where the part of a pharmacy's facility or premises is partitioned, altered, or repaired to establish a medical institution;
 3. Where there is a passage between a medical institution and a pharmacy, such as an exclusive hallway, stairway, elevator or overpass, or where such facility is installed to establish a medical institution;
 4. Where a medical institution is established in a building built, expanded or rebuilt without obtaining permission or filing a report in accordance with the relevant statutes or regulations, such as the Building Act.
- (8) No medical personnel referred to in paragraph (2) 1 shall establish nor operate at least two medical institutions under any pretext: *Provided*, That where a person with at least two medical licenses intends to establish a clinic-level medical institution, he/she may open medical institutions together at one location only by type of his/her licenses. <Newly Inserted by Act No. 9386, Jan. 30, 2009; Act No. 11252, Feb. 1, 2012>
- (9) A medical corporation or nonprofit corporation referred to in paragraph (2) 4 (hereafter referred to as "medical corporation, etc." in this Article) that intends to establish a medical institution shall obtain permission for the modification of its articles of incorporation (when establishing a medical corporation, etc., referring to the permission for the establishment thereof; hereafter the same shall apply in this paragraph), as prescribed by Presidential Decree, after specifying in its articles of incorporation the place in which the medical institution is established. In such cases, the competent administrative agency having jurisdiction over the relevant corporation shall consult with the Mayor/Do Governor or the head of the *Si/Gun/Gu* having jurisdiction over the place where the medical institution that the corporation intends to establish is located, before granting permission for modification of the articles of incorporation. <Newly Inserted by Act No. 13658, Dec. 29, 2015>
- (10) No medical corporation, etc. that has established and operates a medical institution shall lend the name of the corporation to a third party. <Newly Inserted by Act No. 13658, Dec. 29, 2015>
- [Paragraph (2) of this Article, which was determined to be inconsistent with the Constitution by the Constitutional Court on Dec. 27, 2007, is amended by Act No. 9386, Jan. 30, 2009.]

#Article 33-2 (Establishment of Medical Institution Establishment Committees)

- (1) To deliberate on matters concerning permission for establishing medical institutions prescribed in Article 33 (4), a medical institution establishment committee shall be established under the control of each City/Do.
 - (2) Persons with a wealth of experience as a medical personnel member of the physicians' association, dentists' association, oriental medical doctors' association, midwives' association and nurses' association prescribed in Article 28, and persons with a wealth of experience in the establishment, operation, etc. of medical institutions within the relevant region as a member of a medical institution association prescribed in Article 52 shall become members of medical institution establishment committees prescribed in paragraph (1).
 - (3) Matters necessary for the organization and operation of medical institution establishment committees and other necessary matters shall be prescribed by Ordinance of the Ministry of Health and Welfare.
- [This Article Newly Inserted by Act No. 17069, Mar. 4, 2020]

Article 34 (Telemedicine)

- (1) Medical personnel (limited only to physicians, dentists or oriental medical doctors who engage in medical practices) may, notwithstanding Article 33 (1), provide telemedicine services (hereinafter referred to as "telemedicine") to furnish medical knowledge or technology to medical personnel in a remote area by using information communication technology, such as computers or video communications systems.
- (2) A person who intends to provide or receive telemedicine services shall have the facilities and equipment prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>
- (3) A person who provides telemedicine services (hereinafter referred to as "remote doctor") shall have the same responsibility as he/she directly gives medical treatment to a patient.
- (4) If any of medical personnel who has performed medical practices following a remote doctor's telemedicine practices, is a physician, dentist or an oriental medical doctor (hereinafter referred to as "local doctor"), and if there is no obvious ground to believe that the remote doctor is negligent in performing his/her medical practice, the local doctor shall be responsible for a patient, notwithstanding paragraph (3).

Article 35 (Special Exception to Establishment of Medical Institutions)

- (1) Where a person other than those set forth in Article 33 (1), (2), and (8) intends to establish a auxiliary medical institution for providing health care to his/her staff, employees, constituents (including inmates) or their dependents, the person shall report to the head of a *Si/Gun/Gu* having jurisdiction over the place where the auxiliary medical institution is to be located: *Provided*, That the establishment of a hospital-level medical institution as an auxiliary medical institution requires permission from a Mayor/Do Governor having jurisdiction over the place where the institution is to be located. <Amended by Act No. 9386, Jan. 30, 2009>
- (2) Procedures and requirements for a report on and permission for the establishment of an auxiliary medical institution under paragraph (1), and other matters necessary for the operation and management of the auxiliary medical institution shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

Article 36 (Matters to Be Observed)

A person who establishes a medical institution in accordance with Article 33 (2) and (8) shall comply with the following matters, as prescribed by Ordinance of the Ministry of Health and Welfare: <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9386, Jan. 30, 2009; Act No. 9932, Jan. 18, 2010; Act No. 14220, May 29, 2016; Act No. 16375, Apr. 23, 2019; Act No. 16555, Aug. 27, 2019>

1. Matters concerning standards for facilities and specifications by type of medical institutions;
2. Matters concerning standards for safety control facilities in medical institutions;
3. Matters concerning standards for the operation of medical institutions and long-term care hospitals;
4. Matters concerning standards for the installation and operation of expensive medical equipment;
5. Matters concerning standards for the number of medical personnel, etc. by type of medical institutions;
6. Matters concerning standards for the management of meal services;
7. Matters concerning the sanitary administration of medical institutions;
8. Matters concerning the use of medicines and disposable medical supplies for injection by medical institutions;
9. Matters concerning standards for medical treatment provided by medical institutions to patients, etc. with an infectious disease prescribed in Article 41 (4) of the Infectious Disease Control and Prevention Act;

10. Matters concerning access standards for facilities requiring infection control in a medical institution, such as an operating room, delivery room and intensive care unit;
11. Matters concerning the installation of security equipment, placement of security personnel, etc. for the safety of medical personnel and patients;
12. Matters concerning the use of body protectors by medical institutions.

#Article 36 (Matters to Be Observed)

A person who establishes a medical institution in accordance with Article 33 (2) and (8) shall comply with the following matters, as prescribed by Ordinance of the Ministry of Health and Welfare: *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9386, Jan. 30, 2009; Act No. 9932, Jan. 18, 2010; Act No. 14220, May 29, 2016; Act No. 16375, Apr. 23, 2019; Act No. 16555, Aug. 27, 2019; Act No. 17069, Mar. 4, 2020>*

1. Matters concerning standards for facilities and specifications by type of medical institutions;
2. Matters concerning standards for safety control facilities in medical institutions;
3. Matters concerning standards for the operation of medical institutions and long-term care hospitals;
4. Matters concerning standards for the installation and operation of expensive medical equipment;
5. Matters concerning standards for the number of medical personnel, etc. by type of medical institutions;
6. Matters concerning standards for the management of meal service;
7. Matters concerning the sanitary administration of medical institutions;
8. Matters concerning the use of medicines and disposable medical instruments by medical institutions;
9. Matters concerning standards for medical treatment provided by medical institutions to patients, etc. with an infectious disease prescribed in Article 41 (4) of the Infectious Disease Control and Prevention Act;
10. Matters concerning access standards for facilities requiring infection control in a medical institution, such as an operating room, delivery room and intensive care unit;
11. Matters concerning the installation of security equipment, placement of security personnel, etc. for the safety of medical personnel and patients;
12. Matters concerning the use of body protectors by medical institutions;
13. Matters concerning the prevention of medical care-related infections by medical institutions.

Article 36-2 (Prohibition against Employment of Public Health Doctors)

- (1) No founder of a medical institution shall have a public health doctor defined in subparagraph 1 of Article 2 of the Act on Special Measures for Health and Medical Services in Agricultural and Fishing Villages perform medical practices nor appoint him/her as medical personnel on duty under Article 41 (1), unless the relevant medical institution is an institution or facility to which a public health doctor is assigned under Article 5-2 of the same Act or to which a public health doctor is dispatched under Article 6-2 of the same Act. *<Amended by Act No. 14438, Dec. 20, 2016; Act No. 15540, Mar. 27, 2018>*
- (2) No founder of a medical institution shall have doctors exclusively in charge of draft physical examination prescribed in subparagraph 14 of Article 2 of the Military Service Act perform medical practices nor appoint them as medical personnel on duty prescribed in Article 41 (1), unless they undergo training related to their duties at military hospitals or hospitals designated by the Commissioner of the Military Manpower Administration pursuant to Article 34-2 (2) of the same Act. *<Newly Inserted by Act No. 15540, Mar. 27, 2018>*

[This Article Newly Inserted by Act No. 13658, Dec. 29, 2015]

Article 37 (Radiation Generator for Diagnosis)

- (1) Where a medical institution intends to install and operate a radiation generator for diagnosis, the

medical institution shall report to the head of a *Si/Gun/Gu* in compliance with Ordinance of the Ministry of Health and Welfare and shall install and operate the generator in conformity with safety control standards prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

- (2) The founder or manager of each medical institution which has installed a radiation generator for diagnosis shall appoint a person responsible for safety control prescribed by Ordinance of Ministry of Health and Welfare, receive a periodic inspection and measurement, and control radiation exposure to staff members in radiation-related services. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>
- (3) Necessary matters concerning a radiation generator for diagnosis under paragraphs (1) and (2) such as scope, report, inspection, installation, and standards for measurement shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

Article 38 (Installation and Operation of Special Medical Equipment)

- (1) Where a medical institution intends to install and operate any medical equipment specified and publicly notified by the Minister of Health and Welfare as necessary for adequate installation and use thereof in accordance with the policy on public health and medical services (hereinafter referred to as "special medical equipment"), the medical institution shall register such equipment with the head of the competent *Si/Gun/Gu*, as prescribed by Ordinance of the Ministry of Health and Welfare and shall install and operate such equipment in conformity with the standards for approval for installation, as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11252, Feb. 1, 2012>
- (2) The founder or manager of a medical institution which has installed any special medical equipment in accordance with paragraph (1) shall receive a periodic inspection for quality control by the Minister of Health and Welfare, as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>
- (3) No founder or manager of a medical institution shall use any special medical equipment after it is determined as non-compliant through an inspection for quality control under paragraph (2).
- (4) The Minister of Health and Welfare may entrust the relevant specialized institution with all or some of affairs concerning inspections for quality control under paragraph (2), as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

Article 39 (Mutual Use of Facilities)

- (1) Medical personnel may use facilities, equipment, human resources, etc. of another medical institution for medical treatment with the consent of the head of the medical institution.
- (2) The head of a medical institution may, if deemed necessary for medical treatment of a patient in the medical institution, engage any of medical personnel who does not belong to the medical institution to give medical treatment to such patient.
- (3) Where a medical accident occurs in the course of medical treatment by using any facility, equipment, human resources, or any other instrument of any other medical institution, medical personnel who has given such medical treatment shall be responsible for the consequences of such accident if it has resulted from his/her negligence, while the founder of the medical institution that offered such facility, equipment, human resources, or any other instrument shall be responsible for the consequences of such accident if it has resulted from a defect in such facility, equipment, human resources, etc.

Article 40 (Reports on Closure and Suspension of Business and Transfer of Medical Records)

- (1) Where the founder of a medical institution intends to close business of the medical institution or

suspend it for at least one month (including suspension for a period of less than one month where there is any inpatient; hereafter the same shall apply in this Article), the founder shall report to the head of a *Si/Gun/Gu*, as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 14438, Dec. 20, 2016>

- (2) Where the founder of a medical institution reports the closure or suspension of business prescribed in paragraph (1), the founder shall transfer all medical records, etc. preserved in accordance with Article 22 or 23 to the director of the competent public health clinic: *Provided*, That the founder of a medical institution may keep such records in his/her custody only if he/she submits a plan for keeping such medical records, etc. as prescribed by Ordinance of the Ministry of Health and Welfare, and obtains approval from the director of the competent public clinic. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>
- (3) Notwithstanding the provisions of paragraph (1), the head of a *Si/Gun/Gu* need not accept the report on the closure of a medical institution if deemed necessary for an epidemiological investigation, when the Director of the Korea Centers for Disease Control and Prevention, a Mayor/*Do* Governor, or the head of the *Si/Gun/Gu* conducts an epidemiological investigation of an infectious disease or an epidemiological investigation on vaccination prescribed in Article 18 or 29 of the Infectious Disease Control and Prevention Act, or when any medical personnel or the head of a medical institution has requested the Minister of Health and Welfare or a Mayor/*Do* Governor to conduct an epidemiological investigation prescribed in Article 18-2 of the same Act. <Newly Inserted by Act No. 14220, May 29, 2016>
- (4) The founder of a medical institution who closes or suspends the medical institution shall take measures to protect the rights and interests of patients, such as the transfer of inpatients of the relevant medical institution to another medical institution, as prescribed by Ordinance of the Ministry of Health and Welfare. <Newly Inserted by Act No. 14438, Dec. 20, 2016>
- (5) The head of a *Si/Gun/Gu* in receipt of a report on the closure or suspension of a medical institution under paragraph (1) shall confirm whether the founder of the relevant medical institution has taken measures to protect the rights and interests of patients pursuant to paragraph (4) or shall take measures prescribed by Presidential Decree. <Newly Inserted by Act No. 14438, Dec. 20, 2016>

#Article 40 (Reports on Closure and Suspension of Business)

- (1) Where the founder of a medical institution intends to close the medical institution or suspend it for at least one month (including suspension for a period of less than one month where there is any inpatient; hereafter the same shall apply in this Article), the founder shall report to the head of a *Si/Gun/Gu*, as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 14438, Dec. 20, 2016>
- (2) Deleted. <by Act No. 17069, Mar. 4, 2020>
- (3) Notwithstanding the provisions of paragraph (1), the head of a *Si/Gun/Gu* need not accept the report on the closure of a medical institution if deemed necessary for an epidemiological investigation, when the Director of the Korea Centers for Disease Control and Prevention, a Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* conducts an epidemiological investigation of an infectious disease or an epidemiological investigation on vaccination prescribed in Article 18 or 29 of the Infectious Disease Control and Prevention Act, or when any medical personnel or the head of a medical institution has requested the Minister of Health and Welfare or a Mayor/*Do* Governor to conduct an epidemiological investigation prescribed in Article 18-2 of the same Act. <Newly Inserted by Act No. 14220, May 29, 2016>
- (4) The founder of a medical institution who closes or suspends the medical institution shall take measures to protect the rights and interests of patients, such as the transfer of inpatients of the relevant medical institution to' another medical institution, as prescribed by Ordinance of the Ministry of Health and Welfare. <Newly Inserted by Act No. 14438, Dec. 20, 2016>

- (5) The head of a *Si/Gun/Gu* in receipt of a report on the closure or suspension of a medical institution under paragraph (1) shall confirm whether the founder of the relevant medical institution has taken measures to protect the rights and interests of patients pursuant to paragraph (4) or shall take measures prescribed by Presidential Decree. <Newly Inserted by Act No. 14438, Dec. 20, 2016>

#Article 40-2 (Transfer of Medical Records)

- (1) Where the founder of a medical institution reports the closure or suspension of the medical institution pursuant to Article 40 (1), the founder shall confirm the quantities and lists of the medical records, etc. he/she recorded and preserves pursuant to Article 22 or 23 and transfer the medical records, etc. to the head of the competent public health clinic: Provided That where the founder of a medical institution obtains permission from the head of the competent public health clinic by submitting a plan for keeping medical records, etc. as prescribed by Ordinance of the Ministry of Health and Welfare, he/she may directly keep such medical records, etc.
- (2) Where a matter included in a keeping plan is changed, which is a matter prescribed by Ordinance of the Ministry of Health and Welfare, the founder of a medical institution who directly keeps medical records, etc. by obtaining permission from the head of the competent public health clinic shall report it to the head of the competent public health clinic, and where the founder of a medical institution directly keeping medical records, etc. is placed in a difficult situation to preserve and manage the medical records, etc. due to the causes prescribed by Ordinance of the Ministry of Health and Welfare, such as a disease or emigration, the founder shall designate a person to take charge of keeping the medical records, etc. vicariously, or transfer the medical records, etc. to the head of the competent public health clinic.
- (3) The founder of a medical institution who directly keeps medical records, etc. by obtaining permission from the head of the competent public health clinic pursuant to paragraph (1) shall observe the period and methods of keeping and other matters prescribed by Ordinance of the Ministry of Health and Welfare.
- (4) Articles 21 and 22 (2) shall apply *mutatis mutandis* to the reading and preservation of medical records which the founder of a medical institution (including persons in charge designated pursuant to paragraph (2)) directly keeps by obtaining permission from the head of the competent public health clinic pursuant to paragraph (1).
- (5) Matters necessary for methods, procedures, etc. of transferring medical records, etc. shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 17069, Mar. 4, 2020]

#Article 40-3 (Establishment and Operation of Medical Record Keeping System)

- (1) The Minister of Health and Welfare may establish and operate a system to assist the heads of the competent public health clinics keeping the medical records, etc. of medical institutions closing or suspending business pursuant to Article 40-2, and the founders of medical institutions to safely and effectively preserve and manage the medical records, etc. (hereinafter referred to as "medical record keeping system").
- (2) The heads of the competent public health clinics keeping the medical records, etc. of medical institutions closing or suspending business pursuant to Article 40-2 and the founders of medical institutions may keep medical records, etc. in the medical record keeping system.
- (3) The heads of the competent public health clinics and the founders of medical institution who keep medical records, etc. in the medical record keeping system pursuant to paragraph (2) (including the medical personnel and persons working for the relevant public health clinics and medical institutions) shall not read or confirm the details of information kept in the medical record keeping system, other than the medical records, etc. they directly kept in the medical record keeping system.
- (4) The Minister of Health and Welfare may entrust business to establish and operate the medical record

keeping system prescribed in paragraph (1) to a relevant specialized institution or organization. In such cases, the Minister of Health and Welfare may provide subsidies for the entire or some of costs incurred for business to establish and operate the medical record keeping system.

- (5) A specialized institution or organization to which business to establish and operate the medical record keeping system is entrusted pursuant to the former part of paragraph (4) shall be equipped with facilities and equipment necessary to manage and preserve medical records, etc. safely, as prescribed by Ordinance of the Ministry of Health and Welfare.
- (6) For the efficient operation of the medical record keeping system, the Minister of Health and Welfare may preserve and manage medical records, etc. by changing the forms of the medical records, etc. within the extent not to change the information included in the original, and may issue copies of medical records, etc. in forms changed.
- (7) No person shall damage, destruct, change, forge, disclose, search nor reproduce the information kept in the medical record keeping system without justifiable access authority or in excess of permitted access authority.
- (8) Matters necessary for the scope of establishment, operating procedures, etc. of the medical record keeping system shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 17069, Mar. 4, 2020]

Article 41 (Medical Personnel on Duty)

- (1) All kinds of hospitals shall have medical personnel on duty necessary to treat emergency patients and inpatients. *<Amended by Act No. 14438, Dec. 20, 2016>*
- (2) The number of medical personnel on duty and the standards for their placement under paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare, taking into account the types of hospitals, number of inpatients and other relevant matters. *<Newly Inserted by Act No. 14438, Dec. 20, 2016>*

Article 42 (Names of Medical Institutions)

- (1) No medical institution shall use any name, other than that designated for the type of medical institutions prescribed in Article 3 (2): *Provided*, That this shall not apply to any of the following cases: *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9386, Jan. 30, 2009; Act No. 9932, Jan. 18, 2010>*
 1. When a general hospital names itself a hospital;
 2. When a medical institution designated as a tertiary hospital pursuant to Article 3-4 (1), or as a specialized hospital pursuant to Article 3-5 (1) uses the name during the period of designation;
 3. When a clinic-level medical institution established pursuant to the proviso to Article 33 (8) uses a name together with the type of licenses;
 4. When a medical institution established by the State or a local government uses a name agreed upon with the Minister of Health and Welfare or a Mayor/*Do* Governor;
 5. When any name separately specified by any other statutes or regulations is used.
- (2) Matters necessary for the indication of the name of each medical institution shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*
- (3) No institution, other than medical institutions, shall use any name indicating a medical institution or any other similar name.

#Article 42 (Names of Medical Institutions)

- (1) No medical institution shall use any name, other than that designated for the type of medical institutions prescribed in Article 3 (2): *Provided*, That this shall not apply to any of the following cases: *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9386, Jan. 30, 2009; Act No. 9932, Jan.*

18, 2010; Act No. 17069, Mar. 4, 2020>

1. When a general hospital or a mental health hospital names itself a hospital;
 2. When a medical institution designated as a tertiary hospital pursuant to Article 3-4 (1), or as a specialized hospital pursuant to Article 3-5 (1) uses the name during the period of designation;
 3. When a clinic-level medical institution established pursuant to the proviso to Article 33 (8) uses the name together with the type of licenses;
 4. When a medical institution established by the State or a local government uses a name agreed upon with the Minister of Health and Welfare or a Mayor/*Do* Governor;
 5. When any name separately specified by any other statutes or regulations is used.
- (2) Matters necessary for the indication of the name of each medical institution shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*
- (3) No institution, other than medical institutions, shall use any name indicating a medical institution or any other similar name.

Article 43 (Specialized Department)

- (1) A hospital, dental hospital or general hospital may additionally establish and operate a specialized department for oriental medicine by hiring an oriental medical doctor.
- (2) A oriental medical hospital or dental hospital may additionally establish and operate a specialized department for medicine by hiring a physician.
- (3) A hospital, oriental medical hospital or long-term care hospital may additionally establish and operate a specialized department for dentistry by hiring a dentist.
- (4) Where a specialized department is additionally established and operated pursuant to paragraphs (1) through (3), facilities and equipment necessary for medical treatment shall be furnished, as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 9932, Jan. 18, 2010>*
- (5) Specialized departments of a medical institution, including those additionally established pursuant to paragraphs (1) through (3) shall be indicated in compliance with Ordinance of the Ministry of Health and Welfare: *Provided*, That specialized departments of dentistry may be indicated only by general hospitals and dental hospitals prescribed by Presidential Decree pursuant to Article 77 (3). *<Amended by Act No. 9932, Jan. 18, 2010>*

[This Article Wholly Amended by Act No. 9386, Jan. 30, 2009]

#Article 43 (Specialized Department)

- (1) A hospital, dental hospital or general hospital may additionally establish and operate a specialized department for oriental medicine by hiring an oriental medical doctor.
- (2) A oriental medical hospital or dental hospital may additionally establish and operate a specialized department for medicine by hiring a physician.
- (3) A hospital, oriental medical hospital, long-term care hospital or mental health hospital may additionally establish and operate a specialized department for dentistry by hiring a dentist. *<Amended by Act No. 17069, Mar. 4, 2020>*
- (4) Where a specialized department is additionally established and operated pursuant to paragraphs (1) through (3), facilities and equipment necessary for medical treatment shall be furnished, as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 9932, Jan. 18, 2010>*
- (5) Specialized departments of a medical institution, including those additionally established pursuant to paragraphs (1) through (3) shall be indicated in compliance with Ordinance of the Ministry of Health and Welfare: *Provided*, That specialized departments for dentistry may be indicated only by general hospitals and dental hospitals prescribed by Presidential Decree pursuant to Article 77 (3). *<Amended by Act No. 9932, Jan. 18, 2010>*

[This Article Wholly Amended by Act No. 9386, Jan. 30, 2009]

Article 44 Deleted. *<by Act No. 9386, Jan. 30, 2009>*

Article 45 (Notification of Non-Covered Medical Expenses)

- (1) The founder of a medical institution shall notify, as prescribed by Ordinance of the Ministry of Health and Welfare, the expenses (hereinafter referred to as "non-covered medical expenses") incurred in relation to items excluded from those eligible for health care benefits pursuant to Article 41 (4) of the National Health Insurance Act, or items excluded from those eligible for medical benefits pursuant to Article 7 (3) of the Medical Care Assistance Act in order for patients or his/her guardians to easily understand them. *<Amended by Act No. 9932, Jan. 18, 2010; Act No. 11141, Dec. 31, 2011; Act No. 14084, Mar. 22, 2016>*
- (2) The founder of a medical institution shall post the charges collected by the medical institution for issuing all kinds of certificates, as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 9932, Jan. 18, 2010>*
- (3) No founder of a medical institution may collect fees and charges in excess of an amount notified or posted under paragraphs (1) and (2).

[This Article Wholly Amended by Act No. 9386, Jan. 30, 2009]

Article 45-2 (Investigation of Current Status of Non-Covered Medical Expenses)

- (1) The Minister of Health and Welfare may investigate and analyze the current status of non-covered medical expenses and the items, standards, amount, etc. of charges for issuing all kinds of certificates referred to in Article 45 (2) (hereafter referred to as "non-covered medical expenses, etc." in this Article) of all medical institutions and disclose the results thereof: *Provided*, That in cases of hospital-level medical institutions, such results shall be disclosed. *<Amended by Act No. 14438, Dec. 20, 2016>*
- (2) For the investigation and analysis of the current status of non-covered medical expenses prescribed in paragraph (1), the Minister of Health and Welfare may order the head of a medical institution to submit related data. In such cases, the head of the relevant medical institution shall comply with such order, except in extenuating circumstances. *<Newly Inserted by Act No. 14438, Dec. 20, 2016>*
- (3) Matters necessary for the scope, methods, procedures, etc. of investigation of current status, analysis thereof, and disclosure of the results prescribed in paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 13658, Dec. 29, 2015]

Article 45-3 (Public Notification of Standards for Charges for Issuing All Types of Certificates)

The Minister of Health and Welfare shall determine and publicly notify the standards for items and amount of charges for issuing all types of certificates, taking into account the results of the investigation and analysis of the current status conducted under Article 45-2 (1).

[This Article Newly Inserted by Act No. 14438, Dec. 20, 2016]

Article 46 (Patients' Choice of Physicians for Medical Treatment)

- (1) A patient and his/her guardian may request the provision of medical treatment by choosing a specific physician, dentist or oriental medical doctor of a general hospital, hospital, dental hospital, oriental medical hospital or long-term care hospital. In such cases, the head of each medical institution shall assign the physician, dentist, or oriental medical doctor chosen by the patient or his/her guardian to treat the patient, except in extenuating circumstances. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 15540, Mar. 27, 2018>*
- (2) Any patient who receives a medical treatment by choosing a physician pursuant to paragraph (1) or the guardian of such patient may request the replacement of the physician, dentist or oriental medical doctor. In such cases, the head of the medical institution shall comply with such request unless

he/she has a justifiable ground therefor. *<Amended by Act No. 15540, Mar. 27, 2018>*

- (3) The head of each medical institution shall provide patients and their guardians with information for selecting a physician. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 15540, Mar. 27, 2018>*
- (4) No head of a medical institution shall charge any additional fee on patients or their guardians even though they receive a medical treatment pursuant to paragraph (1). *<Amended by Act No. 15540, Mar. 27, 2018>*
- (5) and (6) Deleted. *<by Act No. 15540, Mar. 27, 2018>*

#Article 46 (Patients' Choice of Physicians for Medical Treatment)

- (1) A patient and his/her guardian may request the provision of medical treatment by choosing a specific physician, dentist or oriental medical doctor of a general hospital, hospital, dental hospital, oriental medical hospital, long-term care hospital, or mental health hospital. In such cases, the head of each medical institution shall assign the physician, dentist, or oriental medical doctor chosen by the patient or his/her guardian to treat the patient, except in extenuating circumstances. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 15540, Mar. 27, 2018; Act No. 17069, Mar. 4, 2020>*
- (2) Any patient who receives a medical treatment by choosing a physician pursuant to paragraph (1) or the guardian of such patient may request the replacement of the physician, dentist or oriental medical doctor. In such cases, the head of the medical institution shall comply with such request unless he/she has a justifiable ground therefor. *<Amended by Act No. 15540, Mar. 27, 2018>*
- (3) The head of each medical institution shall provide patients and their guardians with information for selecting a physician. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 15540, Mar. 27, 2018>*
- (4) No head of a medical institution shall charge any additional fee on patients or their guardians even though they receive a medical treatment pursuant to paragraph (1). *<Amended by Act No. 15540, Mar. 27, 2018>*
- (5) and (6) Deleted. *<by Act No. 15540, Mar. 27, 2018>*

Article 47 (Preventive Measures against Hospital Infection)

- (1) The head of each hospital-level medical institution, the size of which is greater than the size prescribed by Ordinance of the Ministry of Health and Welfare, shall take necessary measures for preventing hospital infection including the establishment and operation of an infection control committee and infection control rooms and the placement of personnel dedicated to infection control as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11005, Aug. 4, 2011>*
- (2) To prevent infectious diseases prescribed in subparagraph 1 of Article 2 of the Infectious Disease Control and Prevention Act, the head of a medical institution shall educate medical personnel and persons working for the medical institution on a regular basis. *<Newly Inserted by Act No. 16375, Apr. 23, 2019>*
- (3) The head of a medical institution shall, where an infectious disease defined in subparagraph 1 of Article 2 of the Infectious Disease Control and Prevention Act prevails, provide patients, patients' guardians, and persons who conduct their duties inside the relevant medical institution, such as medical personnel, persons working for the medical institution, and security guards defined in subparagraph 3 of Article 2 of the Security Services Industry Act, with information necessary to prevent the spread of the infectious disease. *<Newly Inserted by Act No. 13658, Dec. 29, 2015; Act No. 16375, Apr. 23, 2019>*
- (4) Matters necessary for the organization and operation of infection control committees and the operation of infection control rooms under paragraph (1), education under paragraph (2), provision

of information under paragraph (3), etc. shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11005, Aug. 4, 2011; Act No. 13658, Dec. 29, 2015; Act No. 16375, Apr. 23, 2019>

#Article 47 (Preventive Measures against Medical Care-Related Infections)

- (1) The head of each hospital-level medical institution, the size of which is greater than the size prescribed by Ordinance of the Ministry of Health and Welfare, shall take necessary measures for preventing medical care-related infections including the establishment and operation of an infection control committee and infection control rooms and the placement of personnel dedicated to infection control as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11005, Aug. 4, 2011; Act No. 17069, Mar. 4, 2020>
- (2) To prevent infectious diseases prescribed in subparagraph 1 of Article 2 of the Infectious Disease Control and Prevention Act, the head of a medical institution shall educate medical personnel and persons working for the medical institution on a regular basis. <Newly Inserted by Act No. 16375, Apr. 23, 2019>
- (3) The head of a medical institution shall, where any infectious disease defined in subparagraph 1 of Article 2 of the Infectious Disease Control and Prevention Act prevails, provide patients, patients' guardians, and persons who conduct their duties inside the relevant medical institution, such as medical personnel, persons working for the medical institution, and security guards defined in subparagraph 3 of Article 2 of the Security Services Industry Act, with information necessary to prevent the spread of the infectious disease. <Newly Inserted by Act No. 13658, Dec. 29, 2015; Act No. 16375, Apr. 23, 2019>
- (4) The Minister of Health and Welfare may establish and operate a medical care-related infection surveillance system for the medical and scientific surveillance of outbreaks, causes, etc. of medical-care related infections. <Newly Inserted by Act No. 17069, Mar. 4, 2020>
- (5) A medical institution may register the outbreak of medical care-related infections with the system prescribed in paragraph (4) monthly. <Newly Inserted by Act No. 17069, Mar. 4, 2020>
- (6) The Minister of Health and Welfare may entrust business to establish and operate the system prescribed in paragraph (4) to a relevant specialized institution, as prescribed by Presidential Decree. <Newly Inserted by Act No. 17069, Mar. 4, 2020>
- (7) The Minister of Health and Welfare may order a specialized institution to which business is entrusted pursuant to paragraph (6) to submit a report or materials on such business. <Newly Inserted by Act No. 17069, Mar. 4, 2020>
- (8) The head of a medical institution, medical personnel, a person working for a medical institution, a patient, etc. who comes to know the outbreak of a medical care-related infection may report such fact (hereafter referred to as "voluntary report" in this Article) to the Minister of Health and Welfare, as prescribed by Ordinance of the Ministry of Health and Welfare. In such cases, the Minister of Health and Welfare shall not disclose the identification of a person who files a voluntary report against the will of such person. <Newly Inserted by Act No. 17069, Mar. 4, 2020>
- (9) Where a person who files a voluntary report has violated the relevant statutes and regulations in connection with the relevant medical care-related infection, the administrative sanctions taken against such person may be mitigated or exempted. <Newly Inserted by Act No. 17069, Mar. 4, 2020>
- (10) Information on medical care-related infections for which a voluntary report is filed shall undergo the omission of personally identifiable parts after a verification prescribed by Ordinance of the Ministry of Health and Welfare. <Newly Inserted by Act No. 17069, Mar. 4, 2020>
- (11) No person who engages or engaged in business to receive, analyze, etc. voluntary reports shall divulge confidential information he/she comes to know in the course of conducting his/her duties to

other persons nor use such confidential information for purposes other than for conducting his/her duties. <Newly Inserted by Act No. 17069, Mar. 4, 2020>

- (12) The head of a medical institution shall not take actions in disfavor of persons who file a voluntary report and who belong to the relevant medical institution in relation to their status or treatment, such as dismissal or transferring to another position on the ground of filing such report. <Newly Inserted by Act No. 17069, Mar. 4, 2020>
- (13) The Minister of Health and Welfare may utilize information on medical care-related infections, which is collected pursuant to paragraph (4) or (8) for measures necessary for the prevention and control of infections, formulation of plans, survey, research, education, etc. <Newly Inserted by Act No. 17069, Mar. 4, 2020>
- (14) Matters necessary for the organization and operation of infection control committees and operation of infection control rooms prescribed in paragraph (1), education prescribed in paragraph (2), provision of information prescribed in paragraph (3), types, procedures and methods of registration, etc. of medical care-related infections registered pursuant to paragraph (5) shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 17069, Mar. 4, 2020>

Article 47-2 (Transfer of Inpatients to Another Hospital)

Where an inpatient's life or health is likely to be harmed unless the patient is urgently transferred to another medical institution due to natural disasters, suspected case of infectious disease, or outbreak of multiple casualties but the head of a medical institution is unable to obtain consent from the patient or his/her guardian or has an inevitable cause prescribed by Ordinance of the Ministry of Health and Welfare, the head of the medical institution may transfer the inpatient to another medical institution by obtaining approval from the head of a *Si/Gun/Gu*, as prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 16254, Jan. 15, 2019]

SECTION 2 Medical Corporation

Article 48 (Permission for Establishment)

- (1) A person, who intends to establish a medical corporation under Article 33 (2), shall prepare the articles of association and other documents, as prescribed by Presidential Decree, and shall obtain permission from a Mayor/*Do* Governor having jurisdiction over the principal place of business of the medical corporation.
- (2) A medical corporation shall either be equipped with the facilities or secure the fund required for the medical corporation to be equipped with such facilities.
- (3) A medical corporation shall, whenever it intends to dispose of its property or modify its articles of association, obtain permission from a relevant Mayor/*Do* Governor.
- (4) No entity, other than medical corporations prescribed in this Act shall use the title of a medical corporation or any other similar name.

Article 48-2 (Executive Officers)

- (1) A medical corporation shall have not less than five and not more than 15 directors and two auditors but such number may be increased or decreased with approval from the Minister of Health and Welfare.
- (2) The term of office of directors and auditors shall be prescribed by the articles of incorporation but shall not exceed four years and two years, respectively: *Provided*, That directors and auditors may be re-appointed, respectively.
- (3) The number of directors who have a relationship of relatives prescribed in Article 777 of the Civil Act with the other directors shall not exceed 1/4 of the fixed number of the board of directors.

- (4) None of the following persons shall become an executive officer of a medical corporation:
1. A minor;
 2. A person under adult guardianship or person under limited guardianship;
 3. A person declared bankrupt and not yet reinstated;
 4. A person for whom three years have not passed since his/her imprisonment without labor or heavier punishment declared by a court was completely executed or the non-execution of such sentence became final.
- (5) No auditor shall have a special relationship prescribed in paragraph (3) with directors.
[This Article Newly Inserted by Act No. 16555, Aug. 27, 2019]
 [Enforcement Date: Feb. 28, 2020] Article 48-2

Article 49 (Incidental Business)

- (1) A medical corporation may engage in the following incidental businesses at a medical institution established by the medical corporation, in addition to medical services. In such cases, accounts for the earnings from such incidental business shall be separated from other accounts of the medical corporation: *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 13108, Jan. 28, 2015>*
1. Education and refresher training for medical personnel and other persons involved in medical services;
 2. Research and study on medical services or medical science;
 3. Installation and operation of facilities for medical care and welfare for senior citizens prescribed in subparagraph 2 of Article 31 of the Welfare of Senior Citizens Act;
 4. Installation and operation of a funeral parlor prescribed in Article 29 (1) of the Act on Funeral Services, etc.;
 5. Installation and operation of an auxiliary parking lot prescribed in Article 19 (1) of the Parking Lot Act;
 6. Business prescribed by Presidential Decree to develop and operate medical information systems necessary for the provision of medical services;
 7. Operation of snack restaurants, ordinary restaurants, barber shops, beauty shops for the convenience of patients and staff of the medical institution established by the medical corporation, as prescribed by Ordinance of the Ministry of Health and Welfare.
- (2) A medical corporation, which intends to operate incidental business set forth in paragraph (1) 4, 5 and 7, may lease or outsource such business to a third person for operation and management.
- (3) A medical corporation which intends to operate incidental business in accordance with paragraph (1) or (2) shall report in advance to the Mayor/Do Governor who has jurisdiction over the location of a medical institution, as prescribed by Ordinance of the Ministry of Health and Welfare. The foregoing shall also apply to revision to any matter reported. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

Article 50 (Application Mutatis Mutandis of the Civil Act)

Except as otherwise provided for in this Act, the provisions of the Civil Act concerning incorporated foundations shall apply *mutatis mutandis* to medical corporations.

Article 51 (Revocation of Permission for Establishment)

Where a medical corporation falls under any of the following cases, the Minister of Health and Welfare or a relevant Mayor/Do Governor may revoke permission for the establishment of the medical corporation: *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

1. Where a medical corporation engages in any business other than those stipulated in the articles of incorporation;

2. Where a medical corporation fails to establish a medical institution within two years after its incorporation;
3. Where permission for the establishment of a medical institution established by a medical corporation is revoked pursuant to Article 64;
4. Where a medical corporation violates an order issued by the Minister of Health and Welfare or a Mayor/Do Governor for supervision;
5. Where a medical corporation engages in any business, other than incidental businesses under Article 49 (1).

Article 51-2 (Prohibition of Giving and Receiving Money and Valuables in Connection with Appointment of Executive Officers)

No person shall give and receive or promise to give and receive money, valuables, entertainment, or other economic benefits in connection with the appointment of executive officers of medical corporations.

[This Article Newly Inserted by Act No. 16555, Aug. 27, 2019]

SECTION 3 Association of Medical Institutions

Article 52 (Establishment of Association of Medical Institutions)

- (1) The heads of a hospital-level medical institutions may establish an association with a nationwide organization in order to contribute to the sound development of medical institutions and the improvement of public health. *<Amended by Act No. 9386, Jan. 30, 2009>*
- (2) The association under paragraph (1) shall be a legal entity.

Article 52-2 (National Academy of Medicine of Korea)

- (1) The National Academy of Medicine of Korea (hereafter referred to as the "National Academy" in this Article) shall be established to build foundation for the research and promotion of medical science and relevant specialized fields (hereafter referred to as "medical science, etc." in this Article) related to medical personnel and to find and utilize outstanding health and medical personnel.
- (2) The National Academy shall be a corporation.
- (3) The National Academy shall perform the following duties:
 1. Survey, research, and provision of counselling and advice necessary for the promotion of research of medical science, etc.;
 2. Planning and recommendation of mid- and long-term research for each field of medical science, etc.;
 3. International and domestic exchanges and cooperation projects of medical science, etc.;
 4. Provision of counselling and advice on social issues related to medical science, etc. and national health and public relations thereon;
 5. Projects for admiring and preserving honor of health and medical personnel;
 6. Projects designated or entrusted by the Minister of Health and Welfare for the development of medical science, etc.
- (4) The Minister of Health and Welfare may subsidize all or part of the expenses incurred in performing duties of the National Academy within budgetary limits.
- (5) Except as otherwise provided for in this Act, the provisions of the Civil Act concerning incorporated associations shall apply to the National Assembly.
- (6) No person, other than the National Academy, shall use the name "National Academy of Medicine of Korea" or any other similar name.
- (7) Matters necessary for the operation of the National Academy and the performance of its duties shall be prescribed by Presidential Decree.

[This Article Newly Inserted by Act No. 13658, Dec. 29, 2015]

CHAPTER IV Evaluation of New Medical Technology

Article 53 (Evaluation of New Medical Technology)

- (1) In order to protect public health and promote the development of medical technology, the Minister of Health and Welfare shall evaluate the safety, efficacy, etc. of new medical technology (hereinafter referred to as "evaluation of new medical technology") following deliberation at a meeting of the Committee for Evaluation of New Medical Technology under Article 54, as prescribed by Presidential Decree. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*
- (2) "New medical technology" in paragraph (1) means medical technology newly developed, the safety and efficacy of which are deemed to require evaluation by the Minister of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*
- (3) The Minister of Health and Welfare shall notify the results of the evaluation of new medical technology to the President of the Health Insurance Review and Assessment Service under Article 64 of the National Health Insurance Act. In such cases, the results of the evaluation of new medical technology may be publicly announced, as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11141, Dec. 31, 2011>*
- (4) Other matters necessary for the subject matter, procedures, etc. for the evaluation of new medical technology shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

Article 54 (Establishment, etc. of New Medical Technology Evaluation Committee)

- (1) The Minister of Health and Welfare shall establish a New Medical Technology Evaluation Committee (hereinafter referred to as the "Committee") within the Ministry of Health and Welfare for a review on the matters concerning the evaluation of new medical technology. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*
- (2) The Committee shall be composed of 20 or less committee members including one chairperson.
- (3) The committee members shall be commissioned or appointed by the Minister of Health and Welfare from among the persons who fall under any of the following subparagraphs: *Provided*, That the committee chairperson shall be appointed from among the persons who fall under subparagraph 1 or 2: *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*
 1. Persons recommended by the physicians' association, the dentists' association, and the oriental medical doctors' association prescribed by Article 28 (1), respectively;
 2. Persons who have good knowledge about public health and medical services;
 3. Persons recommended by a consumer group;
 4. Licensed attorneys having at least five-year career experience relating to public health and medical services;
 5. Grade V or higher public officials accountable for affairs in policies on public health and medical services in the Ministry of Health and Welfare.
- (4) The term of office for the committee chairperson and members shall be three years, and they may be reappointed or recommissioned: *Provided*, That the term of office for any public official under paragraph (3) 5 shall correspond to the term of his/her service as a public official.
- (5) A vacancy of a committee member shall be filled with a new member appointed, and the term of office for such new member shall begin on the date on which he/she is appointed.
- (6) The Committee shall have subcommittees for evaluation of specialized fields, each of which shall devote to review on the matters of a specific field among the matters brought before the Committee.
- (7) Other necessary matters concerning the organization, management, etc. of the Committee and subcommittees shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

Article 55 (Entrustment of Affairs Relating to Collection of Data)

The Minister of Health and Welfare may entrust the relevant specialized institution or organization with the affairs incidental to the evaluation including collection of data and survey, as prescribed by Ordinance of the Ministry of Health and Welfare, if necessary for executing the affairs relating to the evaluation of new medical technology. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

CHAPTER V Advertisement of Medical Services

Article 56 (Prohibition against Medical Advertisements)

- (1) No person who is not the founder of a medical institution, the head of a medical institution, or medical personnel (hereinafter referred to as "medical personnel, etc.") shall run an advertisement for medical services (referring to acts of indicating information on medical services, medical institutions and medical personnel, etc. or giving such information to consumers by means of newspapers, magazines, voices, sound, images, the internet, printed materials, signboards and others methods; hereinafter referred to as "medical advertisement"). <Amended by Act No. 15540, Mar. 27, 2018>
- (2) No medical personnel, etc. shall run any of the following advertisements of medical services: <Amended by Act No. 9386, Jan. 30, 2009; Act No. 14220, May 29, 2016; Act No. 15540, Mar. 27, 2018>
 1. Advertisement of new medical technology without undergoing the evaluation prescribed in Article 53;
 2. Advertisement including contents that are likely to mislead consumers about the effect of medical treatment, such as a story of one's experience in treating patients;
 3. Advertisement indicating a false fact;
 4. Advertisement with any content that compares with a function or treatment method of any other medical personnel, etc.;
 5. Advertisement with any content that defames any other medical personnel, etc.;
 6. Advertisement with any content that directly exposes medical treatment, such as the scene of operation;
 7. Advertisement in which any important information, such as serious side effects in relation to the functions of medical personnel, etc. or the treatment methods, is omitted;
 8. Advertisement that exaggerates an objective fact;
 9. Advertisement that expresses a legally groundless qualification or name;
 10. Advertisement that shows its contents in the form of a news article or expert opinion using a newspaper, broadcasting medium, magazine, or any other medium;
 11. Advertisement with contents not examined in accordance with Article 57 or different from the contents examined;
 12. Domestic advertisements for attracting foreign patients prescribed in Article 27 (3);
 13. Advertisement with any content that causes consumers to obtain reduction of or exemption from non-covered medical expenses referred to in Article 45 in the manner that is likely to deceive consumers or give them wrong information;
 14. Advertisement using various certificates of merit, letters of appreciation, etc. or advertisement using the fact of obtaining certification, guarantee or recommendation or expressing anything similar thereto: *Provided*, That the following cases shall be excluded:
 - (a) Advertisement indicating the accreditation of medical institution prescribed in Article 58;
 - (b) Advertisement indicating certification or guarantee obtained from central administrative

- agencies, and special local administrative agencies and affiliated bodies prescribed in Articles 2 through 4 of the Government Organization Act, local governments prescribed in Article 2 of the Local Autonomy Act, or public institutions prescribed in Article 4 of the Act on the Management of Public Institutions;
- (c) Advertisement indicating certification or guarantee obtained by other statutes or regulations;
- (d) Advertisement prescribed by Presidential Decree, such as an advertisement indicating certification obtained from an international evaluation organization that has signed for cooperation with the World Health Organization;
15. Other advertisements of medical services prescribed by Presidential Decree, the methods or contents of which are likely to impair the public health and the sound order of medical services competition or to cause damage to consumers.
- (3) No medical advertisement shall be run in any of the following methods: *<Amended by Act No. 15540, Mar. 27, 2018>*
1. Broadcasting prescribed in subparagraph 1 of Article 2 of the Broadcasting Act;
 2. Other methods prescribed by Presidential Decree, when necessary to impose a restriction in order to protect the public health and maintain the sound order of medical services competition.
- (4) Matters necessary for medical advertisements, including the details of medical advertisements prohibited pursuant to paragraph (2), shall be prescribed by Presidential Decree. *<Amended by Act No. 15540, Mar. 27, 2018>*
- (5) Where the Minister of Health and Welfare or the head of a *Si/Gun/Gu* intends to take measures prescribed in Articles 63, 64 or 67 for medical personnel, etc. who have violated paragraph (2) 2 through 5 and 7 through 9, he/she shall notify the Fair Trade Commission of the details thereof without delay. *<Newly Inserted by Act No. 14220, May 29, 2016; Act No. 15540, Mar. 27, 2018>*
- [This Article, which was determined to be inconsistent with the Constitution by the Constitutional Court on Dec. 23, 2015, is amended by Act No. 15540, Mar. 27, 2018]*

Article 57 (Deliberation of Medical Advertisements)

- (1) Where medical personnel, etc. intend to run a medical advertisement by using any of the following media, he/she shall in advance undergo deliberation by institutions or organizations prescribed in paragraph (2) on whether such medical advertisement is in violation of Article 56 (1) through (3): *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11005, Apr. 4, 2011; Act No. 13726, Jan. 6, 2016; Act No. 15540, Mar. 27, 2018>*
1. Newspapers or on-line newspapers referred to in Article 2 of the Act on the Promotion of Newspapers, or periodicals referred to in Article 2 of the Act on Promotion of Periodicals, including Magazines;
 2. Placards, posters, leaflets and those displayed on transport facilities and transport means (including advertisements displayed inside transport means and advertisements made with images, voices and sound and the combination thereof) among outdoor advertisements referred to in subparagraph 1 of Article 2 of the Act on the Management of Outdoor Advertisements and Promotion of Outdoor Advertisement Industry;
 3. Electronic display boards;
 4. Internet media (including applications used by mobile devices) prescribed by Presidential Decree;
 5. Other advertising media prescribed by Presidential Decree in consideration of the nature, influence, etc. of advertising media.
- (2) The following institutions or organizations may have an organization, etc. for voluntary deliberation, report it to the Minister of Health and Welfare, and conduct deliberation on medical advertisements, as prescribed by Presidential Decree: *<Amended by Act No. 15540, Mar. 27, 2018>*
1. A physicians' association, dentists' association and oriental medical doctors' association prescribed in Article 28 (1);

2. An organization that meets the standards prescribed by Presidential Decree as a consumer organization registered pursuant to Article 29 of the Framework Act on Consumers.
- (3) Notwithstanding paragraph (1), medical personnel, etc. may not undergo deliberation by an institution or organization reported to the Minister of Health and Welfare pursuant to paragraph (2) (hereinafter referred to as "voluntary deliberation agency") as to medical advertisements consisting of the following matters: *<Amended by Act No. 15540, Mar. 27, 2018>*
 1. Name, location and telephone number of a medical institution;
 2. Specialized departments established and operated by a medical institution (referring to specialized departments prescribed in Article 43 (5));
 3. Names, gender and types of license of medical personnel belonging to a medical institution;
 4. Other matters prescribed by Presidential Decree.
- (4) A voluntary deliberation agency shall prepare the standards applicable to deliberation prescribed in paragraph (1) through mutual consultation. *<Amended by Act No. 15540, Mar. 27, 2018>*
- (5) Any person who intends to undergo deliberation on a medical advertisement shall pay a fee determined by the voluntary deliberation agency. *<Newly Inserted by Act No. 15540, Mar. 27, 2018>*
- (6) Articles 29 (3), 30 (1), 32 and 83 (1), and Article 37 of the Civil Act shall not apply to deliberation on medical advertisements and business affairs related thereto the voluntary deliberation agency prescribed in paragraph (2) 1 conducts, and Article 37 of the Civil Act shall not apply to deliberation on medical advertisements and business affairs related thereto conducted by the voluntary deliberation agency prescribed in paragraph (2) 2. *<Newly Inserted by Act No. 15540, Mar. 27, 2018>*
- (7) A voluntary deliberation agency may propose its opinion about the improvement of medical advertisement systems and statutes or regulations to the Minister of Health and Welfare. *<Newly Inserted by Act No. 15540, Mar. 27, 2018>*
- (8) The validity period of deliberation prescribed in paragraph (1) shall be three years from the date on which a request for deliberation is approved. *<Newly Inserted by Act No. 15540, Mar. 27, 2018>*
- (9) Where medical personnel, etc. intend to continue to run a medical advertisement after the validity prescribed in paragraph (8) expires, he/she shall request deliberation on the medical advertisement from the voluntary deliberation agency not later than six months before the expiration of the validity period. *<Newly Inserted by Act No. 15540, Mar. 27, 2018>*
- (10) Except as provided in paragraphs (1) through (9), a voluntary deliberation agency shall determine matters necessary for the organization, operation and deliberation of the voluntary deliberation agency. *<Newly Inserted by Act No. 15540, Mar. 27, 2018>*
- (11) A voluntary deliberation agency shall conduct deliberation-related business prescribed in paragraphs (1) and (4) in a fair and transparent manner pursuant to Article 56 (1) through (3). *<Newly Inserted by Act No. 15540, Mar. 27, 2018>*

Article 57-2 (Deliberation Committees for Medical Advertisements)

- (1) To deliberate medical advertisements, a voluntary deliberation agency shall establish and operate a deliberation committee as classified in the subparagraphs of paragraph (2) (hereafter referred to as "deliberation committee" in this Article).
- (2) Types of deliberation committees and subject matters of deliberation shall be as follows:
 1. A deliberation committee for medical advertisements: Deliberating medical advertisements run by physicians, medical clinics, founders of medical clinics, hospitals, founders of hospitals, long-term care hospitals (excluding those founded by oriental medical doctors), founders of long-term care hospitals, general hospitals (excluding dental hospitals; hereafter the same shall apply in this subparagraph), founders of general hospitals, midwives, midwifery clinics, and founders of midwifery clinics;

2. A deliberation committee for dental advertisements: Deliberating medical advertisements run by dentists, dental clinics, founders of dental clinics, dental hospitals, founders of dental hospitals, general hospitals (limited to general dental hospitals; hereafter the same shall apply in this subparagraph), and founders of general hospitals;
 3. A deliberation committee for oriental medical advertisements: Deliberating medical advertisements run by oriental medical doctors, oriental medical clinics, founders of oriental medical clinics, oriental medical hospitals, founders of oriental medical hospitals, long-term care hospitals (limited to those founded by oriental medical doctors; hereafter the same shall apply in this subparagraph), and founders of long-term care hospitals.
- (3) A physicians' association, dentists' association and oriental medical doctors' association shall establish and operate only a deliberation committee prescribed in paragraph (2) 1, a deliberation committee prescribed in subparagraph 2 of the same paragraph, and a deliberation committee prescribed in subparagraph 3 of the same paragraph among voluntary deliberation agencies prescribed in Article 57 (2) 1, respectively, and a voluntary deliberation agency prescribed in Article 57 (2) 2 shall establish and operate only a deliberation committee which falls under any of the subparagraphs of paragraph (2).
- (4) A deliberation committee shall be comprised of not less than 15 and not more than 25 members including one chairperson and one vice-chairperson. In such cases, it shall be organized according to the following classifications based on the types of deliberation committees prescribed in the subparagraphs of paragraph (2):
1. A deliberation committee for medical advertisements: Its members shall include each one of the persons prescribed in paragraph (5) 2 through 9 but at least 1/3 of its members shall be comprised of persons prescribed in subparagraphs 4 through 9 of the same paragraph;
 2. A deliberation committee for dental advertisements: Its members shall include each one of the persons prescribed in paragraph (5) 1 and 3 through 9 but at least 1/3 of its members shall be comprised of persons prescribed in subparagraphs 4 through 9 of the same paragraph;
 3. A deliberation committee for oriental medical advertisements: Its members shall include each one of the persons prescribed in paragraph (5) 1, 2 and 4 through 9 but at least 1/3 of its members shall be comprised of persons prescribed in subparagraphs 4 through 9 of the same paragraph.
- (5) The head of a voluntary deliberation agency shall commission the members of each deliberation committee from among the following persons:
1. A physician;
 2. A dentist;
 3. A oriental medical doctor;
 4. A pharmacist prescribed in subparagraph 2 of Article 2 of the Pharmaceutical Affairs Act;
 5. A person recommended by the head of a consumer organization prescribed in subparagraph 3 of Article 2 of the Framework Act on Consumers;
 6. An attorney-at-law registered with the Korean Bar Association prescribed in Article 78 of the Attorney-at-Law Act pursuant to Article 7 (1) of the same Act and recommended by the President of the Korean Bar Association;
 7. A person recommended by the head of a corporation established pursuant to Article 32 of the Civil Act mainly for the purpose of expanding the social participation and promoting the welfare of women;
 8. A person recommended by the head of an organization that is registered pursuant to Article 4 of the Assistance for Non-Profit, Non-Governmental Organizations Act and is established mainly for the purpose of protecting the rights and interests of patients;
 9. Other persons with abundant knowledge and experience in public health and medical services or medical advertisements.
- (6) Except as provided in paragraphs (1) through (5), a voluntary deliberation agency shall determine

matters necessary for the organization and operation of the deliberation committee.

[This Article Newly Inserted by Act No. 15540, Mar. 27, 2018]

#Article 57-2 (Deliberation Committees for Medical Advertisements)

- (1) To deliberate medical advertisements, a voluntary deliberation agency shall establish and operate a deliberation committee as classified in the subparagraphs of paragraph (2) (hereafter referred to as "deliberation committee" in this Article).
- (2) Types of deliberation committees and subject matters of deliberation shall be as follows: *<Amended by Act No. 17069, Mar. 4, 2020>*
 1. A deliberation committee for medical advertisements: Deliberating medical advertisements run by physicians, medical clinics, founders of medical clinics, hospitals, founders of hospitals, long-term care hospitals (excluding those founded by oriental medical doctors), founders of long-term care hospitals, mental health hospitals, founders of mental health hospitals, general hospitals (excluding dental hospitals; hereafter the same shall apply in this subparagraph), founders of general hospitals, midwives, midwifery clinics, and founders of midwifery clinics;
 2. A deliberation committee for dental advertisements: Deliberating medical advertisements run by dentists, dental clinics, founders of dental clinics, dental hospitals, founders of dental hospitals, general hospitals (limited to general dental hospitals; hereafter the same shall apply in this subparagraph), and founders of general hospitals;
 3. A deliberation committee for oriental medical advertisements: Deliberating medical advertisements run by oriental medical doctors, oriental medical clinics, founders of oriental medical clinics, oriental medical hospitals, founders of oriental medical hospitals, long-term care hospitals (limited to those founded by oriental medical doctors; hereafter the same shall apply in this subparagraph), and founders of long-term care hospitals.
- (3) A physicians' association, dentists' association and oriental medical doctors' association shall establish and operate only a deliberation committee prescribed in paragraph (2) 1, a deliberation committee prescribed in subparagraph 2 of the same paragraph, and a deliberation committee prescribed in subparagraph 3 of the same paragraph among voluntary deliberation agencies prescribed in Article 57 (2) 1, respectively, and a voluntary deliberation agency prescribed in Article 57 (2) 2 shall establish and operate only a deliberation committee which falls under any of the subparagraphs of paragraph (2).
- (4) A deliberation committee shall be comprised of not less than 15 and not more than 25 members including one chairperson and one vice-chairperson. In such cases, it shall be organized according to the following classifications based on the types of deliberation committees prescribed in the subparagraphs of paragraph (2):
 1. A deliberation committee for medical advertisements: Its members shall include each one of the persons prescribed in paragraph (5) 2 through 9 but at least 1/3 of its members shall be comprised of persons prescribed in subparagraphs 4 through 9 of the same paragraph;
 2. A deliberation committee for dental advertisements: Its members shall include each one of the persons prescribed in paragraph (5) 1 and 3 through 9 but at least 1/3 of its members shall be comprised of persons prescribed in subparagraphs 4 through 9 of the same paragraph;
 3. A deliberation committee for oriental medical advertisements: Its members shall include each one of the persons prescribed in paragraph (5) 1, 2 and 4 through 9 but at least 1/3 of its members shall be comprised of persons prescribed in subparagraphs 4 through 9 of the same paragraph.
- (5) The head of a voluntary deliberation agency shall commission the members of each deliberation committee from among the following persons:
 1. A physician;
 2. A dentist;
 3. A oriental medical doctor;

4. A pharmacist prescribed in subparagraph 2 of Article 2 of the Pharmaceutical Affairs Act;
 5. A person recommended by the head of a consumer organization prescribed in subparagraph 3 of Article 2 of the Framework Act on Consumers;
 6. An attorney-at-law registered with the Korean Bar Association prescribed in Article 78 of the Attorney-at-Law Act pursuant to Article 7 (1) of the same Act and recommended by the President of the Korean Bar Association;
 7. A person recommended by the head of a corporation established pursuant to Article 32 of the Civil Act mainly for the purpose of expanding the social participation and promoting the welfare of women;
 8. A person recommended by the head of an organization that is registered pursuant to Article 4 of the Assistance for Non-Profit, Non-Governmental Organizations Act and is established mainly for the purpose of protecting the rights and interests of patients;
 9. Other persons with abundant knowledge and experience in public health and medical services or medical advertisements.
- (6) Except as provided in paragraphs (1) through (5), a voluntary deliberation agency shall determine matters necessary for the organization and operation of the deliberation committee.

[This Article Newly Inserted by Act No. 15540, Mar. 27, 2018]

Article 57-3 (Monitoring Medical Advertisements)

A voluntary deliberation agency shall monitor whether medical advertisements are in compliance with Article 56 (1) through (3), and submit the results of the monitoring to the Minister of Health and Welfare as prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 15540, Mar. 27, 2018]

CHAPTER VI Supervision

Article 58 (Accreditation of Medical Institutions)

- (1) The Minister of Health and Welfare may accredit a hospital-level medical institution (hereinafter referred to as "accreditation of medical institutions") in order to improve the quality of medical services and the safety of patients.
- (2) The Minister of Health and Welfare may entrust affairs pertaining to the accreditation of medical institutions to the relevant specialized institution (hereinafter referred to as "accrediting institution"), as prescribed by Presidential Decree. In such cases, the Minister may provide the budget subsidies as required.
- (3) The Minister of Health and Welfare may integrate evaluations conducted for medical institutions under other statutes or regulations and have the accrediting institution conduct such integrated evaluations.

[This Article Wholly Amended by Act No. 10387, Jul. 23, 2010]

#Article 58 (Accreditation of Medical Institutions)

- (1) The Minister of Health and Welfare may accredit hospital-level medical institutions, and medical institutions prescribed by Presidential Decree (hereinafter referred to as "accreditation of medical institutions") in order to improve the quality of medical services and the safety of patients. *<Amended by Act No. 17069, Mar. 4, 2020>*
- (2) The Minister of Health and Welfare may entrust affairs pertaining to the accreditation of medical institutions to the Korea Institute for Healthcare Accreditation prescribed in Article 58-11, as prescribed by Presidential Decree. *<Amended by Act No. 17069, Mar. 4, 2020>*

- (3) The Minister of Health and Welfare may integrate evaluations conducted for medical institutions under other statutes or regulations and have the Korea Institute for Healthcare Accreditation prescribed in Article 58-11 conduct such integrated evaluations. *<Amended by Act No. 17069, Mar. 4, 2020>*

[This Article Wholly Amended by Act No. 10387, Jul. 23, 2010]

Article 58-2 (Medical Institution Accreditation Commission)

- (1) The Minister of Health and Welfare shall establish the Medical Institution Accreditation Commission under his/her jurisdiction (hereinafter referred to as "Commission") to review major policies on accreditation of medical institutions.
- (2) The Commission shall be comprised of 15 or less members, including one chairperson.
- (3) The Vice Minister of Health and Welfare shall serve as the chairperson of the Commission, and the commission members shall be commissioned or appointed by the Minister of Health and Welfare from among the following persons: *<Amended by Act No. 14220, May 29, 2016>*
 1. Persons recommended by an organization of medical personnel prescribed in Article 28 and an association of medical institutions prescribed in Article 52;
 2. Persons recommended by a labor circle, civic organization (referring to a non-profit, non-governmental organization prescribed in Article 2 of the Assistance for Non-Profit, Non-Governmental Organizations Act), and a consumer organization prescribed in Article 29 of the Framework Act on Consumers;
 3. Persons with abundant knowledge and experiences in public health;
 4. Person with abundant knowledge and experiences in safety diagnosis of facilities;
 5. A public official of Grade III or higher who belongs to the Ministry of Health and Welfare, or a public official who belongs to the Senior Civil Service.
- (4) The Commission shall review the following:
 1. Matters concerning major policies on accreditation of medical institutions, including accreditation standards and accreditation publication;
 2. Matters concerning integration of medical institution evaluation systems prescribed in Article 58 (3);
 3. Matters concerning utilization of accreditation of medical institutions prescribed in Article 58-7 (2);
 4. Other matters referred for deliberation by the chairperson of the Commission.
- (5) The organization and operation of the Commission and other necessary matters therefor shall be prescribed by Presidential Decree.

[This Article Newly Inserted by Act No. 10387, Jul. 23, 2010]

Article 58-3 (Accreditation Standards and Methods of Medical Institutions)

- (1) The accreditation standards of medical institutions shall include the following:
 1. Patient's rights and safety;
 2. Activities to promote service quality of medical institutions;
 3. Procedures for providing medical services and outcomes therefrom;
 4. Organization, human resource management and operation of medical institutions;
 5. Patient satisfaction.
- (2) The Minister of Health and Welfare shall evaluate whether a medical institution which has requested meets the accreditation standards under paragraph (2).
- (3) The Minister of Health and Welfare shall notify, without delay, the head of the relevant medical institution of the results and accreditation level evaluated under paragraph (2).
- (4) Accreditation levels shall be divided into accreditation, conditional accreditation and non-accreditation.
- (5) The validity of accreditation shall be four years: *Provided*, That the validity of conditional accreditation shall be one year.
- (6) The head of a medical institution which has been granted conditional accreditation shall obtain

re-accreditation within the validity, as prescribed by Ordinance of the Ministry of Health and Welfare.

- (7) Details in accreditation standards pursuant to paragraph (1) shall be determined by the Minister of Health and Welfare.

[This Article Newly Inserted by Act No. 10387, Jul. 23, 2010]

#Article 58-3 (Accreditation Standards and Methods of Medical Institutions)

- (1) The accreditation standards of medical institutions shall include the following:
1. Patient's rights and safety;
 2. Activities to promote service quality of medical institutions;
 3. Procedures for providing medical services and outcomes therefrom;
 4. Organization, human resource management and operation of medical institutions;
 5. Patient satisfaction.
- (2) Accreditation levels shall be divided into accreditation, conditional accreditation and non-accreditation. *<Amended by Act No. 17069, Mar. 4, 2020>*
- (3) The validity of accreditation shall be four years: *Provided*, That the validity of conditional accreditation shall be one year. *<Amended by Act No. 17069, Mar. 4, 2020>*
- (4) The head of a medical institution which has been granted conditional accreditation shall obtain re-accreditation within the validity, as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 17069, Mar. 4, 2020>*
- (5) The Minister of Health and Welfare shall determine details of accreditation standards prescribed in paragraph (1). *<Amended by Act No. 17069, Mar. 4, 2020>*

[This Article Newly Inserted by Act No. 10387, Jul. 23, 2010]

Article 58-4 (Application for Accreditation of Medical Institutions)

- (1) The head of a medical institution may file an application for accreditation with the Minister of Health and Welfare, as prescribed by Ordinance of the Ministry of Health and Welfare.
- (2) Notwithstanding the provisions of paragraph (1), the head of a long-term care hospital referred to in Article 3 (2) 3 (excluding medical institutions which meet the requirements under Article 3-2 for medical rehabilitation facilities under Article 58 (1) 2 of the Act on Welfare of Persons with Disabilities) shall file an application for accreditation with the Minister of Health and Welfare, as prescribed by Ordinance of the Ministry of Health and Welfare.
- (3) Upon approval from the Minister of Health and Welfare, the accrediting institution may collect fees required for accreditation from the head of a medical institution which has filed an application therefor.

[This Article Newly Inserted by Act No. 10387, Jul. 23, 2010]

#Article 58-4 (Application for Accreditation and Evaluation of Medical Institutions)

- (1) The head of a medical institution may file an application for accreditation with the Minister of Health and Welfare, as prescribed by Ordinance of the Ministry of Health and Welfare.
- (2) Notwithstanding the provisions of paragraph (1), the head of a long-term care hospital referred to in Article 3 (2) 3 (excluding medical institutions which meet the requirements under Article 3-2 for medical rehabilitation facilities under Article 58 (1) 4 of the Act on Welfare of Persons with Disabilities) shall file an application for accreditation with the Minister of Health and Welfare, as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 17069, Mar. 4, 2020>*
- (3) Where a long-term care hospital required to apply for accreditation pursuant to paragraph (2) obtains conditional accreditation or non-accreditation, or its accreditation or conditional accreditation is cancelled pursuant to Article 58-10 (1) 4 and 5, the head of the relevant long-term care hospital shall

apply for re-accreditation within the period prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 17069, Mar. 4, 2020>

- (4) The Minister of Health and Welfare shall evaluate whether a medical institution applying for accreditation is in compliance with the accreditation standards prescribed in Article 58-3 (1). In such cases, the Minister of Health and Welfare may conduct necessary investigations, as prescribed by Ordinance of the Ministry of Health and Welfare, and the medical institution applying for accreditation shall cooperate therefor unless it has any justifiable ground to the contrary. <Newly Inserted by Act No. 17069, Mar. 4, 2020>
- (5) The Minister of Health and Welfare shall notify the head of the relevant medical institution of the results of evaluation prescribed in paragraph (4) and the accreditation level of such medical institution without delay. <Newly Inserted by Act No. 17069, Mar. 4, 2020>

[This Article Newly Inserted by Act No. 10387, Jul. 23, 2010]

Article 58-5 (Applications for Objections)

- (1) The head of a medical institution that has filed an application for accreditation may file an application for objections with the Minister of Health and Welfare with regards to evaluation results or accreditation level.
- (2) The application for objections under paragraph (1) shall be filed within 30 days from the date the head of a medical institution is notified of the evaluation results or accreditation level: *Provided*, That where the head of a medical institution could not observe the period due to any cause not attributable to himself/herself, it shall be counted from the date on which such cause has been extinguished.
- (3) Necessary matters concerning the means to file an application for objections under paragraph (1) and notification of process results, etc. shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 10387, Jul. 23, 2010]

Article 58-6 (Certificate of Accreditation and Accreditation Mark)

- (1) The Minister of Health and Welfare may grant a certificate of accreditation to a medical institution which has been accredited, produce a mark showing the accreditation (hereinafter referred to as "accreditation mark"), and permit the medical institution to use such mark.
- (2) Without being accredited pursuant to Article 58 (1), no person shall produce or use a certificate of accreditation or an accreditation mark or assume accreditation in other means.
- (3) Necessary matters concerning the design of an accreditation mark and methods of indication, etc. shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 10387, Jul. 23, 2010]

Article 58-7 (Publication and Utilization of Accreditation)

- (1) The Minister of Health and Welfare shall publish, on its website, etc., matters prescribed by Ordinance of the Ministry of Health and Welfare, such as accreditation standards, validity of accreditation, and evaluation results under Article 58-3 (2) of a medical institution which has been accredited.
- (2) The Minister of Health and Welfare may provide a medical institution with the following administrative and financial support, etc. based on the evaluation results and accreditation levels under Article 58-3 (3):
 1. Designation of tertiary hospitals under Article 3 (4);
 2. Designation of specialized hospitals under Article 3 (5);
 3. Other matters prescribed in other Acts or deemed necessary by the Minister of Health and Welfare.
- (3) Necessary matters concerning notification, etc. under paragraph (1) shall be prescribed by Ordinance

of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 10387, Jul. 23, 2010]

#Article 58-7 (Publication and Utilization of Accreditation)

- (1) The Minister of Health and Welfare shall publish, on its website, etc., matters prescribed by Ordinance of the Ministry of Health and Welfare, such as accreditation standards, term of validity of accreditation, and evaluation results under Article 58-4 (4) of a medical institution which has been accredited. *<Amended by Act No. 17069, Mar. 4, 2020>*
- (2) The Minister of Health and Welfare may provide a medical institution with the following administrative and financial support, etc. based on the evaluation results and accreditation levels under Article 58-4 (4): *<Amended by Act No. 17069, Mar. 4, 2020>*
 1. Designation of tertiary care hospitals under Article 3 (4);
 2. Designation of specialized hospitals under Article 3 (5);
 3. Support for education and consulting to upgrade the quality of medical services and safety of patients;
 4. Other matters prescribed in other Acts or deemed necessary by the Minister of Health and Welfare.
- (3) Necessary matters concerning notification, etc. under paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 10387, Jul. 23, 2010]

Article 58-8 (Request for Data)

- (1) If necessary for accreditation, the Minister of Health and Welfare may request the relevant administrative agency, medical institution, other public organization, etc. to provide data and cooperation.
- (2) A person who has been requested to provide data and cooperation shall comply with such request unless there exist any justifiable grounds to the contrary.

[This Article Newly Inserted by Act No. 10387, Jul. 23, 2010]

Article 58-9 (Cancellation of Accreditation of Medical Institutions)

- (1) The Minister of Health and Welfare may cancel accreditation or conditional accreditation of a medical institution where it falls under any of the following cases: *Provided*, That if it falls under subparagraphs 1 and 2, the Minister shall cancel accreditation or conditional accreditation:
 1. Where it obtains accreditation or conditional accreditation by fraud or other unlawful means;
 2. Where permission for the establishment of a medical institution is cancelled or where an order for the closure of a medical institution is issued pursuant to Article 64 (1);
 3. Where a grave fact which serves as the premise or basis of accreditation or conditional accreditation such as alteration to the type of a medical institution, is changed.
- (2) No medical institution whose accreditation has been cancelled pursuant to paragraph (1) 1 shall file an application for accreditation within one year from the date on which its accreditation or conditional accreditation is cancelled.

[This Article Newly Inserted by Act No. 10387, Jul. 23, 2010]

#Article 58-9 (Post-Management of Accreditation of Medical Institutions)

To maintain the effectiveness of accreditation, the Minister of Health and Welfare may investigate whether a medical institution that has obtained accreditation is in compliance with the accreditation standards prescribed in Article 58-3 (1), as prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 17069, Mar. 4, 2020]

#Article 58-10 (Cancellation of Accreditation of Medical Institutions)

- (1) Where a medical institution that has obtained accreditation falls into any of the following cases during the validity of the accreditation, the Minister of Health and Welfare may order the cancellation of the accreditation or conditional accreditation of such medical institution, suspension of use of accreditation mark or correction: *Provided*, That where falling under subparagraphs 1 and 2, the Minister shall cancel the accreditation or conditional accreditation: <Amended by Act No. 17069, Mar. 4, 2020>
 1. Where a medical institution obtains accreditation or conditional accreditation by false or other unjust methods;
 2. Where permission for the establishment of a medical institution is cancelled or an order for the closure of a medical institution is issued pursuant to Article 64 (1);
 3. Where a grave fact that serves as the premise or basis of accreditation or conditional accreditation, such as the change of type of medical institution, is changed;
 4. Where a medical institution fails to meet the accreditation standards prescribed in Article 58-3 (1);
 5. Where a medical institution violates an order for the suspension of use of accreditation mark or correction.
- (2) No medical institution of which accreditation is cancelled pursuant to paragraph (1) 1 shall apply for accreditation within one year from the date on which its accreditation or conditional accreditation is cancelled.
- (3) Procedures necessary for the cancellation of accreditation or conditional accreditation of medical institutions, suspension of use of accreditation marks, etc., standards for sanctions, etc. prescribed in paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Newly Inserted by Act No. 17069, Mar. 4, 2020>

[This Article Newly Inserted by Act No. 10387, Jul. 23, 2010]

#Article 58-11 (Establishment of the Korea Institute for Healthcare Accreditation)

- (1) The Korea Institute for Healthcare Accreditation (hereinafter referred to as the "KOIHA") shall be established to efficiently conduct business concerning the accreditation of medical institutions and various evaluation business for medical institutions.
- (2) The KOIHA shall conduct the following business:
 1. Business concerning the accreditation of medical institutions, which is entrusted pursuant to Article 58 (2);
 2. Evaluation business for medical institutions under other statutes, which the Minister of Health and Welfare entrusts;
 3. Other business the Minister of Health and Welfare entrusts under this Act or other statutes.
- (3) The KOIHA shall be a juristic person and shall be established by filing a registration of incorporation at the location of its principal office.
- (4) The KOIHA shall have executives and necessary employees, as prescribed by the articles of association.
- (5) The Minister of Health and Welfare may provide subsidies for expenses necessary for the operation and business of the KOIHA within budgetary limits.
- (6) The KOIHA may collect costs incurred for accreditation from the heads of medical institutions applying for accreditation by obtaining approval from the Minister of Health and Welfare.
- (7) The KOIHA may conduct profit-making business, such as education and consulting, within the extent not interfering with conducting business prescribed in paragraph (2), as prescribed by Ordinance of the Ministry of Health and Welfare.
- (8) The provisions pertaining to incorporated foundations in the Civil Act shall apply *mutatis mutandis* to the KOIHA except for the matters prescribed by this Act and the Act on the Management of Public Institutions.

[This Article Newly Inserted by Act No. 17069, Mar. 4, 2020]

Article 59 (Guidance and Order)

- (1) The Minister of Health and Welfare or a relevant Mayor/*Do* Governor may provide guidance or issue an order to medical institutions or medical personnel, if considered necessary for policies on public health and medical services, or if a serious hazard occurs or is likely to occur to public health. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*
- (2) The Minister of Health and Welfare, a relevant Mayor/*Do* Governor or the head of a relevant *Si/Gun/Gu* may order medical personnel or founders of medical institutions to resume medical service, if there is a reasonable ground to believe that suspension of medical service by the medical personnel without any justifiable ground, or temporary shutdown or closure of medical institutions by a group of the founders causes or is likely to cause great difficulties in giving medical treatment to patients. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*
- (3) Any medical personnel or founder of a medical institution shall comply with an order issued pursuant to paragraph (2) without any justifiable ground.

Article 60 (Establishment of Plan for Supply and Demand for Patient Beds)

- (1) The Minister of Health and Welfare shall formulate a basic implementation policy for the reasonable supply and placement of hospital beds every five years. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 16555, Aug. 27, 2019>*
- (2) A Mayor/*Do* Governor shall formulate a plan for supply and demand and management of hospital beds of medical institutions by region, by function and by type for each Special Metropolitan City, Metropolitan City or *Do* based on the basic implementation policy prescribed in paragraph (1) and in consideration of the actual status of the relevant region, and submit the plan to the Minister of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 16555, Aug. 27, 2019>*
- (3) Where a plan for supply and demand and management of hospital beds submitted pursuant to paragraph (2) is not in compliance with the basic implementation policy prescribed in paragraph (1) or there is any other ground prescribed by Ordinance of the Ministry of Health and Welfare, the Minister of Health and Welfare shall amend the plan in consulting with a Mayor/*Do* Governor, as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 16555, Aug. 27, 2019>*

Article 60-2 (Medical Personnel Supply and Demand Plans)

- (1) The Minister of Health and Welfare shall formulate basic policies for securement and appropriate supply of outstanding medical personnel.
- (2) The basic policies prescribed in paragraph (1) shall be formulated in connection with plans on development of health and medical services referred to in Article 15 of the Framework Act on Health and Medical Services.

[This Article Newly Inserted by Act No. 13658, Dec. 29, 2015]

Article 60-3 (Establishment and Operation of Employment Training Centers for Nursing Work Force)

- (1) For the purpose of providing and expanding integrated nursing and caring services and the smooth supply and demand of nursing work force, the Minister of Health and Welfare may establish and operate regional employment training centers for nursing work force, which perform the following duties:
 1. Survey on the current securement of nursing work force of each region and each medical institution;
 2. Support for employment education for prospective graduates of universities, colleges, or junior colleges (including vocational schools and nursing schools under the old system) majoring in nursing science and new nursing work force;
 3. Support for career development for continuous employment of nursing work force;

4. Support for employment education of nursing work force idling or separated from employment;
 5. Other matters prescribed by Ordinance of the Ministry of Health and Welfare to provide support for employment education of nursing work force.
- (2) To efficiently operate an employment training center for nursing work force, the Minister of Health and Welfare may entrust the affairs related to the operation thereof to a related specialized institution or organization in accordance with the procedures and methods prescribed by Presidential Decree.
 - (3) Where the affairs related to the operation of an employment training center for nursing work force are entrusted under paragraph (2), the State or a local government may subsidize expenses incurred in relation to the operation of such center.
 - (4) Other matters necessary for the operation, etc. of employment training centers for nursing work force shall be prescribed by Ordinance of the Minister of Health and Welfare.

[This Article Newly Inserted by Act No. 13658, Dec. 29, 2015]

Article 61 (Reports and Inspection of Business)

- (1) The Minister of Health and Welfare, a Mayor/*Do* Governor or the head of a *Si/Gun/Gu* may order the founders of medical institutions or medical personnel to report necessary matters or may have relevant public officials inspect the current status of business affairs, facilities, or related documents including medical records, midwifery records and nursing records or ascertain facts by hearing statements of interested persons. In such cases, the founders of the medical institutions or medical personnel shall not reject such order or inspection without good cause. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11005, Aug. 4, 2011; Act No. 14438, Dec. 20, 2016; Act No. 15540, Mar. 27, 2018; Act No. 15540, Mar. 27, 2018; Act No. 16555, Aug. 27, 2019>*
- (2) In the case of paragraph (1), a related public official shall carry an identification verifying his/her authority and a written order for inspection indicating the period of inspection, scope of inspection, person in charge of inspection, relevant statutes or regulations, etc. and present them to interested persons. *<Amended by Act No. 11005, Aug. 4, 2011>*
- (3) Matters necessary for reports referred to in paragraph (1) and written orders for inspection referred to in paragraph (2) shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11005, Aug. 4, 2011>*

Article 61-2 (Request for Materials)

- (1) If necessary to conduct the relevant duties, such as ascertaining whether this Act is violated, the Minister of Health and Welfare may request medical personnel, the heads of medical institutions, the National Health Insurance Service and the Health Insurance Review and Assessment Service under the National Health Insurance Act, other relevant administrative agencies and organizations, etc. to submit necessary materials or to make a statement of opinion, etc.
- (2) Any person requested to provide materials or render cooperation pursuant to paragraph (1) shall comply therewith unless there is a compelling reason not to do so.

[This Article Newly Inserted by Act No. 16555, Aug. 27, 2019]

Article 62 (Accounting Standards for Medical Institutions)

- (1) The founder of a medical institution shall endeavor to keep its accounts transparent.
- (2) The founder of a general hospital equivalent to or greater than the size prescribed by Ordinance of the Ministry of Health and Welfare shall comply with the accounting standards for medical institutions to keep its accounts transparent. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*
- (3) The accounting principles for medical institutions under paragraph (2) shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

#Article 62 (Accounting Standards for Medical Institutions)

- (1) The founder of a medical institution shall endeavor to keep its accounts transparent.
- (2) The founder of a hospital-level medical institution with not less than 100 patient beds and above the size prescribed by Ordinance of the Ministry of Health and Welfare shall comply with the accounting standards for medical institutions to keep its accounts transparent. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 17069, Mar. 4, 2020>
- (3) The accounting principles for medical institutions under paragraph (2) shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

Article 63 (Corrective Order)

- (1) Where a medical institution violates Articles 15 (1) and 16 (2), the latter part of Article 21 (1), and Articles 21 (2) and (3), 23 (2), 34 (2), 35 (2), 36, 36-2, 37 (1) and (2), 38 (1) and (2), 41 through 43, 45, 46, 47 (1), 58-4 (2) and 62 (2), a general hospital, tertiary hospital, or specialized hospital fails to meet the requirements prescribed in Article 3-3 (1), 3-4 (1) or 3-5 (2), respectively, or the head of a medical institution violates Article 4 (5), or an voluntary deliberation agency violates Article 57 (11), the Minister of Health and Welfare or the head of a *Si/Gun/Gu* may fully or partially restrict or ban the use of the facilities and equipment thereof for a specific period or issue an order for correcting such violations. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9386, Jan. 30, 2009; Act No. 9932, Jan. 18, 2010; Act No. 10387, Jul. 23, 2010; Act No. 10609, Apr. 28, 2011; Act No. 13599, Dec. 22, 2015; Act No. 13658, Dec. 29, 2015; Act No. 14220, May 29, 2016; Act No. 14438, Dec. 20, 2016; Act No. 15540, Mar. 27, 2018>
- (2) Where medical personnel, etc. violate Article 56 (2) or (3), the Minister of Health and Welfare or the head of a *Si/Gun/Gu* may issue an order to take the following measures: <Newly Inserted by Act No. 15540, Mar. 27, 2018>
 1. Suspension of the violation;
 2. Publication of the violation;
 3. Advertisement for corrections.
- (3) Matters necessary to take the measures under paragraph (2) 2 and 3 shall be prescribed by Presidential Decree. <Newly Inserted by Act No. 15540, Mar. 27, 2018>

#Article 63 (Corrective Order)

- (1) Where a medical institution violates Articles 15 (1) and 16 (2), the latter part of Article 21 (1), and Articles 21 (2) and (3), 23 (2), 34 (2), 35 (2), 36, 36-2, 37 (1) and (2), 38 (1) and (2), 41 through 43, 45, 46, 47 (1), 58-4 (2) and (3) and 62 (2), a general hospital, tertiary hospital, or specialized hospital fails to meet the requirements prescribed in Article 3-3 (1), 3-4 (1) or 3-5 (2), respectively, or the head of a medical institution violates Article 4 (5), or an voluntary deliberation agency violates Article 57 (11), the Minister of Health and Welfare or the head of a *Si/Gun/Gu* may fully or partially restrict or ban the use of the facilities and equipment thereof for a specific period or issue an order for correcting such violations. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9386, Jan. 30, 2009; Act No. 9932, Jan. 18, 2010; Act No. 10387, Jul. 23, 2010; Act No. 10609, Apr. 28, 2011; Act No. 13599, Dec. 22, 2015; Act No. 13658, Dec. 29, 2015; Act No. 14220, May 29, 2016; Act No. 14438, Dec. 20, 2016; Act No. 15540, Mar. 27, 2018; Act No. 17069, Mar. 4, 2020>
- (2) Where medical personnel, etc. violates Article 56 (2) or (3), the Minister of Health and Welfare or the head of a *Si/Gun/Gu* may issue an order to take the following measures: <Newly Inserted by Act No. 15540, Mar. 27, 2018>
 1. Suspension of the violation;
 2. Publication of the violation;

3. Advertisement for corrections.

- (3) Matters necessary to take the measures under paragraph (2) 2 and 3 shall be prescribed by Presidential Decree. <Newly Inserted by Act No. 15540, Mar. 27, 2018>

Article 64 (Revocation of Permission for Establishment)

- (1) The Minister of Health and Welfare or the head of a relevant *Si/Gun/Gu* may suspend the medical services of a medical institution for a period of up to one year or an order to revoke establishment permission or to close business, if the medical institution falls under any of the following subparagraphs: *Provided*, That in cases falling under subparagraph 8, the Minister of Health and Welfare or the head of a related *Si/Gun/Gu* shall revoke permission for the establishment or issue an order for closure, while an order for closure may be issued only to any of the medical institutions reported under Article 33 (3) and the main sentence of Article 35 (1): <Amended by Act No. 8559, Jul. 27, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9386, Jan. 30, 2009; Act No. 9932, Jan. 18, 2010; Act No. 11005, Aug. 4, 2011; Act No. 12069, Aug. 13, 2013; Act No. 13599, Dec. 22, 2015; Act No. 13658, Dec. 29, 2015; Act No. 14220, May 29, 2016; Act No. 14438, Dec. 20, 2016; Act No. 15716, Aug. 14, 2018; Act No. 16375, Apr. 23, 2019; Act No. 16555, Aug. 27, 2019>
1. When a medical institution fails to commence its services without just ground within three months after reporting on, or obtaining permission for, its establishment;
 2. When a medical institution allows a disqualified person to provide medical services or has any medical personnel provide medical services not included in the licensed services, in violation of Article 27 (5);
 3. When a medical institution avoids or hinders the relevant public official's duties pursuant to Article 61 or violates an order issued pursuant to Article 59 or 63;
 4. When a medical corporation, non-profit corporation, quasi-government agency, local medical center or the Korea Veterans Welfare and Health Care Corporation prescribed in Article 33 (2) 3 through 5 is subject to the revocation of its establishment, or is dissolved;
 - 4-2. When a medical institution is established, in violation of Article 33 (2);
 5. When a medical institution violates Article 33 (5), (7), (9) or (10), 40, or 56: *Provided*, That the same shall not apply where it violates Article 33 (7) 4 for any reason not attributable to the founder of the medical institution himself/herself;
 - 5-2. Where a medical institution fails to provide medical services for at least six months without filing a report of closure or suspension of business prescribed in Article 40 (1) without good cause;
 6. When a medical institution fails to comply with a corrective order issued pursuant to Article 63 (excluding a corrective order issued against a violation of Article 4 (5));
 7. When a medical institution commits an act in collusion with others, in violation of Article 24 (2) of the Pharmaceutical Affairs Act;
 8. When the founder of a medical institution is sentenced to imprisonment without labor or heavier punishment on a charge of a fraudulent claim for medical expenses, and such sentence becomes final and conclusive;
 9. Where a medical institution inflicts damage on a human life or body in violation of the matters to be observed prescribed in Article 36.
- (2) Any person, whose permission for the establishment is revoked or who receives an order for closure pursuant to paragraph (1), shall be barred from establishing or operating a medical institution within six months from the date when permission is revoked or the order for closure is issued; or a person who has received the disposition of the suspension of medical services shall be barred from establishing or operating a medical institution during a period for suspension of business: *Provided*, That a person, whose permission for the establishment of a medical institution is revoked or who receives an order for closure pursuant to paragraph (1) 8, shall be barred from establishing or

operating a medical institution within three years from the date when permission is revoked or the order for closure is issued.

- (3) Where a medical institution is suspended from its medical services or receives an order for revocation of permission for its establishment or for its closure, the Minister of Health and Welfare or the head of a *Si/Gun/Gu* shall take measures to protect the rights and interests of patients, such as the transfer of inpatients of the relevant medical institution to another medical institution. <Newly Inserted by Act No. 14438, Dec. 20, 2016>

#Article 64 (Revocation of Permission for Establishment)

- (1) The Minister of Health and Welfare or the head of a relevant *Si/Gun/Gu* may suspend medical services of a medical institution for a period of up to one year or issue an order to revoke establishment permission or to close business if the medical institution falls under any of the following subparagraphs: *Provided*, That in cases falling under subparagraph 8, the Minister of Health and Welfare or the head of a related *Si/Gun/Gu* shall revoke permission for the establishment or issue an order for closure, while an order for closure may be issued only to any of the medical institutions reported under Article 33 (3) and the main sentence of Article 35 (1): <Amended by Act No. 8559, Jul. 27, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9386, Jan. 30, 2009; Act No. 9932, Jan. 18, 2010; Act No. 11005, Aug. 4, 2011; Act No. 12069, Aug. 13, 2013; Act No. 13599, Dec. 22, 2015; Act No. 13658, Dec. 29, 2015; Act No. 14220, May 29, 2016; Act No. 14438, Dec. 20, 2016; Act No. 15716, Aug. 14, 2018; Act No. 16375, Apr. 23, 2019; Act No. 16555, Aug. 27, 2019; Act No. 17069, Mar. 4, 2020>
1. When a medical institution fails to commence its service without just ground within three months after reporting on, or obtaining permission for, its establishment;
 2. When a medical institution allows a disqualified person to provide medical services or has any medical personnel provide medical services not included in the licensed services, in violation of Article 27 (5);
 3. When a medical institution avoids or hinders the relevant public official's duties pursuant to Article 61 or violates an order issued pursuant to Article 59 or 63;
 4. When a medical corporation, non-profit corporation, quasi-government agency, local medical center or the Korea Veterans Welfare and Health Care Corporation prescribed in Article 33 (2) 3 through 5 is subject to the revocation of its establishment, or is dissolved;
 - 4-2. When a medical institution is established, in violation of Article 33 (2);
 5. When a medical institution violates Article 33 (5), (7), (9) or (10), 40, 40-2 or 56: *Provided*, That the same shall not apply where it violates Article 33 (7) 4 for any reason not attributable to the founder of the medical institution himself/herself;
 - 5-2. Where a medical institution fails to provide medical services for at least six months without filing a report on closure or suspension of business prescribed in Article 40 (1) without good cause;
 6. When a medical institution fails to comply with a corrective order issued pursuant to Article 63 (excluding a corrective order issued against a violation of Article 4 (5));
 7. When a medical institution commits an act in collusion with others, in violation of Article 24 (2) of the Pharmaceutical Affairs Act;
 8. When the founder of a medical institution is sentenced to imprisonment without labor or heavier punishment on a charge of a fraudulent claim for medical expenses, and such sentence becomes final and conclusive;
 9. Where a medical institution inflicts damage on a human life or body in violation of the matters to be observed prescribed in Article 36.
- (2) Any person, whose permission for the establishment is revoked or who receives an order for closure pursuant to paragraph (1), shall be barred from establishing or operating a medical institution within

six months from the date when permission is revoked or the order for closure is issued; or a person who has received the disposition of the suspension of medical services shall be barred from establishing or operating a medical institution during a period for suspension of business: *Provided*, That a person, whose permission for the establishment of a medical institution is revoked or who receives an order for closure pursuant to paragraph (1) 8, shall be barred from establishing or operating a medical institution within three years from the date when permission is revoked or the order for closure is issued.

- (3) Where a medical institution is suspended from its medical services or receives an order for revocation of permission for its establishment or for its closure, the Minister of Health and Welfare or the head of a *Si/Gun/Gu* shall take measures to protect the rights and interests of patients, such as the transfer of inpatients of the relevant medical institution to another medical institution. <Newly Inserted by Act No. 14438, Dec. 20, 2016>

Article 65 (Revocation and Re-Issuance of Licenses)

- (1) Where medical personnel falls under any of the following cases, the Minister of Health and Welfare may revoke his/her license: *Provided*, That the license of medical personnel who falls under subparagraph 1 shall be revoked: <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9386, Jan. 30, 2009; Act No. 9906, Dec. 31, 2009; Act No. 9932, Jan. 18, 2010; Act No. 13658, Dec. 29, 2015; Act No. 14220, May 29, 2016; Act No. 17069, Mar. 4, 2020>

1. When he/she falls under any subparagraph of Article 8;
2. When he/she continues medical practices during the period for which his/her qualification is suspended pursuant to Article 66 or receives the disposition of qualification suspension at least three times;
3. When he/she fails to fulfill any condition attached to his/her license pursuant to Article 11 (1);
4. Where he/she leases his/her license in violation of Article 4-3 (1);
5. Deleted; <by Act No. 14438, Dec. 20, 2016>
6. Where he/she causes serious hazard to human life or body in violation of Article 4 (6).

- (2) The Minister of Health and Welfare may re-issue a license to a person whose license has been revoked pursuant to paragraph (1), if grounds for such revocation cease to exist, or if it is found that the person has shown significant signs of repentance: *Provided*, That no license shall be re-issued within one year after revocation thereof if the license was revoked pursuant to paragraph (1) 3, within two years if the license was revoked pursuant to paragraph (1) 2, or within three years if the former license was revoked pursuant to paragraph (1) 4 or 6, or subparagraph 4 of Article 8, respectively. <Amended by Act No. 8559, Jul. 27, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 14220, May 29, 2016; Act No. 14438, Dec. 20, 2016; Act No. 16555, Aug. 27, 2019>

Article 66 (Suspension of Qualification)

- (1) The Minister of Health and Welfare may suspend qualification of a licensed medical personnel for up to one year, if he/she falls under any of the following cases. In such cases, matters necessary for medico-technical judgment may be decided after hearing the opinions of relevant experts: <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9906, Dec. 31, 2009; Act No. 9932, Jan. 18, 2010; Act No. 10325, May 27, 2010; Act No. 10565, Apr. 7, 2011; Act No. 11005, Aug. 4, 2011; Act No. 14220, May 29, 2016; Act No. 14438, Dec. 20, 2016; Act No. 16375, Apr. 23, 2019; Act No. 16555, Aug. 27, 2019>

1. When he/she severely undermines the dignity of medical personnel;
2. When he/she is employed by a person disqualified as the founder of a medical institution and performs medical practices;
- 2-2. When he/she violates Article 4 (6);

3. When he/she falsely prepares and issues a medical certificate or a postmortem examination report or certificate prescribed in Article 17 (1) and (2), or falsely prepares a medical record, etc. referred to in Article 22 (1) or intentionally make additional indications/corrections thereto different from the fact;
 4. When he/she violates Article 20;
 5. When he/she has any person, other than medical personnel, provide medical services, in violation of Article 27 (5);
 6. When he/she has any person, other than a medical service technologist, perform the duties of a medical service technologist or assigns a medical service technologist any job beyond the scope of the technologist's job;
 7. When he/she makes a claim for medical expenses by fraud or other improper means, such as falsification or alteration of related documents;
 8. Deleted; <by Act No. 11005, Aug. 4, 2011>
 9. When he/she receives economic benefits, etc. in violation of Article 23-5;
 10. When he/she violates this Act or any order issued pursuant to this Act.
- (2) The scope of the acts defined in paragraph (1) 1 shall be prescribed by Presidential Decree.
 - (3) When the disposition of qualification suspension prescribed in paragraph (1) 7 is imposed on the founder of a medical institution, the medical institution shall not provide medical services during the period for suspension of qualification. <Amended by Act No. 10387, Jul. 23, 2010>
 - (4) When any medical personnel fails to submit a report referred to in Article 25, the Minister of Health and Welfare may suspend the validity of his/her license until the report is submitted. <Newly Inserted by Act No. 10609, Apr. 28, 2011>
 - (5) When any medical personnel who violates paragraph (1) 2 reports the violation voluntarily, the disposition thereof may be mitigated or exempted as prescribed by Ordinance of the Ministry of Health and Welfare, notwithstanding paragraph (1). <Newly Inserted by Act No. 11252, Feb. 1, 2012>
 - (6) A disposition for the suspension of qualification prescribed in paragraph (1) shall not be imposed if five years (seven years in cases of a disposition for the suspension of qualification prescribed in paragraph (1) 5 or 7) elapse from the date of occurrence of the ground therefor: *Provided*, That where any public prosecution is instituted under Article 246 of the Criminal Procedure Act against the relevant ground, the period from the date on which the public prosecution is instituted to the date on which the final and conclusive judgment for the relevant case is made by the court shall not be included in the prescriptive period. <Newly Inserted by Act No. 14220, May 29, 2016>

Article 66-2 (Central Associations' Request for Suspension of Qualification)

When any medical personnel falls under Article 66 (1) 1, the head of each central association may request the Minister of Health and Welfare to suspend the qualification of the medical personnel through deliberation and resolution by the ethics committee of the relevant central association.

[This Article Newly Inserted by Act No. 10609, Apr. 28, 2011]

Article 67 (Penalty Surcharges)

- (1) The Minister of Health and Welfare or the head of a relevant *Si/Gun/Gu* may impose a penalty surcharge not exceeding one billion won on a medical institution, if it falls under any of subparagraphs of Article 64 (1), in lieu of the suspension of medical services, as prescribed by Presidential Decree, and in such cases, such penalty surcharge shall not be imposed more than three times: *Provided*, That where a penalty surcharge is imposed pursuant to Article 9 of the Act on Fair Labeling and Advertising for the same violation, the penalty surcharge (including the suspension of medical services) may be mitigated or exempted. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 14220, May 29, 2016; Act No. 16555, Aug. 27, 2019>

- (2) The amount of a penalty surcharge prescribed in paragraph (1) depending upon the type, severity, etc. of a violation, and other necessary matters shall be prescribed by Presidential Decree.
- (3) If any penalty surcharge prescribed in paragraph (1) is not paid by the deadline, the Minister of Health and Welfare or the head of a *Si/Gun/Gu* shall collect the penalty surcharge in the same manner as delinquent national or local taxes are collected. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

Article 68 (Criteria for Administrative Disposition)

The detailed criteria for administrative dispositions under Articles 63, 64 (1), 65 (1), and 66 (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

Article 69 (Medical Instructors)

- (1) The Ministry of Health and Welfare, a *City/Do* and a *Si/Gun/Gu* shall have medical instructors responsible for the duties under Article 61. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>
- (2) A medical instructor shall be appointed by the Minister of Health and Welfare, a relevant Mayor/*Do* Governor, or the head of a relevant *Si/Gun/Gu* from among public officials under his/her control, and necessary matters concerning qualification, appointment, etc. shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>
- (3) No medical instructor and public official shall disclose any confidential information on medical institutions, medical personnel or patients that he/she becomes aware of in the course of performing his/her duties.

CHAPTER VII (Articles 70 through 76) Deleted.

CHAPTER VIII Supplementary Provisions

Article 77 (Medical Specialists)

- (1) Any physician, dentist or oriental medical doctor who intends to become a medical specialist shall have his/her qualification accredited by the Minister of Health and Welfare after completing the training course prescribed by Presidential Decree. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>
- (2) No person, other than those accredited as a medical specialist pursuant to paragraph (1), shall indicate his/her specialized medical department: *Provided*, That the Minister of Health and Welfare may, in order to efficiently manage the medical system, allow any dentist or oriental medical doctor who has been accredited as a medical specialist to indicate his/her specialized department only at a medical institution prescribed by Ordinance of the Ministry of Health and Welfare, among general hospitals, dental hospitals, and oriental medical hospitals. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9386, Jan. 30, 2009; Act No. 9932, Jan. 18, 2010>
- (3) Deleted. <by Act No. 14438, Dec. 20, 2016>
- (4) Matters necessary for the accreditation of medical specialists and specialized medical departments shall be prescribed by Presidential Decree.

[In accordance with Article 2 of the Addenda to Act No. 9386 dated Jan. 30, 2009, the part concerning a dentist in the amended provisions of the proviso to paragraph (2) of this Article shall remain effective

until Dec. 31, 2013, and the part concerning an oriental medical doctor in the same amended provisions until December 31, 2009]

<Paragraph (3) of this Article was deleted by Act No. 14438, promulgated December 20, 2016 pursuant to the decision of unconstitutionality by the Constitutional Court made on May 28, 2015>

Article 78 (Nurse Practitioners)

- (1) The Minister of Health and Welfare may accredit a licensed nurse as a nurse practitioner. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*
- (2) Any person who intends to become a nurse practitioner shall comply with any of the following and obtain accreditation of qualification from the Minister of Health and Welfare after passing a qualification examination for nurse practitioners implemented by the Minister of Health and Welfare: *<Amended by Act No. 15540, Mar. 27, 2018>*
 1. A person who completes the educational courses for nurse practitioners prescribed by Ordinance of the Ministry of Health and Welfare;
 2. A person holding a foreign license for nurse practitioners in the relevant area accredited by the Minister of Health and Welfare.
- (3) A nurse practitioner shall conduct nursing practices in the relevant area for which his/her qualification is accredited pursuant to paragraph (2). *<Newly Inserted by Act No. 15540, Mar. 27, 2018>*
- (4) The types of qualifications, standards for qualification, qualification examinations, certificates of qualification, and scope of duties of nurse practitioners and other necessary matters shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Newly Inserted by Act No. 15540, Mar. 27, 2018>*

Article 79 (Medical Personnel Licensed to Practise in Limited Area)

- (1) A physician, dentist or oriental medical doctor who has been licensed to practise in a limited area pursuant to the previous provisions before this Act enters into force, shall be deemed medical personnel, only when he/she is licensed to practise in a limited area.
- (2) The Minister of Health and Welfare may revoke a license of any medical personnel under paragraph (1), if he/she practises outside a limited area. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*
- (3) Any change of a limited area referred to in paragraph (1) and other necessary matters shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*
- (4) Notwithstanding Article 5, a physician, dentist or oriental medical doctor who has practised in a limited area for at least ten years, or who has an at least five-year career experience in medical services as at the time this Act enters into force, may be licensed to practise in a limited area, as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

Article 80 (Qualification of Assistant Nurses)

- (1) A person who intends to be an assistant nurse shall comply with any of the following and obtain accreditation of qualification from the Minister of Health and Welfare after completing the curricula prescribed by Ordinance of the Ministry of Health and Welfare and passing the national examination for assistant nurses. In such cases, Article 10 shall apply *mutatis mutandis* to restrictions on taking qualification examinations: *<Amended by Act No. 16555, Aug. 27, 2019>*
 1. A person who has graduated from a department related to nursing at a specialized high school referred to in the Elementary and Secondary Education Act and statutes or regulations (including persons expecting the graduation within six months from the date of the national examination for assistant nurses);

2. A person who has completed training courses at a national or public training center for assistant nurses prescribed by Ordinance of the Ministry of Health and Welfare, as a person who has graduated from a high school referred to in Article 2 of the Elementary and Secondary Education Act (including persons expecting the graduation within six months from the date of the national examination for assistant nurses) or a person recognized to have an equivalent academic background under the Elementary and Secondary Education Act and its statutes or regulations (hereafter referred to as "person recognized to have the academic background equivalent to a high school graduate" in this Article);
 3. A person who has graduated from a department related to nursing at a lifelong educational institutions referred to in the Lifelong Education Act and its statutes or regulations among the curricula corresponding to the high school curricula, as a person recognized to have the academic background equivalent to a high school graduate (including persons expecting the graduation within six months from the date of the national examination for assistant nurses);
 4. A person who has completed assistant nurse training courses at a private teaching institute referred to in Article 2-2 (2) of the Act on the Establishment and Operation of Private Teaching Institutes and Extracurricular Lessons, as a person recognized to have the academic background equivalent to a high school graduate;
 5. A person who has been qualified as an assistant nurse in a foreign country after completing assistant nurse training courses in such country (referring to training courses that meet the accreditation standards determined and publicly notified by the Minister of Health and Welfare), as a person recognized to have the academic background equivalent to a high school graduate;
 6. A person who falls under Article 7 (1) 1 or 2.
- (2) An education and training institute for assistant nurses referred to in paragraph (1) 1 through 4 shall be designated and evaluated by the Minister of Health and Welfare. In such cases, the Minister of Health and Welfare may entrust the affairs related to the evaluation for the designation of an education and training institution for assistant nurses to a related specialized institution in accordance with the procedures and methods prescribed by Presidential Decree.
- (3) Where an education and training institution for assistant nurses referred to in paragraph (2) falls under any ground prescribed by Presidential Decree, such as cases where it has been designated by fraud or other improper means, the designation may be revoked.
- (4) Each assistant nurse shall report his/her current status and employment situation every three years after obtaining the qualifications for the first time.
- (5) Matters necessary for the national examination for assistant nurses and accreditation of qualifications of assistant nurses prescribed in paragraph (1), designation and evaluation of education and training institutions for assistant nurses prescribed in paragraph (2), reports on qualifications prescribed in paragraph (4), and refresher training for assistant nurses shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Wholly Amended by Act No. 13658, Dec. 29, 2015]

Article 80-2 (Duties of Assistant Nurses)

- (1) Notwithstanding Article 27, an assistant nurse may perform the affairs prescribed in Article 2 (2) 5 (a) through (c) by assisting a nurse.
- (2) Notwithstanding paragraph (1), an assistant nurse may perform assistant work for nursing and medical treatment for the convalescence of patients under the guidance of a physician, dentist, or oriental medical doctor only at a clinic-level medical institution referred to in Article 3 (2).
- (3) Matters necessary for the detailed scope and limit of the affairs prescribed in paragraphs (1) and (2) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 13658, Dec. 29, 2015]

Article 80-3 (Provisions Applicable Mutatis Mutandis)

@Articles 8, 9, 12, 16, 19, 20, 22, 23, 59 (1), 61, 65, 66, 68, 83 (1), 84, 85, 87, 87-2, 88, 88-2, and 91 shall apply *mutatis mutandis* to assistant nurses; and in such cases, "license" shall be construed as "qualification" and "license certificate" as "qualification certificate". <Amended by Act No. 14438, Dec. 20, 2016; Act No. 16555, Aug. 27, 2019>

[This Article Newly Inserted by Act No. 13658, Dec. 29, 2015]

Article 81 (Quasi-Medical Personnel)

- (1) Notwithstanding Article 27, any bone-setter, acupuncturist or moxibustionist (hereinafter referred to as "quasi-medical personnel"), who has been accredited pursuant to the previous provisions before this Act enters into force, may engage in such profession within his/her place of practice.
- (2) The provisions concerning medical personnel and medical institutions in this Act shall apply *mutatis mutandis* to quasi-medical personnel. In such cases, "medical personnel" shall be read as "quasi-medical personnel" the "license" as "qualification" "license certificate" as "qualification certificate" and "medical institution" as "place of practice".
- (3) Necessary matters concerning the practices of quasi-medical personnel, the limitations on their practices, the standards of the places of practices, etc. shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

Article 82 (Massage Therapists)

- (1) A massage therapist shall be a visually-impaired person under the Act on Welfare of Persons with Disabilities, who falls under any of the following subparagraphs and who is accredited by a relevant Mayor/Do Governor: <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>
 1. A person who has completed physical therapy courses for a massage therapist as set forth in paragraph (4) at a special school under subparagraph 5 of Article 2 of the Elementary and Secondary Education Act, which provides education equivalent to a high school;
 2. A person who has completed two-year or longer courses for massage therapy at a massage therapy institution designated by the Minister of Health and Welfare, as a person recognized to have the academic background equivalent to a middle school graduate.
- (2) Notwithstanding Article 27, a massage therapist under paragraph (1) may engage in massage business.
- (3) As to massage therapists, Articles 8, 25, 28 through 32, 33 (2) 1, (3), (5), and the main sentence of (8), 36, 40, 59 (1), 61, and 63 (applicable only when violating Article 36), 64 through 66, 68, 83, and 84 shall be applicable *mutatis mutandis*. In such cases, "medical personnel" shall be construed as "massage therapist" "license" as "qualification" "license certificate" as "qualification certificate" "medical institution" as "place of massage practice or massage parlor" and "head of the competent organization relating to medical services" as "president of the massage therapists' association". <Amended by Act No. 9386, Jan. 30, 2009>
- (4) Necessary matters concerning the scope of business of massage therapists, the standards for the facilities of the places for massage practice or massage parlors, etc. shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

Article 83 (Subsidy for Expenses)

- (1) If deemed necessary to improve public health, the Minister of Health and Welfare or a relevant Mayor/Do Governor may fully or partially subsidize expenses incurred in relation to facilities, operation, and survey and research for any medical personnel, medical institution, central association or organization relating to medical services. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

- (2) When any of the following medical institutions files an application for accreditation, the Minister of Health and Welfare may fully or partially subsidize expenses incurred in relation to accreditation for such medical institution within budgetary limits: <Newly Inserted by Act No. 10387, Jul. 23, 2010>
1. A medical institution which shall file an application for accreditation pursuant to Article 58-4 (2);
 2. A medical institution which meets the standards prescribed by the Minister of Health and Welfare among medical institutions with less than 300 patient beds (excluding general hospitals).

#Article 83 (Subsidy for Expenses)

- (1) If deemed necessary to improve public health, the Minister of Health and Welfare or a relevant Mayor/Do Governor may fully or partially subsidize expenses incurred in relation to facilities, operation, and survey and research for any medical personnel, medical institution, central association or organization relating to medical services. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>
- (2) When any of the following medical institutions files an application for accreditation, the Minister of Health and Welfare may fully or partially subsidize expenses incurred in relation to accreditation for such medical institution within budgetary limits: <Newly Inserted by Act No. 10387, Jul. 23, 2010; Act No. 17069, Mar. 4, 2020>
1. A medical institution which shall file an application for accreditation pursuant to Article 58-4 (2) and (3);
 2. A medical institution which meets the standards prescribed by the Minister of Health and Welfare among medical institutions with less than 300 patient beds (excluding general hospitals).

Article 84 (Hearing)

The Minister of Health and Welfare, a relevant Mayor/Do Governor or the head of a relevant *Si/Gun/Gu* shall hold a hearing whenever he/she intends to impose any of the following dispositions: <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10387, Jul. 23, 2010; Act No. 14438, Dec. 20, 2016>

1. Revocation of certification pursuant to Article 23-2 (4);
2. Revocation of permission for establishment pursuant to Article 51;
3. Cancellation of accreditation or conditional accreditation of a medical institution pursuant to Article 58-9;
4. Issuance of an order to ban the use of any facility, equipment, etc. pursuant to Article 63;
5. Revocation of permission for establishment or Issuance of an order to close a medical institution pursuant to Article 64 (1);
6. Revocation of a license pursuant to Article 65 (1).

#Article 84 (Hearing)

The Minister of Health and Welfare, a relevant Mayor/Do Governor or the head of a relevant *Si/Gun/Gu* shall hold a hearing whenever he/she intends to impose any of the following dispositions: <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10387, Jul. 23, 2010; Act No. 14438, Dec. 20, 2016; Act No. 17069, Mar. 4, 2020>

1. Revocation of certification pursuant to Article 23-2 (4);
2. Revocation of permission for establishment pursuant to Article 51;
3. Cancellation of accreditation or conditional accreditation of a medical institution pursuant to Article 58-10;
4. Issuance of an order to ban the use of any facility, equipment, etc. pursuant to Article 63;
5. Revocation of permission for establishment or issuance of an order to close a medical institution pursuant to Article 64 (1);
6. Revocation of a license pursuant to Article 65 (1).

Article 85 (Fees)

- (1) A person, who seeks re-issuance of a license or license certificate, who intends to take the national examination, etc., or who seeks an inspection on a radiation generator for diagnosis pursuant to this Act, shall pay a certain amount of fees, as determined by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>
- (2) The Korea Health Personnel Licensing Examination Institute prescribed in Article 9 (2) may appropriate the fees received for the national examination, etc. pursuant to paragraph (1) for expenses incurred in relation to administration of such examination, subject to approval from the Minister of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 13367, Jun. 22, 2015>

Article 86 (Delegation or Entrustment of Authority)

- (1) The Minister of Health and Welfare or a relevant Mayor/Do Governor may partially delegate his/her authority under this Act to the Mayor/Do Governor, the Director of the Korea Centers for Disease Control and Prevention, the head of a *Si/Gun/Gu*, or the director of a public health clinic, as prescribed by Presidential Decree. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>
- (2) The Minister of Health and Welfare may entrust a related specialized organization with some of affairs under this Act, as prescribed by Presidential Decree. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

Article 86-2 (Legal Fiction as Public Officials in Application of Penalty Provisions)

Members of deliberation committees prescribed in Article 57-2 (4) shall be considered as public officials in the application of Articles 129 through 132 of the Criminal Act.

[This Article Newly Inserted by Act No. 15540, Mar. 27, 2018]

Article 86-3 (Exemption from Responsibility for Preserving and Keeping Records)

Where a record preserved and kept pursuant to Article 22 (2), 23 (1) or 40 (2) is lost due to natural disasters or any other *force majeure*, a person obliged to preserve and keep the relevant record shall be exempt from responsibility prescribed in Article 64, 66 or 90.

[This Article Newly Inserted by Act No. 16375, Apr. 23, 2019]

#Article 86-3 (Free from Responsibility for Preserving and Keeping Records)

Where a record preserved and kept pursuant to Article 22 (2), 23 (1) or 40-2 (1) is lost due to natural disasters or any other *force majeure*, a person responsible for preserving and keeping the relevant record shall be free from such responsibility prescribed in Article 64, 66 or 90. <Amended by Act No. 17069, Mar. 4, 2020>

[This Article Newly Inserted by Act No. 16375, Apr. 23, 2019]

CHAPTER IX Penalty Provisions**Article 87 (Penalty Provisions)**

A person who establishes or operates a medical institution in violation of Article 33 (2) shall be punished by imprisonment with labor for not more than 10 years or by a fine not exceeding 100 million won.

[This Article Newly Inserted by Act No. 16555, Aug. 27, 2019]

Article 87-2 (Penalty Provisions)

- (1) A person who inflicts an injury on another person by committing an offense in violation of Article 12 (3) shall be punished by imprisonment with labor for not more than seven years or by a fine of not less than 10 million won but not more than 70 million won; a person who inflicts a serious injury on another person by committing an offense in violation of Article 12 (3) shall be punished by imprisonment with labor for not less than three years but not more than 10 years; and a person who causes the death of another person shall be punished by imprisonment with labor for an indefinite term or for not less than five years. <Newly Inserted by Act No. 16375, Apr. 23, 2019>
- (2) Any of the following persons shall be punished by imprisonment with labor for not more than five years or by a fine not exceeding 50 million won: <Amended by Act No. 9386, Jan. 30, 2009; Act No. 13658, Dec. 29, 2015; Act No. 14220, May 29, 2016; Act No. 14438, Dec. 20, 2016; Act No. 16555, Aug. 27, 2019>
1. A person who leases his/her license to a third person in violation of Article 4-3 (1);
 - 1-2. A person who borrows a license or arranges the borrowing of a license in violation of Article 4-3 (2);
 2. A person who violates Article 12 (2) or (3), 18 (3), 21-2 (5) or (8), 23 (3), 27 (1), 33 (2) (limited to cases applied *mutatis mutandis* under Article 82 (3)), (8) (including cases applied *mutatis mutandis* under Article 82 (3)) or (10): *Provided*, That no public prosecution against an offense referred to in Article 12 (3) shall be instituted against the explicit will of the victim.

#Article 87-2 (Penalty Provisions)

- (1) A person who inflicts an injury on another person by committing an offense in violation of Article 12 (3) shall be punished by imprisonment with labor for not more than seven years or by a fine of not less than 10 million won but not more than 70 million won; a person who inflicts a serious injury on another person by committing an offense in violation of Article 12 (3) shall be punished by imprisonment with labor for not less than three years but not more than 10 years; and a person who causes the death of another person shall be punished by imprisonment with labor for an indefinite term or for not less than five years. <Newly Inserted by Act No. 16375, Apr. 23, 2019>
- (2) Any of the following persons shall be punished by imprisonment with labor for not more than five years or by a fine not exceeding 50 million won: <Amended by Act No. 9386, Jan. 30, 2009; Act No. 13658, Dec. 29, 2015; Act No. 14220, May 29, 2016; Act No. 14438, Dec. 20, 2016; Act No. 16555, Aug. 27, 2019; Act No. 17069, Mar. 4, 2020>
1. A person who leases his/her license in violation of Article 4-3 (1);
 - 1-2. A person who borrows a license or arranges the borrowing of a license in violation of Article 4-3 (2);
 2. A person who violates Article 12 (2) or (3), 18 (3), 21-2 (5) or (8), 23 (3), 27 (1), 33 (2) (limited to cases applied *mutatis mutandis* under Article 82 (3)), (8) (including cases applied *mutatis mutandis* under Article 82 (3)) or (10): *Provided*, That no public prosecution against an offense referred to in Article 12 (3) shall be instituted against the explicit will of the victim;
 3. A person who reads or confirms the details of information kept in the medical record keeping system other than the medical records, etc. that he/she directly kept, in violation of Article 40-3 (3);
 4. A person who damages, destructs, changes, forges, divulges, searches or reproduces the information kept in the medical record keeping system without justifiable access authority or in excess of permitted access authority, in violation of Article 40-3 (7).

Article 88 (Penalty Provisions)

Any of the following persons shall be punished by imprisonment with labor for not more than three years or by a fine not exceeding 30 million won: <Amended by Act No. 16555, Aug. 27, 2019>

1. A person who violates Article 19, 21 (2), 22 (3), 27 (3) or (4), 33 (4), the proviso to Article 35 (1), Article 38 (3), 59 (3), 64 (2) (including cases applied *mutatis mutandis* under Article 82 (3)), or 69 (3): *Provided*, That the public prosecution against a person who violates Article 19, 21 (2), or 69 (3) requires a criminal complaint filed by a victim;
2. A person who violates Article 23-5. In such cases, the acquired economic benefit, etc. shall be confiscated; and where it is impracticable to confiscate it, its value shall be collected as a penalty;
3. A person who provides massage services for profits without obtaining qualifications as a massage therapist accredited pursuant to Article 82 (1).

[This Article Wholly Amended by Act No. 14438, Dec. 20, 2016]

#Article 88 (Penalty Provisions)

Any of the following persons shall be punished by imprisonment with labor for not more than three years or by a fine not exceeding 30 million won: <Amended by Act No. 16555, Aug. 27, 2019; Act No. 17069, Mar. 4, 2020>

1. A person who violates Article 19, 21 (2) (including cases where Article 21 (2) applies *mutatis mutandis* in Article 40-2 (4)), 22 (3), 27 (3) or (4), 33 (4), the proviso to Article 35 (1), Article 38 (3), 47 (11), 59 (3), 64 (2) (including cases applied *mutatis mutandis* under Article 82 (3)), or 69 (3): *Provided*, That the public prosecution against a person who violates Article 19, 21 (2) (including cases where Article 21 (2) applies *mutatis mutandis* in Article 40-2 (4)), or 69 (3) requires a criminal complaint filed by a victim;
2. A person who violates Article 23-5. In such cases, the acquired economic benefit, etc. shall be confiscated; and where it is impracticable to confiscate it, its value shall be collected as a penalty;
3. A person who provides massage services for profits without obtaining qualifications as a massage therapist accredited pursuant to Article 82 (1).

[This Article Wholly Amended by Act No. 14438, Dec. 20, 2016]

Article 88-2 (Penalty Provisions)

Any person who violates Article 20 shall be punished by imprisonment with labor for not more than two years or by a fine not exceeding 20 million won. <Amended by Act No. 14438, Dec. 20, 2016>

[This Article Newly Inserted by Act No. 9906, Dec. 31, 2009]

#Article 88-2 (Penalty Provisions)

Any of the following persons shall be punished by imprisonment with labor for not more than two years or by a fine not exceeding 20 million won: <Amended by Act No. 14438, Dec. 20, 2016; Act No. 17069, Mar. 4, 2020>

1. A person who violate Article 20;
2. A person who takes measures in disfavor of a person who files a voluntary report, in violation of Article 47 (12).

[This Article Newly Inserted by Act No. 9906, Dec. 31, 2009]

Article 89 (Penalty Provisions)

Any of the following persons shall be punished by imprisonment with labor for not more than one year or by a fine not exceeding 10 million won: <Amended by Act No. 15540, Mar. 27, 2018; Act No. 16555, Aug. 27, 2019>

1. A person who violates Article 15 (1), 17 (1) or (2) (excluding the latter part of the proviso to paragraphs (1) and the proviso to paragraph (2)), Article 17-2 (1) or (2) (limited to the cases of issuing or sending a prescription), the latter part of Article 23-2 (3), Article 33 (9), 56 (1) through (3), or 58-6 (2);
2. A person who fails to take measures to protect rights and interests pursuant to Article 40 (4) without justifiable grounds;

3. A person who receives or gives, or promises to receive or give, money, valuables, etc. in connection with the appointment of executive officers of medical corporations in violation of Article 51-2;
4. A person who refuses, interferes with or evades an inspection prescribed in Article 61 (1) (limited to cases where it is expressed that the inspection is to ascertain whether Article 33 (2) and (10) is violated).

[This Article Wholly Amended by Act No. 14438, Dec. 20, 2016]

Article 90 (Penalty Provisions)

Any person, who has violated Articles 16 (1) or (2), 17 (3) or (4), 17-2 (1) or (2) (limited to cases where a prescription is received), or 18 (4), the latter part of Article 21 (1), Article 21-2 (1) or (2), 22 (1) or (2), 23 (4), 26, 27 (2) or 33 (1), (3) (including cases applied *mutatis mutandis* under Article 82 (3)), or (5) (referring to only the case of permission), the main sentence of Article 35 (1), Articles 41, 42 (1), 48 (3) or (4), or 77 (2), or a corrective order issued under Article 63, or who has been employed by a person who is not eligible for establishing a medical institution to perform medical practice, shall be punished by a fine not exceeding five million won. *<Amended by Act No. 8559, Jul. 27, 2007; Act No. 9386, Jan. 30, 2009; Act No. 10565, Apr. 7, 2011; Act No. 14438, Dec. 20, 2016; Act No. 15540, Mar. 27, 2018; Act No. 16555, Aug. 27, 2019>*

#Article 90 (Penalty Provisions)

Any person, who has violated Articles 16 (1) or (2), 17 (3) or (4), 17-2 (1) or (2) (limited to cases where a prescription is received), or 18 (4), the latter part of Article 21 (1) (including cases where Article 21 (1) applies *mutatis mutandis* in Article 40-2 (4)), Article 21-2 (1) or (2), 22 (1) and (2) (including cases where Article 22 (1) and (2) applies *mutatis mutandis* in Article 40-2 (4)), 23 (4), 26, 27 (2) or 33 (1), (3) (including cases applied *mutatis mutandis* under Article 82 (3)), or (5) (referring to only the case of permission), the main sentence of Article 35 (1), Articles 41, 42 (1), 48 (3) or (4), or 77 (2), or a corrective order issued under Article 63, or who has been employed by a person who is not eligible for establishing a medical institution to perform medical practice, shall be punished by a fine not exceeding five million won. *<Amended by Act No. 8559, Jul. 27, 2007; Act No. 9386, Jan. 30, 2009; Act No. 10565, Apr. 7, 2011; Act No. 14438, Dec. 20, 2016; Act No. 15540, Mar. 27, 2018; Act No. 16555, Aug. 27, 2019; Act No. 17069, Mar. 4, 2020>*

Article 90-2 (Special Cases on Provisions concerning Mitigation under the Criminal Act)

@Article 10 (1) of the Criminal Act may not apply to persons who commit an offense in violation of Article 12 (3) in mental disorders caused by drinking.

[This Article Newly Inserted by Act No. 16375, Apr. 23, 2019]

Article 91 (Joint Penalty Provisions)

Where a representative of a corporation or an agent, employee of, or any other person employed by, the corporation or an individual commits any violation prescribed in Article 87, 87-2, 88, 88-2, 89, or 90 in connection with the business affairs of the corporation or individual, the corporation or individual shall, in addition to punishing the violators accordingly, be punished by a fine under the relevant Article: *Provided*, That this shall not apply where such corporation or individual has not been negligent in giving due attention and supervision concerning the relevant business affairs to prevent such violation. *<Amended by Act No. 10325, May 27, 2010; Act No. 14438, Dec. 20, 2016; Act No. 16555, Aug. 27, 2019>*

[This Article Wholly Amended by Act No. 9906, Dec. 31, 2009]

Article 92 (Administrative Fines)

- (1) Any of the following persons shall be punished by an administrative fine not exceeding three million won: <Amended by Act No. 13107, Jan. 28, 2015; Act No. 14438, Dec. 20, 2016; Act No. 16555, Aug. 27, 2019>
1. A person who fails to provide education prescribed in Article 16 (3);
 - 1-2. A person who fails to notify a medical treatment information breach incident in violation of Article 23-3 (1);
 - 1-3. A person who fails to make explanations to a patient or to obtain a written consent in violation of Article 24-2 (1);
 - 1-4. A person who fails to inform the ground for and details of the change to a patient in violation of Article 24-2 (4);
 2. A person who installs and operates a radiation generator for diagnosis without a report prescribed in Article 37 (1);
 3. A person who fails to appoint a person responsible for safety control, to conduct a periodic inspection and measurement, or to take measures to control radiation exposure to staff in radiation-related services in compliance with Article 37 (2);
 4. Deleted; <by Act No. 15540, Mar. 27, 2018>
 5. A person who fails to submit a report in violation of Article 49 (3).
- (2) Any of the following persons shall be punished by an administrative fine not exceeding two million won: <Amended by Act No. 14438, Dec. 20, 2016; Act No. 16555, Aug. 27, 2019>
1. A person who fails to submit data in violation of the latter part of Article 21-2 (6), or submits false data;
 2. A person who fails to submit data in violation of Article 45-2 (2), or submits false data;
 3. A person who fails to submit a report prescribed in Article 61 (1) or rejects, interferes with or evades an inspection (excluding cases falling under subparagraph 4 of Article 89).
- (3) Any of the following persons shall be punished by an administrative fine not exceeding one million won: <Amended by Act No. 9386, Jan. 30, 2009; Act No. 10609, Apr. 28, 2011; Act No. 11252, Feb. 1, 2012; Act No. 13107, Jan. 28, 2015; Act No. 13658, Dec. 29, 2015; Act No. 14220, May 29, 2016>
1. A person who fails to record and maintain the results of education prescribed in Article 16 (3);
 - 1-2. A person who fails to file a report on a change, suspension, closure or resumption of his/her business prescribed in Article 16 (4);
 2. A person who fails to submit a report on a change prescribed in Article 33 (5) (including cases applied *mutatis mutandis* under Article 82 (3));
 3. A person who fails to submit a report on suspension or temporary shutdown of medical services prescribed in Article 40 (1) (including cases applied *mutatis mutandis* under Article 82 (3)), or who fails to transfer a medical record card or similar, in violation of Article 40 (2);
 4. A person who uses the title of a medical institution or any similar name, in violation of Article 42 (3);
 5. A person who commits any violation in indicating his/her medical department prescribed in Article 43 (5);
 6. A person who fails to put up a notice of a patient's rights, etc. prescribed in Article 4 (3);
 7. A person who uses the title "National Academy of Medicine of Korea" or any other similar title, in violation of Article 52-2 (6);
 8. A person who fails to comply with a corrective order issued under Article 63 against an offense committed in violation of Article 4 (5).
- (4) Administrative fines prescribed in paragraphs (1) through (3) shall be imposed and collected by the Minister of Health and Welfare or the head of each *Si/Gun/Gu*, as prescribed by Presidential Decree. <Newly Inserted by Act No. 9386, Jan. 30, 2009; Act No. 9932, Jan. 18, 2010>

#Article 92 (Administrative Fines)

- (1) Any of the following persons shall be punished by an administrative fine not exceeding three million won: <Amended by Act No. 13107, Jan. 28, 2015; Act No. 14438, Dec. 20, 2016; Act No. 16555, Aug. 27, 2019>
1. A person who fails to provide education prescribed in Article 16 (3);
 - 1-2. A person who fails to notify a medical treatment information breach incident in violation of Article 23-3 (1);
 - 1-3. A person who fails to make explanations to a patient or to obtain a written consent, in violation of Article 24-2 (1);
 - 1-4. A person who fails to inform the ground for and details of the change to a patient, in violation of Article 24-2 (4);
 2. A person who installs and operates a radiation generator for diagnosis without submitting a report prescribed in Article 37 (1);
 3. A person who fails to appoint a person responsible for safety control, to conduct a periodic inspection and measurement, or to take measures to control radiation exposure to staff in radiation-related services, in compliance with Article 37 (2);
 4. Deleted; <by Act No. 15540, Mar. 27, 2018>
 5. A person who fails to submit a report, in violation of Article 49 (3).
- (2) Any of the following persons shall be punished by an administrative fine not exceeding two million won: <Amended by Act No. 14438, Dec. 20, 2016; Act No. 16555, Aug. 27, 2019>
1. A person who fails to submit data, in violation of the latter part of Article 21-2 (6), or submits false data;
 2. A person who fails to submit data, in violation of Article 45-2 (2), or submits false data;
 3. A person who fails to submit a report prescribed in Article 61 (1) or rejects, interferes with, or evades an inspection (excluding cases falling under subparagraph 4 of Article 89).
- (3) Any of the following persons shall be punished by an administrative fine not exceeding one million won: <Amended by Act No. 9386, Jan. 30, 2009; Act No. 10609, Apr. 28, 2011; Act No. 11252, Feb. 1, 2012; Act No. 13107, Jan. 28, 2015; Act No. 13658, Dec. 29, 2015; Act No. 14220, May 29, 2016; Act No. 17069, Mar. 4, 2020>
1. A person who fails to record and maintain the results of education prescribed in Article 16 (3);
 - 1-2. A person who fails to file a report on a change, suspension, closure or resumption of his/her business prescribed in Article 16 (4);
 2. A person who fails to submit a report on a change prescribed in Article 33 (5) (including cases applied *mutatis mutandis* under Article 82 (3));
 3. A person who fails to file a report on the suspension or closure of business prescribed in Article 40 (1) (including cases where Article 40 (1) applies *mutatis mutandis* in Article 82 (3));
 - 3-2. A person who fails to transfer medical records, etc. to the head of the competent public health clinic or files a false report on quantities, lists, etc., in violation of Article 40-2 (1);
 - 3-3. A person who fails to file a report for change or files a false report for change in violation of Article 40-2 (2);
 - 3-4. A person who fails to designate a person in charge to vicariously preserve and read medical records, etc., or fails to transfer medical records, etc. to the head of the competent public health clinic in violation of Article 40-2 (2);
 - 3-5. A person who violates the matters to be observed prescribed in Article 40-2 (3).
 4. A person who uses the title of a medical institution or any similar name, in violation of Article 42 (3);
 5. A person who commits any violation in indicating his/her medical department prescribed in Article 43 (5);
 6. A person who fails to put up a notice of a patient's rights, etc. prescribed in Article 4 (3);

7. A person who uses the title "National Academy of Medicine of Korea" or any other similar title, in violation of Article 52-2 (6);
 8. A person who fails to comply with a corrective order issued under Article 63 against an offense committed in violation of Article 4 (5).
- (4) Administrative fines prescribed in paragraphs (1) through (3) shall be imposed and collected by the Minister of Health and Welfare or the head of each *Si/Gun/Gu*, as prescribed by Presidential Decree. <Newly Inserted by Act No. 9386, Jan. 30, 2009; Act No. 9932, Jan. 18. 2010>

Article 93 Deleted. <by Act No. 9386, Jan. 30, 2009>

Addenda <Act No. 17069, Mar. 4, 2020>

Article 1 (Enforcement Date)

This Act shall enter into force six months after the date of its promulgation: *Provided*, That the amended provisions of Article 21 (3) shall enter into force on the date of promulgation, and the amended provisions of Articles 4 (4), 4-3, 65 (1) 4 and 87-2 (2) 1 and 1-2, three months after the date of promulgation, the amended provisions of Article 3 (2) 3, the latter part, with the exception of the subparagraphs, of Article 33 (2), the former part, with the exception of the subparagraphs, of paragraph (4) of the same Article (excluding the matters concerning deliberation by *City/Do* medical institution establishment committees), and Articles 42 (1) 1, 43 (3), 46 (1), 57-2 (2) 1 and 62 (2), one year after the date of promulgation, the amended provisions of Articles 40, 40-2, 40-3, 64 (1) 5, 86-3, 87-2 (2) 3 and 4, 90, 92 (3) and the parts concerning "Article 21 (2)" in the amended provisions of Article 88, three years after the date of promulgation.

Article 2 (Applicability to Transfer of Medical Records)

The amended provisions of Article 40-2 shall apply, starting from the first case where the founder of a medical institution transfers medical records, etc. to the Minister of Health and Welfare after filing a report on the closure or suspension of business after the said amended provisions enter into force.

Article 3 (Applicability to Accreditation of Long-Term Care Hospitals)

The amended provisions of Article 58-4 (3) shall also apply to long-term care hospitals that have obtained conditional accreditation or non-accreditation before the said amended provisions enter into force.

Article 4 (Applicability to Accounting Standards for Medical Institutions)

The amended provisions of Article 62 (2) shall apply, starting from the point of time at which the first fiscal year begins after the said amended provisions enter into force.

Article 5 (Transitional Measures for Permission for Establishing Mental Health Hospitals)

A medical institution that has obtained permission for establishing a hospital or long-term care hospital pursuant to the previous provisions as at the time this Act enters into force and is established in compliance with the standards prescribed in the latter part of Article 19 (1) of the Act on the Improvement of Mental Health and the Support for Welfare Services for Mental Patients shall be considered to have obtained permission for establishing a mental health hospital prescribed in the amended provisions of Article 3 (2) 3 (e).

Article 6 (Transitional Measures for Incorporated Foundation, Korea Institute for Healthcare Accreditation)

(1) The Incorporated Foundation, the Korea Institute for Healthcare Accreditation established pursuant

to Article 32 of the Civil Act during the period from the date on which this Act is promulgated to the date on which this Act enters into force (hereinafter referred to as the "former corporation") shall request the Minister of Health and Welfare to approve the Korea Institute for Healthcare Accreditation prescribed by this Act (hereinafter referred to as the "new corporation") to succeed all the property, rights and obligations following resolution by the board of directors.

- (2) Notwithstanding the provisions pertaining to the dissolution and liquidation of corporations in the Civil Acts, the former corporation that obtains approval from the Minister of Health and Welfare pursuant to paragraph (1) shall be considered to be dissolved concurrently with the establishment of the new corporation, and the new corporation shall universally succeed all the property, rights and obligations that belonged to the former corporation.
- (3) The value of property to be succeeded to the new corporation pursuant to paragraph (2) shall be the book value of property as at the date preceding the date on which the registration of incorporation of the new corporation is filed.
- (4) The name of the former corporation indicated in the registry or other official books at the time the new corporation is established shall be considered to be the name of the new corporation.
- (5) The executives and employees of the former corporation at the time the new corporation is established shall be considered to be the executives and employees of the new corporation, and the term of office of executives shall be calculated from the date of the former appointment.
- (6) An act conducted by and in relation to the former corporation before the new corporation is established shall be considered to be conducted by and in relation to the new corporation.
- (7) Where other statutes and regulations are citing an institution dedicated to accreditation at the time the new corporation is established, they shall be considered to cite the new corporation in lieu of such institution.

Article 7 Omitted.

2.11 Enforcement Decree of The Medical Service Act

Presidential Decree No. 30480, Feb. 25, 2020

Article 1 (Purpose)

The purpose of this Decree is to prescribe matters mandated by the Medical Service Act and matters necessary for enforcing said Act.

Article 2 (Public Health Services of Nurses)

"Health services prescribed by Presidential Decree" in Article 2 (2) 5 (c) of the Medical Service Act (hereinafter referred to as the "Act") means any of the following public health services: <Amended by Presidential Decree No. 21428, Apr. 20, 2009; Presidential Decree No. 22667, Feb. 14, 2011; Presidential Decree No. 27525, Sep. 29, 2016; Presidential Decree No. 27700, Dec. 27, 2016; Presidential Decree No. 28695, Mar. 6, 2018>

1. Health services provided by a public official exclusively responsible for health care services prescribed in Article 19 of the Act on Special Measures for Health and Medical Services in Agricultural and Fishing Villages;
2. Mother and child health services provided by a mother and child health care specialist referred to in Article 10 (1) of the Mother and Child Health Act;
3. Health services provided under Article 18 of the Tuberculosis Prevention Act;
4. Services determined by other statutes or regulations as health services of nurses.

Article 2-2 (Matters to Be Displayed on Name Tags)

(1) Where persons who perform medical practices need to wear name tags by which they can be identified pursuant to the main sentence of Article 4 (5) of the Act, it shall conform to the following classification:

1. Matters to be displayed on name tags: Matters classified as follows shall be indicated:
 - (a) Medical personnel: Medical job titles and names: *Provided*, That in cases of medical specialists referred to in Article 77 (1) of the Act, specialist titles and names may be indicated;
 - (b) Students referred to in Article 27 (1) 3 of the Act: Major fields of study and names;
 - (c) Assistant nurses referred to in Article 80 of the Act: Assistant nurse titles and names;
 - (d) Medical technologists referred to in Article 2 of the Medical Service Technologists, etc. Act: Medical service technologist titles and names;
 2. Method of wearing a name tag: The name tag shall be marked on or attached to the clothing, or hanged on the neck, or worn in any other similar manner;
 3. Method of manufacturing a name tag: The name tag shall be imprinted, engraved, affixed, stitched, or manufactured by similar methods;
 4. Specifications and colors of a name tag: The contents of the name tag shall be visible with clear specifications and colors.
- (2) Detailed matters to be displayed on name tags; detailed methods of wearing and manufacturing name tags; detailed matters concerning specifications and colors of name tags, etc. under paragraph (1) shall be determined and publicly notified by the Minister of Health and Welfare.
- (3) "Cases prescribed by Presidential Decree" in the proviso to Article 4 (5) of the Act means cases where medical personnel are inside any of the following facilities:
1. An isolated ward;
 2. An aseptic treatment room;

3. Any other facility similar to that prescribed in subparagraph 1 or 2, which is publicly notified by the Minister of Health and Welfare as deemed necessary to prevent hospital-acquired infection.

[This Article Newly Inserted by Presidential Decree No. 27917, Feb. 28, 2017]

Article 3 (Scope of National Examination)

- (1) The national examination for medical doctors, dentists, oriental medical doctors, mid-wives or nurses referred to in Article 9 (1) of the Act (hereinafter "national examination") shall be conducted to test knowledge and skills in medicine, dental medicine, oriental medicine, midwifery, nursing, and public health and medicine-related laws and regulations.
- (2) The preliminary examination for doctors, dentists or oriental medical doctors under Article 9 (1) of the Act (hereinafter "preliminary examination") shall be given to test knowledge and skills necessary for a person having qualifications referred to in Article 5 (1) 3 of the Act to apply for the national examination under paragraph (1), and held divided into first and second examinations. *<Amended by Presidential Decree No. 21428, Apr. 20, 2009>*
- (3) Persons who have passed a preliminary examination shall be exempted from a preliminary examination (including the first and second examinations), starting from the next national examination.

Article 4 (Administration and Public Announcement of National Examinations)

- (1) The Minister of Health and Welfare shall administer national examinations and preliminary examinations (hereinafter referred to as "national examination, etc.") at least once a year. *<Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010>*
- (2) The Minister of Health and Welfare shall order the Korea Health Personnel Licensing Examination Institute established under the Korea Health Personnel Licensing Examination Institute Act (hereinafter referred to as "management agency for national examinations, etc.") to administer the national examinations, etc. *<Amended by Presidential Decree No. 26742, Dec. 22, 2015>*
- (3) When the head of the management agency for national examinations, etc. intends to administer the national examinations, etc., he/she shall obtain prior approval therefor from the Minister of Health and Welfare and give a public announcement of the date and place of the examinations, examination subjects, a period for the submission of an application for the examinations, and other matters necessary for the examinations by no later than 90 days before the examination date: *Provided*, That the place of examination may be publicly announced by no later than 30 days before the examination date after the number of applications for each region is determined. *<Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 23759, May 1, 2012>*

Article 5 (National Examination Subjects)

The subjects and method of examinations, the selection method of successful applicants, and other necessary matters concerning national examinations shall be determined by Ordinance of the Ministry of Health and Welfare. *<Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010>*

Article 6 (Examination Commissioners)

The head of the management agency for national examinations, etc. shall commission examination commissioners, from among persons having professional knowledge in each subject of the examinations whenever he/she conducts national examinations, etc.

Article 7 (Applications for and Announcement of Successful Applicant for National Examinations)

- (1) Any person who intends to apply for national examinations, etc. shall submit to the head of the management agency for national examinations, etc. the applications for examinations determined by

such head.

- (2) The head of the management agency for national examinations, etc. shall determine and announce the successful applicants of the national examinations, etc.

Article 8 (Issuance of License Certificates)

- (1) Those who have passed the national examinations shall, accompanied by the documents determined by Ordinance of the Ministry of Health and Welfare, apply to the Minister of Health and Welfare for issuing a license certificates after the announcement of successful applicants. *<Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010>*
- (2) The license certificates shall be issued according to their classification, as prescribed by Ordinance of the Ministry of Health and Welfare, to those who have applied for the issuance of license certificates under paragraph (1). *<Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010>*

Article 9 (Request for Cooperation with Relevant Institutions)

The head of the management agency for national examinations, etc. may, where it is deemed necessary to properly perform management duties for national examinations, etc., request the Government, local governments, or relevant institutions or associations to provide necessary cooperation, such as providing a place of examination and the supervision of examination.

Article 9-2 (Restriction on Taking National Examinations)

The criteria for restriction on taking the national examination, etc. under Article 10 (3) of the Act shall be as specified in attached Table 1.

[This Article Newly Inserted by Presidential Decree No. 28131, Jun. 20, 2017]

Article 10 (Conditions of License)

- (1) "Specially designated areas" in Article 11 (1) of the Act means areas in need of public health and medical services, designated by the Minister of Health and Welfare, and "specially designated duties" means duties of national, public health and medical institutions, and duties of national, public, private health and medical research institutions in the basic medical science field. *<Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010>*
- (2) An allowance shall be paid, within budgetary limits, to medical personnel who are employed in specially designated areas or for specially designated duties under Article 11 (1) of the Act.
- (3) Matters necessary for the implementation method of license conditions and procedures for the order to serve as referred to in Article 11 (1) of the Act shall be determined by Ordinance of the Ministry of Health and Welfare. *<Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010>*

Article 10-2 (Scope of Vicarious Recipients)

"Persons prescribed by Presidential Decree" in the provisions, with the exception of the subparagraphs, of Article 17-2 (2) of the Act means the following persons:

1. Lineal ascendants, descendants, and lineal ascendants' spouses of patients;
2. Spouse and spouse's lineal ascendants of patients;
3. Siblings of patients;
4. Persons working for medical and welfare institutions for senior citizens prescribed in Article 34 of the Welfare of Senior Citizens Act;
5. Persons the Minister of Health and Welfare deems necessary for the continuous medical treatment of patients.

[This Article Newly Inserted by Presidential Decree No. 30480, Feb. 25, 2020]

Article 10-3 (Reading Records on Patients)

"Public institutions prescribed by Presidential Decree" in Article 21 (3) 15 of the Act means the National Pension Service prescribed in Article 24 of the National Pension Act. <Amended by Presidential Decree No. 28131, Jun. 20, 2017>

[This Article Newly Inserted by Presidential Decree No. 27525, Sep. 29, 2016]

Article 10-4 (Entrustment of Business to Establish and Operate Medical Record Transmission Support System)

- (1) Pursuant to the former part of Article 21-2 (4) of the Act, the Minister of Health and Welfare may entrust business concerning the establishment and operation of a medical record transmission support system prescribed in paragraph (3) of the same Article (hereinafter referred to as "medical record transmission support system") to the following specialized institutions:
 1. A public institution prescribed in Article 4 of the Act on the Management of Public Institutions, the objectives of establishment of which are related to healthcare or social security;
 2. A specialized institution the Minister of Health and Welfare determines and publishes, taking into account organizations, workforce, expertise, etc. necessary to conduct the entrusted business.
- (2) Where the Minister of Health and Welfare intends to entrust business to establish and operate a medical record transmission support system pursuant to the former part of Article 21-2 (4) of the Act, the Minister shall publish matters concerning the criteria, procedures, methods, etc. of entrustment in advance.
- (3) Where the Minister of Health and Welfare entrusts business to establish and operate a medical record transmission support system pursuant to the former part of Article 21-2 (4) of the Act, the Minister shall publish matters concerning the details of entrustment, persons to which such business is entrusted, etc. in the Official Gazette and post such matters on the website of the Ministry of Health and Welfare.
- (4) A specialized institution to which business to establish and operate a medical record transmission support system is entrusted pursuant to the former part of Article 21-2 (4) of the Act shall report a project operation plan, current state of project implementation, fund management plan, fund implementation statement, etc. to the Minister of Health and Welfare.
- (5) The Minister of Health and Welfare shall determine and publish detailed matters necessary for the publication of criteria for entrustment, etc., publication of details of entrustment, etc., reporting on entrusted business, etc.

[This Article Newly Inserted by Presidential Decree No. 28131, Jun. 20, 2017]

Article 10-5 (Measures to Ensure Safety of Information Retained in Medical Record Transmission Support System)

- (1) A specialized institution to which business to establish and operate a medical record transmission support system is entrusted pursuant to the former part of Article 21-2 (4) of the Act shall take the following measures to ensure the safety of the information retained in the medical record transmission support system pursuant to Article 21-2 (5) 1 of the Act:
 1. Formulation and implementation of a management plan to ensure the safety of the information retained in the medical record transmission support system;
 2. Access control and restriction on access authority to the information retained in the medical record transmission support system;
 3. Establishment and operation of firewall, intrusion prevention system, and intrusion detection system to prevent unauthorized access to the medical record transmission support system;
 4. Development and management of encryption technology, etc. which makes it possible to safely save and transmit the information retained in the medical record transmission support system;

5. Installation and update of security programs for the information retained in the medical record transmission support system;
 6. Storage and management of access records to the medical record transmission support system;
 7. Installation and update of anti-forgery and anti-counterfeiting programs for the information retained in the medical record transmission support system;
 8. Development and implementation of safeguards for other information systems interconnected with the medical record transmission support system;
 9. Other measures similar to those prescribed in subparagraphs 1 through 8, which the Minister of Health and Welfare deems particularly necessary to ensure the safety of the information retained in the medical record transmission support system.
- (2) The Minister of Health and Welfare shall determine and publish detailed matters necessary to ensure the safety of the information retained in the medical record transmission support system prescribed in paragraph (1).

[This Article Newly Inserted by Presidential Decree No. 28131, Jun. 20, 2017]

Article 10-6 (Standardization of Electronic Medical Records)

Matters subject to standardization, which the Minister of Health and Welfare determines and publishes pursuant to Article 23-2 (1) of the Act shall be as follows:

1. Forms, terms, contents, etc. of electronic medical records prescribed in Article 23 (1) of the Act (hereinafter referred to as "electronic medical record");
2. Facilities and equipment necessary for the safe management and preservation of electronic medical records under Article 23 (2) of the Act;
3. Structures, forms, functions, etc. of the electronic medical record system prescribed in Article 23-2 (1) of the Act (hereinafter referred to as "electronic medical record system");
4. Other matters similar to those prescribed in subparagraphs 1 through 3, which the Minister of Health and Welfare deems particularly necessary for the efficient and unified management and use of electronic medical records.

[This Article Newly Inserted by Presidential Decree No. 28131, Jun. 20, 2017]

Article 10-7 (Certification of Electronic Medical Record System)

- (1) Criteria for certification of an electronic medical record system shall be as follows:
1. The standards the Minister of Health and Welfare determines and publishes pursuant to Article 23-2 (1) of the Act shall be satisfied;
 2. Compatibility necessary for electronic transmission between electronic medical record systems shall be secured;
 3. Administrative, technical and physical information security shall be secured for the electronic medical record system;
 4. Other criteria similar to those prescribed in subparagraphs 1 through 3, which the Minister of Health and Welfare deems particularly necessary, taking into consideration the functions, structures, forms, etc. of electronic medical record systems.
- (2) A person who intends to obtain certification of an electronic medical record system pursuant to Article 23-2 (2) of the Act shall submit an application for certification of the electronic medical record system (including applications in electronic form) to the Minister of Health and Welfare along with the following documents (including documents in electronic form):
1. Documents evidencing conformity with the criteria for certification prescribed in paragraph (1);
 2. Design plan for the electronic medical record system;
 3. The manual of the electronic medical record system and the performance test results;
 4. Other documents similar to those prescribed in subparagraphs 1 through 3, which the Minister of Health and Welfare publishes, deeming that they are particularly necessary for the certification of

electronic medical record systems.

- (3) The Minister of Health and Welfare may, if necessary for the professional examination of an application for certification submitted pursuant to paragraph (2), request data or opinions from any institution, corporation, organization, expert, etc. related to healthcare or information and communication.
- (4) Where the Minister of Health and Welfare in receipt of an application for certification prescribed in paragraph (2) determines whether to grant certification, he/she shall notify the applicant of such determination in writing.
- (5) Where the Minister of Health and Welfare grants certification to an electronic medical record system pursuant to Article 23-2 (2) of the Act, he/she shall issue a certificate to the applicant, and post the details of the certification on the website of the Ministry of Health and Welfare, etc.
- (6) The Minister of Health and Welfare shall determine and publish detailed matters necessary for certification criteria, certification procedures, certification methods, certification for modification, etc. of electronic medical record systems other than those prescribed in paragraphs (1) through (5).

[This Article Newly Inserted by Presidential Decree No. 28131, Jun. 20, 2017]

Article 10-8 (Labeling Certification of Electronic Medical Record Systems)

- (1) Where a person who has obtained certification of an electronic medical record system pursuant to Article 23-2 (2) of the Act intends to place a label including the matters certified pursuant to the former part of paragraph (3) of the same Article, he/she shall place such label in compliance with the standards the Minister of Health and Welfare determines and publishes for the details, size, color, design, etc. of such label.
- (2) Where the Minister of Health and Welfare deems that it is necessary to supplement or improve the certified matters to be included in labels prescribed in the former part of Article 23-2 (3) of the Act, he/she may recommend matters necessary for such supplementation or improvement to the person who has obtained the certification of the electronic medical record system.

[This Article Newly Inserted by Presidential Decree No. 28131, Jun. 20, 2017]

Article 10-9 (Types of Medical Treatment Information Breach Incidents)

"Incidents prescribed by Presidential Decree, such as the divulgence of medical treatment information or disruption in business of medical institutions" in Article 23-3 (1) of the Act means the following incidents:

1. Stealing and divulgence of medical treatment information;
2. Destruction, damage, concealment and loss of medical treatment information;
3. Disruption and paralysis of electronic medical record systems.

[This Article Newly Inserted by Presidential Decree No. 30480, Feb. 25, 2020]

Article 10-10 (Measures for Preventing and Responding to Medical Treatment Information Breach Incidents)

"Matters prescribed by Presidential Decree" in Article 23-4 (1) 5 of the Act means the following matters:

1. Checking the weak points of the electronic medical record system of a medical institution;
2. Education and training for medical personnel or founders of medical institutions;
3. Matters necessary to ensure the safety and reliability of electronic medical record systems, which the Minister of Health and Welfare determines and publishes.

[This Article Newly Inserted by Presidential Decree No. 30480, Feb. 25, 2020]

Article 10-11 (Explanation about Medical Practices)

- (1) A written consent a patient (where a patient lacks a decision-making capacity, referring to his/her legal representative; hereafter in this Article the same shall apply) gives to a physician, dentist or

oriental medical doctor pursuant to the main sentence of Article 24-2 (1) of the Act, shall bear the signature, or the name and seal of the relevant patient.

- (2) Where a physician, dentist or oriental medical doctor informs a patient in writing of the grounds for changing the methods, details, etc. of the operation, blood transfusion or general anesthesia, and matters changed, pursuant to Article 24-2 (4) of the Act, he/she may, if necessary to protect the patient, provide the patient with oral explanations concurrently, as determined by the Minister of Health and Welfare.
- (3) A physician, dentist, or oriental medical doctor shall preserve and manage documents prescribed in the main sentence of Article 24-2 (1) of the Act for two years from the date on which he/she obtains the consent of patients and documents prescribed in paragraph (4) of the same Article for two years from the date on which he/she informs patients.

[This Article Newly Inserted by Presidential Decree No. 28131, Jun. 20, 2017]

Article 11 (Reporting)

- (1) Pursuant to Article 25 (1) of the Act, medical personnel shall report to the Minister of Health and Welfare their actual state, their current employment status, etc. by no later than December 31 of every third anniversary year from the date on which they obtain a license issued or reissued pursuant to Article 8 or 65 of the Act: *Provided*, That medical personnel who have reported in accordance with Article 2 (1) of the Addenda to the Medical Service Act (Act No. 10609) shall report by no later than December 31 of every third anniversary year from the date of report.
- (2) Pursuant to Article 25 (3) of the Act, the Minister of Health and Welfare shall entrust the receipt and acceptance of reports under paragraph (1) to the physicians' association, dentists' association, oriental medical doctors' association, midwives' association, and nurses' association under Article 28 of the Act (hereinafter referred to as "central associations"), respectively.
- (3) Matters necessary for the method, procedure, etc. for the reporting under paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Wholly Amended by Presidential Decree No. 23753, Apr. 27, 2012]

Article 11-2 (Establishment of Ethics Committee)

- (1) Each ethics committee provided for in Article 28 (7) of the Act (hereinafter referred to as "ethics committee") shall be comprised of 11 members, including one chairperson.
- (2) Each committee chairperson shall be commissioned by the head of each central association, from among committee members.
- (3) Committee members shall be commissioned by the head of each central association from among the following persons taking gender equality into consideration, and at least four committee members specified in subparagraph 2 shall be included therein: *<Amended by Presidential Decree No. 27944, Mar. 20, 2017>*
 1. Members of each central association, who have at least ten years' experience in the medical field;
 2. Non-medical personnel who have abundant experience and knowledge in law, public health, media, the rights and interests of consumers, etc.
- (4) The term of office of each committee member shall be three years, renewable for only one further term.

[This Article Newly Inserted by Presidential Decree No. 23753, Apr. 27, 2012]

Article 11-3 (Operation of Ethics Committee)

- (1) Each ethics committee shall deliberate, and pass a resolution, on the following:
 1. Requests for the suspension of qualification under Article 66-2 of the Act;
 2. Examinations of qualification for members of each central association and disciplinary actions against members;

3. Other matters stipulated by each central association's articles of incorporation as necessary for the establishment of ethics of members.
- (2) Each ethics committee shall meet at the call of the chairperson of the relevant ethics committee or upon request by the head of the relevant central association or by at least one-third of the registered ethics committee members. In such cases, the chairperson of the ethics committee shall notify each ethics committee member of the date, time, and place of the meeting and items on the agenda by no later than seven days before such meeting is held.
- (3) An ethics committee meeting shall commence with the attendance of at least two-thirds of the registered ethics committee members, and a resolution shall be adopted by concurrent votes of at least two-thirds of the ethics committee members present at the meeting: *Provided*, That a quorum for a meeting to pass a resolution on the matters specified in paragraph (1) 2 and 3 may be otherwise stipulated by each central association's articles of incorporation.
- (4) Where intending to deliberate, and pass a resolution, on any matter specified in paragraph (1) 1 or 2, the chairperson of an ethics committee shall grant the parties involved in the relevant case with an opportunity to make oral or written statements (including electronic documents).
- (5) An ethics committee may organize and operate a specialized advisory group for each field in accordance with the standards set by the Minister of Health and Welfare, if necessary for the professional review of the matters to be deliberated on and resolved under its jurisdiction. *<Newly Inserted by Presidential Decree No. 27944, Mar. 20, 2017>*
- (6) Except as otherwise expressly provided for in paragraphs (1) through (5), matters necessary for operating an ethics committee or a specialized advisory group for each field shall be prescribed by each central association's articles of incorporation. *<Amended by Presidential Decree No. 27944, Mar. 20, 2017>*

[This Article Newly Inserted by Presidential Decree No. 23753, Apr. 27, 2012]

Article 11-4 (Exclusion of Members of Ethics Committee)

- (1) In any of the following circumstances, a member of the Ethics Committee shall be excluded from deliberation and resolution by the Ethics Committee:
 1. If a committee member is a party to a case brought to the Ethics Committee for deliberation and resolution (hereafter referred to as “the case at issue” in this Article);
 2. If a committee member is or was a relative of a party to the case at issue;
 3. If a committee member works or worked for an institution to which a party to the case at issue has belonged within the last three years.
- (2) If a party to the case at issue has a ground to exclude a committee member under paragraph (1) or has any other ground to hardly expect impartiality from a committee member in deliberation and resolution, such party may file a petition for challenge against the committee member with the Ethics Committee, stating the reasons therefor in writing.
- (3) Upon receipt of a petition for challenge under paragraph (2), the Ethics Committee shall make a decision on whether to accept the challenge with the attendance of a majority of the registered committee members and by concurring votes of a majority of the committee members present at the meeting. In such cases, the committee member against whom the petition for challenge has been filed shall not participate in making such decision.
- (4) If a member of the Ethics Committee has any ground specified in paragraph (1) or (2), he/she may voluntarily recuse himself/herself from deliberation and resolution.

[This Article Newly Inserted by Presidential Decree No. 23753, Apr. 27, 2012]

Article 12 (Applications for Permission to Establish Central Association)

When a person intends to obtain permission to establish a central association under Article 29 (1) of the Act, he/she shall submit the following documents to the Minister of Health and Welfare: *<Amended by*

Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010>

1. Articles of incorporation;
2. Business plan;
3. Statement of assets;
4. Establishment resolution;
5. Documents concerning the circumstances of election of founding representative;
6. Written consents of inauguration and resumes of executives.

Article 13 (Matters to Be Entered in Articles of Incorporation)

Matters that shall be stated in articles of incorporation of a central association pursuant to Article 29 (2) of the Act shall be as follows: <*Amended by Presidential Decree No. 23753, Apr. 27, 2012*>

1. Objective;
2. Appellation;
3. Seats of the central association, branches, sub-branches;
4. Property or accounts and other matters concerning management and operation;
5. Matters concerning the designation of executive officers;
6. Matters concerning qualifications for and disciplinary actions against members;
7. Matters concerning modification of articles of incorporation;
8. Matters concerning the method of public announcement;
9. Matters concerning the operation of the Ethics Committee.

Article 14 (Applications for Permission to Modify Articles of Incorporation)

Where any central association intends to obtain permission for modification of the articles of incorporation under Article 29 (3) of the Act, it shall submit the following documents to the Minister of Health and Welfare: <*Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010*>

1. Documents stating the details and reasons of the modification of the articles of incorporation;
2. Minutes of the meetings concerning the modification of the articles of incorporation;
3. A comparison chart for the new and old articles of incorporation, and other reference documents.

Article 15 (Branches of Central Association)

Under Article 28 (5) of the Act, any central association shall establish branches each in a Special Metropolitan City, Metropolitan Cities, Dos and Special Self-Governing Provinces within three weeks from the date of the completion of the establishment registration: *Provided*, That branches of doctors' association in foreign countries shall be established within ten weeks from the date of obtaining permission for modifying the articles of incorporation thereof.

Article 16 (Permission to Modify Articles of Incorporation to Establish Medical Corporations)

(1) A medical corporation referred to in Article 33 (2) 3 of the Act (hereinafter referred to as "medical corporation") or a nonprofit corporation referred to in subparagraph 4 of the same paragraph that intends to obtain permission for establishing a corporation or modifying its articles of incorporation pursuant to the former part of paragraph (9) of the same Article, shall submit the documents classified as follows to the competent administrative agency:

1. Where it intends to obtain permission for establishing a corporation: The following documents:
 - (a) A draft of the articles of incorporation which reflects the fact that the establishment and operation of a medical institution coincide with the its purpose business and the seat of the medical institution;
 - (b) A project plan and a fund-raising plan to establish and operate a medical institution;
 - (c) A plan to secure facilities, equipment, human resources, etc. of a medical institution;

- (d) Documents required under related statutes or regulations when a nonprofit corporation referred to in Article 33 (2) 4 of the Act intends to obtain permission for the establishment of a corporation (applicable only to nonprofit corporations);
 - (e) Documents necessary to obtain permission for establishing a medical corporation pursuant to Article 48 (1) of the Act;
 - (f) Other documents publicly notified by the Minister of Health and Welfare as deemed necessary in connection with the establishment and operation of a medical institution;
2. Where it is intended to obtain permission for modifying its articles of incorporation: The following documents:
- (a) A draft of the articles of incorporation which reflects the fact that the establishment and operation of a medical institution coincide with the its purpose business and the seat of the medical institution;
 - (b) Documents set forth in subparagraph 1 (b) and (c);
 - (c) Documents required under related statutes or regulations when a nonprofit corporation referred to in Article 33 (2) 4 of the Act intends to obtain permission for modifying its articles of incorporation (applicable only to nonprofit corporations);
 - (d) Documents necessary to obtain permission for modifying the articles of incorporation pursuant to Article 48 (3) of the Act;
 - (e) Other documents publicly notified by the Minister of Health and Welfare as deemed necessary in connection with the establishment and operation of a medical institution.
- (2) Matters concerning the standards for, methods of preparation and detailed contents of the documents set forth in paragraph (1) (excluding subparagraph 1 (d) and (e) and 2 (c) and (d)), and other relevant matters shall be determined and publicly notified by the Minister of Health and Welfare.

[This Article Newly Inserted by Presidential Decree No. 27525, Sep. 29, 2016]

Article 17 Deleted. <by Presidential Decree No. 23753, Apr. 27, 2012>

Article 17-2 (Measures to Be Taken upon Closure or Suspension of Business)

Upon receipt of a report on the closure or suspension of business of a medical institution pursuant to Article 40 (1) of the Act, the head of a *Si/Gun/Gu* (referring to the head of an autonomous *Gu*; hereinafter the same shall apply) shall take measures to verify the following matters pursuant to paragraph (5) of the same Article: *<Amended by Presidential Decree No. 30480, Feb. 25, 2020>*

1. Whether laundry from the medical institution is appropriately handled in accordance with Article 16 (1) of the Act;
2. Whether medical records, etc. (including electronic medical records: hereinafter referred to as "medical records, etc.") referred to in Article 22 (1) of the Act are appropriately transferred to other medical institutions or are retained in the medical institution in accordance with Article 40 (2) of the Act;
3. Whether measures to protect the rights and interests of patients are taken in accordance with Article 40 (4) of the Act;
4. Other measures similar to those prescribed in subparagraphs 1 through 3, which are deemed particularly necessary by the Minister of Health and Welfare to properly manage the closure or suspension of business of the medical institution.

[This Article Newly Inserted by Presidential Decree No. 28131, Jun. 20, 2017]

Article 18 Deleted. <by Presidential Decree No. 28131, Jun. 20, 2017>

Article 19 (Application for Permission to Establish Medical Corporations)

A person who intends to establish a medical corporation under Article 48 (1) of the Act shall submit an

application for permission to establish a medical corporation and related documents determined by Ordinance of the Ministry of Health and Welfare to the Special Metropolitan City Mayor, a Metropolitan City Mayor, a Do Governor, or a Special Self-Governing Province Governor (hereinafter referred to as "Mayor/Do Governor") having jurisdiction over the area in which the principal office of such corporation is located. <Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 29195, Sep. 28, 2018>

Article 20 (Mission of Medical Corporations)

Medical corporations, as well as non-profit corporations that have established medical institutions under Article 33 (2) 4 of the Act, shall contribute to public hygiene and shall not seek profit, in conducting business of medical treatment (including incidental business that medical corporations conduct under Article 49 of the Act).

Article 21 (Application for Permission to Dispose of Property or Modify Articles of Incorporation)

Where any medical corporation intends to obtain permission to dispose of property or modify the articles of incorporation under Article 48 (3) of the Act, it shall submit an application for permission and related documents determined by Ordinance of the Ministry of Health and Welfare to a Mayor/Do Governor having jurisdiction over the area in which the principal office of such corporation is located: *Provided*, That a medical corporation falling under Article 11 of the Addenda to the Medical Service Act (No. 4732), which has been assisted with public loans from the State, shall submit such application and documents to the Minister of Health and Welfare via a Mayor/Do Governor. <Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 29195, Sep. 28, 2018>

Article 22 (Medical Information System Projects)

"Project prescribed by Presidential Decree" in Article 49 (1) 6 of the Act means any of the following projects: <Amended by Presidential Decree No. 28131, Jun. 20, 2017>

1. System development and operation projects to prepare and manage electronic medical records;
2. System development and operation projects to prepare and manage electronic medical prescriptions;
3. System development and operation projects to save and transmit video records.

Article 22-2 (Operation of National Academy of Medicine of Korea)

- (1) The business year of the National Academy of Medicine of Korea established under Article 52-2 (1) of the Act (hereinafter referred to as the "National Academy") shall coincide with the fiscal year of the Government.
- (2) The National Academy shall report matters concerning the plan for and current status of providing its services, funds management plan, disbursement breakdown of funds, etc. to the Minister of Health and Welfare, as determined by the Minister of Health and Welfare.
- (3) The National Academy shall develop and implement measures necessary for medical personnel, related experts, etc. in various fields to participate in the operation of its organization, provision of its services, and other relevant matters in equilibrium.

[This Article Newly Inserted by Presidential Decree No. 27525, Sep. 29, 2016]

Article 23 (Standards for Prohibition of Medical Service Advertisement)

- (1) Specific standards for prohibiting medical service advertisement under Article 56 (2) of the Act shall be as follows: <Amended by Presidential Decree No. 21148, Dec. 3, 2008; Presidential Decree No. 22003, Jan. 27, 2010; Presidential Decree No. 23753, Apr. 27, 2012; Presidential Decree No. 27917, Feb. 28, 2017; Presidential Decree No. 29195, Sep. 28, 2018>

1. Advertising any new medical technology that has not gone through the assessment of the new

- medical technology pursuant to Article 53 of the Act;
2. Advertising with a clear expression that the medical treatment skills or methods of specific medical institutions or specific medical personnel are effective without failure in the treatment of diseases, or advertising the treatment stories of patients or the clinical experiences of not more than six months;
 3. Falsely advertising, such as advertising matters different from objective facts with respect to medical personnel, medical institutions, medical services, and others related to medical treatment;
 4. Advertising that medical treatment skills or methods performed or advertised by the founder of a specific medical institution, the head of a medical institution, or medical personnel (hereinafter referred to as "medical personnel, etc.") are far superior and more effective than those of other medical personnel, etc.;
 5. Advertising unfavorable matters on medical treatment skills or methods performed or advertised by other medical personnel, etc. for the purpose of slandering the relevant medical personnel, etc.;
 6. Advertising by posting videos or photographs which the general public feel disgusted at such as those showing the scenes of operations of patients performed by medical personnel, or the affected parts, etc. of patients;
 7. Advertising any medical service or therapy provided by medical personnel, etc., which lacks essential information, such as foreseeable side effects likely to cause serious harm to the safety of patients, or which provides such essential information in an inconspicuous manner, such as a hardly readable, small font;
 8. Advertising by exaggerating objective facts with respect to medical personnel, medical institutions, medical services, and various matters related to medical treatment;
 9. Advertising content that contains qualifications or names with no legal basis;
 10. Advertising the medical treatment skills or methods of specific medical institutions or medical personnel by carrying or broadcasting articles or opinions of experts concerning such skills or methods in newspapers or Internet newspapers provided for in Article 2 of the Act on the Promotion of Newspapers, or in periodicals provided for in the Act on Promotion of Periodicals, including Magazines, or in broadcasts provided for in subparagraph 1 of Article 2 of the Broadcasting Act, while carrying or broadcasting information on the contact address and map of the specific medical institutions or medical personnel;
 11. Advertising medical services subject to review under Article 57 (1) of the Act without review or differently from the reviewed contents;
 12. Advertising domestically to perform the acts referred to in Article 27 (3) of the Act for the purpose of attracting foreign patients;
 13. Advertising that contains false or vague contents, information, etc. as to the discount, and amount of exemption, of non-covered medical expenses, and the items eligible for, or the period or scope of non-covered medical expenses referred to in Article 45 of the Act, or the non-covered medical expenses before applying discount or exemption;
 14. Advertising by using various certificates of merit, letters of appreciation, etc. or advertising by using an expression that certification, guarantee, or recommendation is given or by any other similar expression: *Provided*, That cases falling under any item of Article 56 (2) 14 of the Act shall be excluded.
- (2) "Advertisement prescribed by Presidential Decree, such as an advertisement indicating certification obtained from an international evaluation organization that has signed an agreement for collaboration with the World Health Organization" in Article 56 (2) 14 (d) of the Act means any of the following: <Newly Inserted by Presidential Decree No. 29195, Sep. 28, 2018>
1. An advertisement indicating certification obtained from an international evaluation organization that has signed an agreement for collaboration with the World Health Organization;
 2. An advertisement indicating certification from an accreditation agency of each country

recognized by the International Society for Quality in Health Care.

- (3) Where medical personnel, etc. advertise their medical services on their websites, the Minister of Health and Welfare may determine and publicly notify detailed standards for prohibiting medical advertisement pursuant to paragraph (1). <Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 29195, Sep. 28, 2018>

Article 24 (Deliberation on Medical Services Advertisement)

- (1) "Internet media prescribed by Presidential Decree" in Article 57 (1) 4 of the Act means the following media: <Amended by Presidential Decree No. 23753, Apr. 27, 2012>
1. Internet news services prescribed in subparagraph 5 of Article 2 of the Act on the Promotion of Newspapers;
 2. Website operated by a broadcasting business operator prescribed in subparagraph 3 of Article 2 of the Broadcasting Act;
 3. Internet media that mainly provides broadcast programs of a broadcasting business operator prescribed in subparagraph 3 of Article 2 of the Broadcasting Act online under a name or title, such as 'broadcasting', 'TV', or 'radio';
 4. Internet media operated by an information and communications service provider prescribed in Article 2 (1) 3 of the Act on Promotion of Information and Communications Network Utilization and Information Protection, if the average number of daily users was at least 100,000 during the last three months as at the end of the preceding year.
- (2) "Advertising media prescribed by Presidential Decree" in Article 57 (1) 5 of the Act means any advertising medium providing social network services that has at least 100,000 daily users on average for the last three months as at the end of the preceding year. <Amended by Presidential Decree No. 29195, Sep. 28, 2018>
- (3) An institution or organization referred to in the subparagraphs of Article 57 (2) of the Act shall have all of the following to conduct voluntary deliberation: <Amended by Presidential Decree No. 29195, Sep. 28, 2018>
1. At least one department and three full-time workers (persons with abundant knowledge and experience in the field of medical services or advertisement shall be included) that are exclusively responsible for affairs regarding deliberation on and monitoring of medical service advertisements under Articles 57 and 57-3 of the Act;
 2. Computerized equipment and an office to be used to perform affairs regarding deliberation on and monitoring of medical service advertisements under Articles 57 and 57-3 of the Act.
- (4) "Organization that meets the requirements prescribed by Presidential Decree" in Article 57 (2) 2 of the Act means an organization satisfying all of the following requirements: <Newly Inserted by Presidential Decree No. 29195, Sep 28, 2018>
1. It shall be registered with the Fair Trade Commission under Article 29 of the Framework Act on Consumers;
 2. The details related to medical services and advertisements shall be included in the purpose of establishing an organization and the scope of its affairs.
- (5) An institution or organization that intends to report under Article 57 (2) of the Act shall submit a written report and related documents determined by Ordinance of the Ministry of Health and Welfare to the Minister of Health and Welfare. <Newly Inserted by Presidential Decree No. 29195, Sep. 28, 2018>
- (6) The Minister of Health and Welfare shall disclose the current status of reports that he/she has received under paragraph (5) on the website of the Ministry of Health and Welfare. <Newly Inserted by Presidential Decree No. 29195, Sep. 28, 2018>
- (7) "Matters prescribed by Presidential Decree" in Article 57 (3) 4 of the Act means the following:

<Newly Inserted by Presidential Decree No. 29195, Sep. 28, 2018>

1. The founder of a medical institution and the year of its foundation;
2. The website address of a medical institution;
3. The dates and time of diagnosis and treatment by a medical institution;
4. The fact that a medical institution is designated as a specialized hospital under Article 3-5 (1) of the Act;
5. The fact that a medical institution is accredited under Article 58 (1) of the Act;
6. The fact that the founder or medical personnel of a medical institution is recognized for their qualifications as a medical specialist under Article 77 (1) of the Act and their specialized areas.

Articles 25 through 28-2 Deleted. *<by Presidential Decree No. 29195, Sep. 28, 2018>*

Article 29 (Entrustment of Accreditation of Medical Institutions)

(1) Pursuant to Article 58 (2) of the Act, the Minister of Health and Welfare shall entrust the following affairs to a non-profit corporation established for accreditation of medical institutions with permission from the Minister of Health and Welfare (hereafter referred to as “accrediting agency” in this Article): *<Amended by Presidential Decree No. 29195, Sep. 28, 2018>*

1. Development of the standards for accreditation under Article 58-3 (1) of the Act;
2. Examination on whether the standards for accreditation under Article 58-3 (2) of the Act are met;
3. Notification of the results of evaluation and accreditation ratings under Article 58-3 (3) of the Act;
4. Re-accreditation of medical institutions conditionally accredited under Article 58-3 (6) of the Act;
5. Receipt of applications for accreditation under Article 58-4 (1) or (2) of the Act;
6. Receipt of petitions for objection under Article 58-5 of the Act and notification of results thereof;
7. Issuance of certificates of accreditation under Article 58-6 (1) of the Act;
8. Publication of standards for accreditation of medical institutions accredited under Article 58-7 (1) of the Act, the term of validity of accreditation, the results of evaluation conducted pursuant to Article 58-3 (2) of the Act, etc. through Internet websites, etc.

(2) The head of the accrediting agency shall report the details of affairs entrusted to and handled by the agency to the Minister of Health and Welfare, as prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Wholly Amended by Presidential Decree No. 22635, Jan. 24, 2011]

Article 30 (Composition of Medical Institution Accreditation Commission)

Members of the Medical Institution Accreditation Commission under Article 58-2 (1) of the Act (hereinafter referred to as the “Accreditation Commission”) shall be appointed or commissioned by the Minister of Health and Welfare as follows: *<Amended by Presidential Decree No. 29195, Sep. 28, 2018>*

1. Five persons recommended by associations of medical personnel under Article 28 of the Act and associations of medical institutions under Article 52 of the Act;
2. Five persons recommended by labor organizations, civic groups (referring to non-profit, non-governmental organizations under Article 2 of the Assistance for Non-Profit, Non-Governmental Organizations Act), and consumer organizations (referring to consumer organizations under Article 29 of the Framework Act on Consumers);
3. Three persons with abundant knowledge and experience in the field of public health and medical services or safety diagnosis of medical institution facilities;
4. One Grade-III or higher-ranking public official or one public official who is a member of the Senior Executive Service, from among public officials of the Ministry of Health and Welfare.

[This Article Wholly Amended by Presidential Decree No. 22635, Jan. 24, 2011]

Article 31 (Term of Office of Commission Members)

- (1) The term of office of each commission member under subparagraphs 1 through 3 of Article 30 shall be two years.
 - (2) The term of office of a commission member commissioned to replace a commission member resigning from office shall coincide with the remaining term of office of his/her predecessor.
- [This Article Wholly Amended by Presidential Decree No. 22635, Jan. 24, 2011]

Article 31-2 (Dismissal from Office of Members of Accreditation Commission)

The Minister of Health and Welfare may dismiss a member of the accreditation Commission from office if he/she falls under any of the following cases:

1. Where he/she member becomes incapable of performing his/her duties due to any mental disorder;
2. Where he/she engages in misconduct in connection with his/her duties;
3. Where he/she is deemed unsuitable as a member due to neglect of duties, injury to dignity, or any other ground;
4. Where he/she voluntarily admits that it is impracticable for him/her to perform his/her duties.

[This Article Newly Inserted by Presidential Decree No. 27525, Sep. 29, 2016]

Article 31-3 (Operation of Accreditation Commission)

- (1) The chairperson shall represent the Accreditation Commission and shall exercise overall control over the affairs of the Accreditation Commission.
- (2) The Accreditation Commission shall hold a meeting at the call of the chairperson or at least one-third of the registered commission members, and the commission chairperson shall preside over the meeting.
- (3) A meeting of the Accreditation Commission shall be duly formed with the attendance of a majority of the registered members, and a resolution shall be adopted by concurrent votes of a majority of the commission members present at the meeting.
- (4) If the commission chairperson is unable to perform his/her duty due to extenuating circumstances, a commission member appointed by the commission chairperson in advance shall act on behalf of the commission chairperson.
- (5) Except as otherwise expressly provided for in paragraphs (1) through (4), matters necessary for the operation, etc. of the Accreditation Commission shall be determined by the commission chairperson, subject to prior resolution thereon by the Accreditation Commission.

[This Article Newly Inserted by Presidential Decree No. 22635, Jan. 24, 2011]

Article 31-4 (Administrative Secretary)

- (1) The Accreditation Commission shall appoint one administrative secretary, who shall perform administrative affairs of the Accreditation Commission.
- (2) The administrative secretary shall be appointed by the Minister of Health and Welfare, from among public officials of the Ministry of Health and Welfare.

[This Article Newly Inserted by Presidential Decree No. 22635, Jan. 24, 2011]

Article 31-5 (Allowances)

Commission members who attend a meeting of the Accreditation Commission, except for public officials, shall be reimbursed for allowances and travel expenses within budgetary limits.

[This Article Newly Inserted by Presidential Decree No. 22635, Jan. 24, 2011]

Article 31-6 (Entrustment of Operation of Vocational Training Centers for Nursing Workforce)

- (1) Pursuant to Article 60-3 (2) of the Act, the Minister of Health and Welfare may entrust the affairs related to the operation of a vocational training center for nursing workforce referred to in paragraph

(1) of the same Article (hereinafter referred to as "vocational training center for nursing workforce") to any of the following specialized institutions or organizations:

1. A nurses' association or a branch of a nurses' association referred to in Article 28 (1) or (5) of the Act;
 2. A public institution established with the objective of providing health and medical services, among the public institutions set forth in Article 4 of the Act on the Management of Public Institutions;
 3. Any other specialized institution or organization publicly notified by the Minister of Health and Welfare, taking into account the organizational structure, workforce, expertise, etc. necessary for the performance of entrusted services.
- (2) Where the Minister of Health and Welfare intends to entrust the operation of a vocational training center for nursing workforce pursuant to Article 60-3 (2) of the Act, he/she shall publicly announce matters related to the criteria and procedures for, and the methods, etc. of the entrustment in advance.
- (3) When the Minister of Health and Welfare entrusts the operation of a vocational training center for nursing workforce pursuant to Article 60-3 (2) of the Act, he/she shall publish matters related to the details of the entrustment, trustee, etc. in the Official Gazette and post them on the website of the Ministry of Health and Welfare.
- (4) A specialized institution or organization entrusted with the operation of a vocational training center for nursing workforce pursuant to Article 60-3 (2) of the Act, shall report matters related to the plan for and current status of providing its services, funds management plan, disbursement breakdown of funds, etc. to the Minister of Health and Welfare, as determined by the Minister of Health and Welfare.
- (5) Detailed matters necessary for the public announcement of criteria for entrustment, public notice of details, etc. of entrustment, reporting on entrusted affairs, and other relevant matters prescribed in paragraphs (2) through (4) shall be determined and publicly notified by the Minister of Health and Welfare.

[This Article Newly Inserted by Presidential Decree No. 27525, Sep. 29, 2016]

Article 31-7 (Publication of Offense and Corrective Advertisement)

- (1) When the Minister of Health and Welfare or the head of a *Si/Gun/Gu* orders medical personnel, etc. to publish an offense or run a corrective advertisement under Article 63 (2) 2 or 3 of the Act, he/she shall determine the details, frequency, size, or medium of such publication or corrective advertisement, considering the following:
1. The details and degree of an offense;
 2. The duration and frequency of an offense.
- (2) When the Minister of Health and Welfare or the head of a *Si/Gun/Gu* orders medical personnel, etc. to publish an offense or run a corrective advertisement under paragraph (1), he/she may determine the details, frequency, size, or medium of such publication or corrective advertisement in consultation with the deliberation committees established under Article 57-2 (2) of the Act.

[This Article Newly Inserted by Presidential Decree No. 29195, Sep. 28, 2018]

Article 32 (Scope of Acts of Degrading Medical Personnel's Dignity)

- (1) The scope of acts of degrading the dignity of medical personnel referred to in Article 66 (2) of the Act shall be as follows: *<Amended by Presidential Decree No. 26526, Sep. 15, 2015>*
1. Conducting medical treatment not recognized academically (including midwifery services and nursing services; hereinafter the same shall apply);
 2. Conducting unethical medical treatment;
 3. Running false or exaggerated advertisements;
 - 3-2. Providing the following health and medical information (referring to information on medical

science, dentistry, midwifery, and nursing science; hereinafter the same shall apply) through broadcasting defined in subparagraph 1 of Article 2 of the Broadcasting Act, a newspaper or online newspaper defined in subparagraphs 1 and 2 of Article 2 of the Act on the Promotion of Newspapers, Etc., or a periodical defined in subparagraph 1 of Article 2 of the Act on Promotion of Periodicals, Including Magazines in a false or exaggerated manner:

- (a) Health and medical information on foods defined in subparagraph 1 of Article 2 of the Food Sanitation Act;
 - (b) Health and medical information on functional health foods defined in subparagraph 1 of Article 3 of the Health Functional Foods Act;
 - (c) Health and medical information on drugs, herbs, herb medications, or quasi-drugs defined in subparagraphs 4 through 7 of Article 2 of the Pharmaceutical Affairs Act;
 - (d) Health and medical information on medical devices defined in Article 2 (1) of the Medical Devices Act;
 - (e) Health and medical information on cosmetics, functional cosmetics or organic cosmetics defined in subparagraphs 1 through 3 of Article 2 of the Cosmetics Act;
4. Conducting excessive medical treatment, such as unnecessary tests, medication or surgery, or requesting unjustly excessive medical treatment fees;
 5. Giving and receiving money and other valuables in connection with work, such as selection of specialized doctors;
 6. Enticing or causing enticement of patients who are about to use other medical institutions into going to medical institutions at which they are employed or which they have established, for profits;
 7. Enticing patients who get prescriptions from them into visiting a particular drugstore in collusion with the opener of such drugstore or a person employed at such drugstore, for profit.
- (2) Deleted. <by Presidential Decree No. 23753, Apr. 27, 2012>

Article 33 (Request of Central Association for Suspension of Qualification)

A request for the suspension of qualification under Article 66-2 of the Act shall be made by submitting a document which states the date, time, and place of the meeting of the Ethics Committee and the reasons and grounds for the request for suspension of qualification, to the Minister of Health and Welfare.

[This Article Wholly Amended by Presidential Decree No. 23753, Apr. 27, 2012]

Articles 34 through 39 Deleted. <by Presidential Decree No. 23753, Apr. 27, 2012>

Article 40 (Entrustment of Affairs Related to Evaluation for Designation of Education and Training Centers for Assistant Nurses)

- (1) Pursuant to the latter part of Article 80 (2) of the Act, the Minister of Health and Welfare may entrust affairs related to the designation of an education and training center for assistant nurses to any of the following institutions:
 1. A public institution established with the objective of providing health and medical services or developing human resources, among the public institutions set forth in Article 4 of the Act on the Management of Public Institutions;
 2. Any other institution publicly notified by the Minister of Health and Welfare as a specialized institution with the organizational structure, workforce, expertise, etc. necessary to perform the entrusted affairs.
- (2) Where the Minister of Health and Welfare entrusts affairs related to the evaluation for designation of an education and training center for assistant nurses pursuant to the latter part of Article 80 (2) of the Act, Article 31-6 (2) through (5) shall apply *mutatis mutandis* to the public announcement of criteria for entrustment, public notice of details of the entrustment, reporting on the entrusted affairs, etc.

[This Article Newly Inserted by Presidential Decree No. 27700, Dec. 27, 2016]

Article 41 (Grounds for Revocation of Designation of Education and Training Center for Assistant Nurses)

"Grounds prescribed by Presidential Decree, such as obtaining the designation by fraudulent or illegal means" in Article 80 (3) of the Act, means any of the following grounds:

1. Where an education and training center for assistant nurses is designated by fraud or other improper means;
2. Where an education and training center for assistant nurses fails to meet the criteria for designation of an education and training center for assistant nurses;
3. Where an education and training center for assistant nurses refuses to perform affairs of education and training or provides no education or training for at least three months;
4. Where an education and training center for assistant nurses issues a diploma of education and training or a certificate of completion of the course by fraudulent or other illegal means;
5. Where the curricula or contents of education are in contravention of statutes or regulations, or where it is deemed impracticable to attain the purpose of designation of an education and training center.

[This Article Newly Inserted by Presidential Decree No. 27700, Dec. 27, 2016]

Article 42 (Entrustment of Business)

- (1) The Minister of Health and Welfare may entrust business for preparing standards for medical terms, and forms and details of medical records, etc. prescribed in Article 22 (4) of the Act to the following institutions pursuant to Article 86 (2) of the Act: *<Newly Inserted by Presidential Decree No. 30480, Feb. 25, 2020>*
 1. A public institution prescribed in Article 4 of the Act on the Management of Public Institutions, the objectives of establishment of which is related to healthcare or health industries;
 2. A specialized institutions equipped with organizations, human resources, expertise, etc. necessary to conduct the business entrusted, which the Minister of Health and Welfare determines and publishes.
- (2) The Minister of Health and Welfare may entrust business concerning the receipt of applications for the certification of electronic medical record systems, notification of results of certification, and issuance of certificates prescribed in Article 23-2 (2), and business concerning the promotion of development of technology and use of electronic medical record systems prescribed in paragraph (5) of the same Article to the following institutions pursuant to Article 86 (2) of the Act: *<Newly Inserted by Presidential Decree No. 28131, Jun. 20, 2017; Presidential Decree No. 30480, Feb. 25, 2020>*
 1. A public institution prescribed in Article 4 of the Act on the Management of Public Institutions, the objectives of establishment of which are related to healthcare or social security;
 2. An institution the Minister of Health and Welfare determines and publishes, taking into account the organizational structure, workforce, expertise, etc. necessary to conduct the business entrusted.
- (3) The Minister of Health and Welfare may entrust business concerning the investigation and analysis of non-covered medical expenses and charges for issuing all types of certificates and the disclosure of results of such investigation and analysis prescribed in Article 45-2 (1) of the Act to the following specialized institutions pursuant to Article 86 (2) of the Act: *<Amended by Presidential Decree No. 28131, Jun. 20, 2017; Presidential Decree No. 30480, Feb. 25, 2020>*
 1. A physicians' association, dentists' association or oriental medical doctors' association prescribed in Article 28 of the Act;
 2. A public institution prescribed in Article 4 of the Act on the Management of Public Institutions, the objectives of establishment of which are related to healthcare;
 3. Other institutions the Minister of Health and Welfare publishes, taking into account the organizational structure, workforce, expertise, etc. necessary to conduct the business entrusted.

- (4) The Minister of Health and Welfare may entrust business concerning the operation of accounting standards for medical institutions prescribed in Article 62 (2) of the Act to the following institutions pursuant to Article 86 (2) of the Act: <Newly Inserted by Presidential Decree No. 29195, Sep. 28, 2018; Presidential Decree No. 30480, Feb. 25, 2020>
1. A public institution prescribed in Article 4 of the Act on the Management of Public Institutions, the objectives of establishment of which are related to healthcare or health industries;
 2. A specialized institution equipped with organizations, workforce, expertise, etc. necessary to conduct the business entrusted, which is an institution the Minister of Health and Welfare determines and publishes.
- (5) The Minister of Health and Welfare may entrust business concerning the receipt of applications to obtain designation as assistant nurse education and training institutions prescribed in Article 80 (2) of the Act and the issuance of certificates of designation to the following institutions pursuant to Article 86 (2) of the Act: <Newly Inserted by Presidential Decree No. 27700, Dec. 27, 2016; Presidential Decree No. 28131, Jun. 20, 2017; Presidential Decree No. 30480, Feb. 25, 2020>
1. A public institution prescribed in Article 4 of the Act on the Management of Public Institutions, the objectives of establishment of which are related to healthcare or development of human resources;
 2. A specialized institution equipped with organizations, workforce, expertise, etc. necessary to conduct the business entrusted, which the Minister of Health and Welfare determines and publishes.
- (6) The Minister of Health and Welfare may entrust business concerning reporting on the actual state, employment, etc. of assistant nurses prescribed in Article 80 (4) of the Act and refresher training for assistant nurses prescribed in Article 80 (5) of the Act to the following institutions pursuant to Article 86 (2) of the Act: <Newly Inserted by Presidential Decree No. 27700, Dec. 27, 2016; Presidential Decree No. 28131, Jun. 20, 2017; Presidential Decree No. 30480, Feb. 25, 2020>
1. A public institution prescribed in Article 4 of the Act on the Management of Public Institutions, the objectives of establishment of which are related to healthcare or development of human resources;
 2. An institution established with assistant nurses as its members and having a nationwide organization;
 3. A specialized institution equipped with organizations, workforce, expertise, etc. necessary to conduct the business entrusted, which the Minister of Health and Welfare determines and publishes (limited to refresher training for assistant nurses prescribed in Article 80 (5) of the Act).
- (7) Where the Minister of Health and Welfare entrusts business prescribed in paragraphs (1) through (6) pursuant to Article 86 (2) of the Act, Article 31-6 (2) through (5) shall apply *mutatis mutandis* to the publication of criteria for entrustment, public notice of details of entrustment, etc., and reports on entrusted business, etc. <Amended by Presidential Decree No. 27700, Dec. 27, 2016; Presidential Decree No. 28131, Jun. 20, 2017; Presidential Decree No. 29195, Sep. 28, 2018; Presidential Decree No. 30480, Feb. 25, 2020>

[This Article Newly Inserted by Presidential Decree No. 27525, Sep. 29, 2016]

Article 42-2 (Management of Sensitive Information and Personally Identifiable Information)

The Minister of Health and Welfare (including persons entrusted with affairs of the Minister of Health and Welfare pursuant to Articles 10-4 (1), 11 (2), 31-6 (1), and 42 (1) through (5)); a Mayor/*Do* Governor; the head of a *Si/Gun/Gu* (including persons with authority delegated or entrusted, where a Mayor/*Do* Governor or the head of a *Si/Gun/Gu* delegates or entrusts his/her authority for relevant affairs); medical personnel; the head of a medical institution; a person working for a medical institution; the founder or manager of a medical institution prescribed in Article 37 of the Act; or an agency responsible for the management of national examinations, may manage information about health prescribed in Article 23 of the Personal Information Protection Act; criminal records prescribed in

subparagraph 2 of Article 18 of the Enforcement Decree of the aforesaid Act; and materials in which a resident registration number or alien registration number prescribed in subparagraph 1 or 4 of Article 19 of the aforesaid Decree is included, if essential to perform any of the following affairs: <Amended by Presidential Decree No. 23753, Apr. 27, 2012; Presidential Decree No. 27525, Sep. 29, 2016; Presidential Decree No. 27700, Dec. 27, 2016; Presidential Decree No. 27917, Feb. 28, 2017; Presidential Decree No. 28131, Jun. 20, 2017; Presidential Decree No. 30480, Feb. 25, 2020>

1. Administering national examinations, etc. prescribed in Article 9 of the Act (including cases applied *mutatis mutandis* under Article 80-3 of the Act);
2. Verifying eligibility for national examinations, etc. prescribed in Article 10 of the Act (including cases applied *mutatis mutandis* under Article 80-3 of the Act);
3. Issuing licenses prescribed in Article 11 of the Act;
- 3-2. Preparing, issuing or transmitting (limited to online prescriptions) medical certificates, post mortem examination reports, certificates or prescriptions under Article 17 or 18 of the Act;
- 3-3. Verifying details of patients' records under Article 21 of the Act;
- 3-4. Verifying details of medical records, or sending or transmitting copies of medical records, clinical opinions on the progress of medical treatment of patients, etc. under Article 21-2 (1) of the Act;
- 3-5. Sending copies of medical records, etc. under Article 21-2 (2) of the Act;
- 3-6. Preparing medical records, etc. under Article 22 of the Act;
4. Reporting the actual status of medical personnel, his/her current employment status, etc. prescribed in Article 25 of the Act;
- 4-2. Establishing, etc. a medical institution prescribed in Articles 33 and 35 of the Act;
5. Controlling exposure of radiation to workers involved in radiation from radiation generators for diagnosis prescribed in Article 37 of the Act;
- 5-2. Investigating and analyzing non-covered medical expenses and charges to issue all types of certificates, and disclosing the results thereof prescribed in Article 45-2 (1) of the Act;
- 5-3. Supporting the survey of the current securement of nursing workforce, and vocational education of nursing workforce and their career development prescribed in Article 60-3 (1) 1 through 5 of the Act;
6. Taking administrative dispositions prescribed in Articles 63 through 66 of the Act;
7. Imposing and collecting penalty surcharges prescribed in Article 67 of the Act;
8. Accrediting qualification for medical specialists prescribed in Article 77 of the Act;
9. Accrediting qualification for nurse practitioners prescribed in Article 78 of the Act;
10. Accrediting qualification for assistant nurses prescribed in Article 80 (1) of the Act;
11. Reporting the actual status of assistant nurses and their current employment status prescribed in Article 80 (4) of the Act.

[This Article Newly Inserted by Presidential Decree No. 23488, Jan. 6, 2012]

Article 43 (Calculation Basis of Penalty Surcharges)

The amount of penalty surcharges referred to in Article 67 of the Act shall be assessed by applying criteria of attached Table 1-2, based on the criteria for medical service suspension disposition determined by Ordinance of the Ministry of Health and Welfare, with kinds and degree of offenses taken into consideration. <Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 21428, Apr. 20, 2009; Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 28131, Jun. 20, 2017>

Article 44 (Procedure for Imposition and Collection of Penalty Surcharges)

- (1) When intending to impose penalty surcharges under Article 67 of the Act, the Minister of Health and Welfare, a Mayor/Do Governor or head of a *Si/Gus/Gu* shall clearly state the kinds of the relevant offenses and the amount of penalty surcharges in writing and issue a notice for payment. <Amended

by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010>

- (2) Procedures for the collection of penalty surcharges shall be determined by Ordinance of the Ministry of Health and Welfare. *<Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010>*

Article 44-2 (Re-Examination of Regulation)

- (1) The Minister of Health and Welfare shall re-exam the propriety of the following matters every three years (referring to the date before the base date of every third anniversary) based on the following base dates and take measures for improvement, etc.: *<Amended by Presidential Decree No. 26526, Sep. 15, 2015; Presidential Decree No. 28131, Jun. 20, 2017>*

1. Base date for the calculation of penalty surcharges referred to in Article 43 and Table 1-2: January 1, 2014;
2. Base date for the imposition of administrative fines referred to in Article 45 and Table 2: January 1, 2014.

- (2) The Minister of Health and Welfare shall re-exam the propriety of the standards for prohibiting medical advertisement prescribed in Article 23 every two years (referring to the date before January 1 of every second anniversary) based on January 1, 2015 and take measures for improvement, etc. *<Newly Inserted by Presidential Decree No. 25840, Dec. 9, 2014>*

[This Article Newly Inserted by Presidential Decree No. 25050, Dec. 30, 2013]

Article 45 (Imposition and Collection of Administrative Fines)

Criteria for the imposition of administrative fines prescribed in Article 92 of the Act shall be prescribed in attached Table 2.

[This Article Wholly Amended by Presidential Decree No. 26526, Sep. 15, 2015]

Addenda *<Presidential Decree No. 30480, Feb. 25, 2020>*

Article 1 (Enforcement Date)

This Decree shall enter into force on February 28, 2020.

Articles 2 (Transitional Measures for Standards for Calculating Penalty Surcharges)

Notwithstanding the amended provisions of attached Table 1-2, the application of standards for calculating penalty surcharges to offenses committed before this Decree enters into force shall be governed by the former provisions.

2.12 Pharmaceutical Affairs Act

Act No. 16250, Jan. 15, 2019

CHAPTER I General Provisions

Article 1 (Purpose)

The purpose of this Act is to prescribe matters necessary to deal with pharmaceutical affairs smoothly, thereby contributing to the improvement of the national public health.

Article 2 (Definitions)

The terms used in this Act are defined as follows: <Amended by Act No. 8643, Oct. 17, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9847, Dec. 29, 2009; Act No. 9932, Jan. 18, 2010; Act No. 10788, Jun. 7, 2011; Act No. 11690, Mar. 23, 2013; Act No. 12450, Mar. 18, 2014; Act No. 14328, Dec. 2, 2016; Act No. 14926, Oct. 24, 2017>

1. The term "pharmaceutical affairs" means the manufacturing, dispensation, evaluation, storage, import, and distribution (including presentation; hereinafter the same shall apply) of drugs and quasi-drugs, and other matters related to pharmaceutical technology;
2. The term "pharmacist" means a person who is responsible for matters concerning pharmaceutical affairs (including those concerning herbal medication), with exception to those concerning herbal drugs; the term "oriental medicine pharmacist" means a person who takes charge of matters concerning pharmaceutical affairs related to herbal drugs and medication thereof; and they respectively shall be licensed by the Minister of Health and Welfare;
3. The term "pharmacy" means a place where a pharmacist or oriental medicine pharmacist dispenses drugs [including pharmacy medication] for the purpose of presentation (where the founder of a pharmacy engages in drug distribution business concurrently, including the place required for the distribution business): *Provided*, That dispensaries of medical institutions shall be excluded herefrom;
4. The term "drug" means any of the following:
 - (a) Those other than quasi-drugs, among the articles listed in the Korean Pharmacopoeia;
 - (b) Articles, other than appliances, machinery, or equipment, used for the purposes of diagnosis, treatment, alleviation, care, or prevention of diseases in human beings or animals;
 - (c) Articles, other than appliances, machinery, or equipment, used for the purpose of exerting pharmacological effects upon the structure or functions of human beings or animals;
5. The term "herbal drug" means a raw drug collected from animals, plants, or minerals and dried, cut, or refined without altering the original forms in most cases;
6. The term "herbal medication" means any drug made by combining herbal drugs according to the principles of oriental medicine;
7. The term "quasi-drug" means any of the following articles designated by the Minister of Food and Drug Safety (excluding articles which shall be used for the purposes prescribed in subparagraph 4 (b) or (c)):
 - (a) Fibers, rubber products, or similar products used for the purpose of treatment, alleviation, care, or prevention of human or animal diseases;
 - (b) Non-appliance, non-machinery, or similar articles that have insignificant influences on or do not directly act upon human bodies;
 - (c) Medication for sterilization, insecticide, and other similar uses for the purpose of preventing infectious diseases;

8. The term "new drug" means a drug composed of new materials, the chemical structure or the construction of substance of which is wholly unique, or a drug of composite medication containing new materials as effective ingredients, which is designated by the Minister of Food and Drug Safety;
9. The term "over-the-counter drug" means any of the following drugs that meets the standards determined and publicly notified by the Minister of Food and Drug Safety, upon consultations with the Minister of Health and Welfare:
 - (a) A drug for which the misuse or abuse is of little concern and the safety and effectiveness may be expected even when used without a prescription by a physician or a dentist;
 - (b) A drug that may be used to treat a disease without the professional knowledge of a physician or a dentist;
 - (c) A drug that has a relatively small side effect on human bodies in consideration of dosage form and pharmacological action;
10. The term "prescription drug" means a drug that is not an over-the-counter drug;
11. The term "dispensation of a drug" means dispensing drugs for the purposes of treatment, prevention, etc. for a certain disease by a specific individual in accordance with the specific dose regimen through the combination of at least two drugs or by dividing one kind of drug into specified doses according to a specific prescription;
12. The term "medication counselling" means any of the following:
 - (a) Providing information on the names, dose regimen and dose, efficacy and effects, storage methods, side effects, interactions, properties, etc. of drugs;
 - (b) Assisting consumers in choosing the necessary drugs without providing diagnostic judgment when distributing over-the-counter drugs;
13. The term "safety container or package" means a container or package designed and devised to make it difficult for children under the age of five to open;
14. The term "contract manufacturing and distribution business" means the business of manufacturing and distributing drugs without retaining manufacturing facilities by entrusting a drug manufacturer with the manufacturing and distribution of drugs for which permission for manufacturing and distribution of items is granted by the Minister of Food and Drug Safety;
15. The term "clinical trial" means a trial (including bioequivalence tests) that verifies pharmacodynamic, pharmacokinetic, pharmacological, and clinical effects of drugs, etc. and investigates adverse reactions to the human body to validate the safety and effectiveness of the relevant drugs, etc.;
16. The term "non-clinical study" means a study conducted through the use of animals, plants, microorganisms, physical or chemical mediums, or the components thereof in the same conditions as those in a laboratory, so as to obtain various data on the nature or safety of study materials which influence the health of humans;
17. The term "bioequivalence test" means a medical examination using a living body to prove bioequivalence, which validates that the bioavailability of two medications containing the same major ingredients is statistically equivalent among clinical trials;
18. The term "orphan drug" means any of the following drugs under subparagraph 4 that is designated by the Minister of Food and Drug Safety:
 - (a) A drug used for the purposes of diagnosis or treatment of rare diseases under subparagraph 1 of Article 2 of the Rare Disease Management Act;
 - (b) A drug with a rare subject of application, for which an alternative drug does not exist or whose safety or effectiveness has been significantly improved compared to the alternative drug;
19. The term "national essential drug" means a drug essential for health and medical treatment, such as disease control and prevention of a radiation disaster, for which the stable supply is difficult solely due to market functions and which is designated by the Minister of Health and Welfare and the Minister of Food and Drug Safety in consultation with the head of a relevant central administrative agency.

CHAPTER II Pharmacists and Oriental Medicine Pharmacists

SECTION 1 Qualification and Licenses

Article 3 (Qualification and Licenses of Pharmacists)

- (1) A person who intends to become a pharmacist shall obtain a license from the Minister of Health and Welfare, as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*
- (2) A pharmacist license prescribed in paragraph (1) shall be granted to any of the following persons: *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 14560, Feb. 8, 2017; Act No. 16250, Jan. 15, 2019>*
 1. A person who has graduated from a college of pharmacy, received a bachelor's degree in pharmacy, and has passed the national examination for a pharmacist license;
 2. A person who has graduated from a foreign college of pharmacy (referring to a college meeting the standards for recognition determined and publicly notified by the Minister of Health and Welfare), obtained a foreign pharmacist license, and has passed a preliminary examination for a pharmacist license and a national examination for a pharmacist license.
- (3) A person who has not obtained a pharmacist license shall be prohibited from using the title of "pharmacist".

Article 4 (Qualification and Licenses of Oriental Medicine Pharmacists)

- (1) A person who intends to become an oriental medicine pharmacist shall obtain a license from the Minister of Health and Welfare, as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*
- (2) An oriental medicine pharmacist license prescribed in paragraph (1) shall be granted to a person who has graduated from herb pharmacy in a college, received a bachelor's degree in herb pharmacy, and passed a national examination for an oriental medicine pharmacist license.
- (3) Any person who has not obtained an oriental medicine pharmacist license shall be prohibited from using the title of "oriental medicine pharmacist".

Article 5 (Grounds for Disqualification)

A pharmacist or oriental medicine pharmacist license shall not be granted to any of the following persons: *<Amended by Act No. 8643, Oct. 17, 2007; Act No. 11118, Dec. 2, 2011; Act No. 11251, Feb. 1, 2012; Act No. 12450, Mar. 18, 2014; Act No. 15891, Dec. 11, 2018>*

1. A mentally ill person prescribed in subparagraph 1 of Article 3 of the Act on the Improvement of Mental Health and the Support for Welfare Services for Mental Patients: *Provided*, That this shall not apply to a person who is recognized by a medical specialist as being competent for the responsibility for pharmaceutical affairs;
2. A person under adult guardianship or person under limited guardianship;
3. A person addicted to narcotics, marijuana, or psychotropic drugs;
4. A person who was sentenced to imprisonment without labor or a heavier punishment declared by a court for violating the Pharmaceutical Affairs Act, the Narcotics Control Act, the Act on Special Measures for the Control of Public Health Crimes, the Medical Service Act, Article 347 of the Criminal Act (limited to cases of deceiving patients, or institutions or organizations paying the drug expenses by requesting payment of the drug expenses by fraud; hereinafter the same shall apply) and other statutes and regulations related to pharmaceutical affairs and for whom the sentence was not completely executed or the non-execution of such sentence has not become final;
5. A person for whom three years have not elapsed since the revocation of a license for committing crimes under Article 347 of the Criminal Act or for whom two years have not elapsed since the

revocation of a license for violating the statutes and regulations related to pharmaceutical affairs.

Article 6 (Issuance and Registration of Licenses)

- (1) When the Minister of Health and Welfare issues a pharmacist or oriental medicine pharmacist license, he or she shall register matters relating to the license in the registration register, respectively, and issue the relevant license. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*
- (2) If a license referred to in paragraph (1) has been lost or damaged or the matters stated therein have been modified, a new license may be issued in lieu thereof.
- (3) No license shall be lent to others.
- (4) Matters necessary for registration of a pharmacist or oriental medicine pharmacist license and issuance thereof shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

Article 7 (Notification by Pharmacists or Oriental Medicine Pharmacists)

A pharmacist or oriental medicine pharmacist shall file a notification with the Minister of Health and Welfare as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10788, Jun. 7, 2011>*

Article 8 (National Examinations for Pharmacist License and Oriental Medicine Pharmacist License)

- (1) National examinations for a pharmacist license, national examinations for an oriental medicine pharmacist license, and preliminary examinations for a pharmacist license (hereinafter referred to as “national examinations, etc.”) shall be administered by the Minister of Health and Welfare at least once each year. *<Amended by Act No. 88562, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 14560, Feb. 8, 2017>*
- (2) The Minister of Health and Welfare may commission the Korea Health Personnel Licensing Examination Institute established under the Korea Health Personnel Licensing Examination Institute Act to administer national examinations, etc. referred to in paragraph (1), as prescribed by Presidential Decree. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 13367, Jun. 22, 2015; Act No. 14560, Feb. 8, 2017>*
- (3) The Minister of Health and Welfare may provide subsidies to the Korea Health Personnel Licensing Examination Institute which administer national examinations pursuant to paragraph (2). *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 13367, Jun. 22, 2015>*
- (4) Matters necessary for national examinations, etc. shall be prescribed by Presidential Decree. *<Amended by Act No. 14560, Feb. 8, 2017>*

Article 9 (Restrictions on Application for Examination)

No person falling under subparagraphs 1 through 3 of Article 5 shall apply for the national examination, etc. *<Amended by Act No. 14560, Feb. 8, 2017>*

Article 10 (Cheating of Examinees)

- (1) A person who cheats on the national examination, etc. shall be suspended from taking the examination, and where the fact of cheating is discovered after a candidate has passed the examination, the pass shall be nullified. *<Amended by Act No. 14560, Feb. 8, 2017>*
- (2) The Minister of Health and Welfare may disqualify persons falling under paragraph (1) from applying for any national examination, etc. for two years. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 14560, Feb. 8, 2017>*

SECTION 2 The Pharmaceutical Association and the Oriental Pharmacy Association

Article 11 (The Pharmaceutical Association)

- (1) Pharmacists shall establish the Korean Pharmaceutical Association (hereinafter referred to as the "Pharmaceutical Association") to research pharmaceutical affairs, establish a code of ethics, promote the rights and interests of pharmacists, and improve the quality of pharmacists, as prescribed by Presidential Decree.
- (2) The Pharmaceutical Association shall be a corporation.
- (3) Upon establishment of the Pharmaceutical Association, pharmacists shall automatically become members.
- (4) Except as provided in this Act, the provisions of the Civil Act relating to the corporate juridical person shall apply *mutatis mutandis* to the Pharmaceutical Association.
- (5) The Pharmaceutical Association shall establish the Ethics Committee to deliberate and decide on requests for revocation of a license or suspension of qualifications prescribed in Article 79-2. <Newly Inserted by Act No. 10788, Jun. 7, 2011; Act No. 14926, Oct. 24, 2017>
- (6) Matters regarding the organization, operation, etc. of the Ethics Committee shall be prescribed by Presidential Decree. <Newly Inserted by Act No. 10788, Jun. 7, 2011>

Article 12 (The Oriental Pharmacy Association)

- (1) Oriental medicine pharmacists shall establish the Association of Korea Oriental Pharmacy (hereinafter referred to as the "Oriental Pharmacy Association") to research pharmaceutical affairs related to herbal drugs and herbal medication, establish a code of ethics, promote the rights and interests of oriental medicine pharmacists, and improve the quality of oriental medicine pharmacists, as prescribed by Presidential Decree.
- (2) The Oriental Pharmacy Association shall be a juridical person.
- (3) Upon establishment of the Oriental Pharmacy, oriental medicine pharmacists shall automatically become members.
- (4) Except as provided in this Act, the provisions of the Civil Act concerning a corporate juridical person shall apply *mutatis mutandis* to the Oriental Pharmacy Association.
- (5) The Oriental Pharmacy Association shall establish the Ethics Committee to deliberate and decide on requests for revocation of a license or suspension of qualifications prescribed in Article 79-2. <Newly Inserted by Act No. 10788, Jun. 7, 2011; Act No. 14926, Oct. 24, 2017>
- (6) Matters regarding the organization, operation, etc. of the Ethics Committee shall be prescribed by Presidential Decree. <Newly Inserted by Act No. 10788, Jun. 7, 2011>

Article 13 (Authorization)

- (1) In order to establish the Pharmaceutical Association or the Oriental Pharmacy Association, the articles of association and other necessary documents shall be submitted to the Minister of Health and Welfare and authorization from the Minister of Health and Welfare shall be obtained, as prescribed by Presidential Decree. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>
- (2) Matters to be stated in the articles of association by the Pharmaceutical Association or by the Oriental Pharmacy Association shall be prescribed by Presidential Decree.
- (3) If the Pharmaceutical Association or the Oriental Pharmacy Association intends to modify its articles of association, it shall obtain authorization therefor from the Minister of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

Article 14 (Chapters of the Pharmaceutical Association and the Oriental Pharmacy Association)

- (1) The Pharmaceutical Association or the Oriental Pharmacy Association shall establish its chapters in

the Special Metropolitan City, a Metropolitan City, a Special Self-Governing City, a *Do*, and a Special Self-Governing Province (hereinafter referred to as "City/Do") and may establish branches in the Gus of the Special Metropolitan City and Metropolitan Cities, Sis (referring to an administrative *Si* in cases of a Special Self-Governing Province; hereinafter the same shall apply) and Guns. *<Amended by Act No. 10788, Jun. 7, 2011; Act No. 13114, Jan. 28, 2015>*

- (2) When the Pharmaceutical Association or the Oriental Pharmacy Association has established its chapters or branches, it shall, without delay, file a notification thereof with the Special Metropolitan City Mayor, a Metropolitan City Mayor, a Special Self-Governing City Mayor, a *Do* Governor, or a Special Self-Governing Province Governor (hereinafter referred to as the "Mayor/*Do* Governor"). *<Amended by Act No. 13114, Jan. 28, 2015>*

Article 15 (Training and Education)

- (1) The Minister of Health and Welfare may order pharmacists and oriental medicine pharmacists to undergo training and education for the improvement of their qualities. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*
- (2) Matters necessary for training and education under paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

Article 16 (Duties of Cooperation and Entrustment)

- (1) Upon receipt of a request for cooperation from the Minister of Health and Welfare concerning projects necessary for the improvement of national public health, pharmaceutical affairs, or the ethics of pharmacists or oriental medicine pharmacists, the Pharmaceutical Association or the Oriental Pharmacy Association shall provide cooperation therein. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*
- (2) The Minister of Health and Welfare may entrust part of affairs concerning pharmaceutical affairs and the ethics of pharmacists or oriental medicine pharmacists to the Pharmaceutical Association or the Oriental Pharmacy Association, as prescribed by Presidential Decree. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

Article 17 (Subsidization)

Where the Minister of Health and Welfare deems that programs of the Pharmaceutical Association or the Oriental Pharmacy Association are necessary for the improvement of national public health, or orders or entrusts such Association to conduct education, investigation, and research concerning pharmacists or oriental medicine pharmacists, he or she may fully or partially subsidize necessary expenses. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

CHAPTER III Pharmaceutical Affairs Advisory Committee

Article 18 (The Central Pharmaceutical Affairs Advisory Committee)

- (1) The Central Pharmaceutical Affairs Advisory Committee (hereafter in this Article, referred to as the "Advisory Committee") shall be established under the authority of the Minister of Food and Drug Safety to respond to inquiries from the Minister of Health and Welfare and the Minister of Food and Drug Safety when requested. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013; Act No. 16250, Jan. 15, 2019>*
- (2) The Advisory Committee shall consist of not more than 100 members, including one Chairperson and two Vice Chairpersons. In such cases, the members who are not public officials shall constitute a

majority of the Advisory Committee. <Newly Inserted by Act No. 16250, Jan. 15, 2019>

- (3) The Minister of Food and Drug Safety shall serve as the Chairperson of the Advisory Committee, and the Vice Chairpersons shall be appointed from among public officials of the Senior Executive Service of the Ministry of Health and Welfare and the Ministry of Food and Drug Safety, respectively. <Newly Inserted by Act No. 16250, Jan. 15, 2019>
- (4) Members of the Advisory Committee shall be appointed or commissioned by the Minister of Food and Drug Safety, from among the public officials related to pharmaceutical affairs, persons recommended by the head of an organization related to pharmaceutical affairs, or persons with much knowledge and experience in pharmaceutical affairs; and the Minister of Health and Welfare may make a recommendation for a member of the Advisory Committee. <Newly Inserted by Act No. 16250, Jan. 15, 2019>
- (5) The term of office of a member shall be two years: *Provided*, That the term of office of any member who is a public official shall be the period during which he or she retains the relevant position. <Newly Inserted by Act No. 16250, Jan. 15, 2019>
- (6) Other matters necessary for the organization, operation, etc. of the Advisory Committee shall be prescribed by Presidential Decree. <Amended by Act No. 16250, Jan. 15, 2019>

Article 19 Deleted. <by Act No. 10512, Mar. 30, 2011>

CHAPTER IV Pharmacies and Dispensation of Drugs

SECTION 1 Pharmacies

Article 20 (Registration for Establishment of Pharmacies)

- (1) No person, other than a pharmacist or oriental medicine pharmacist, shall establish a pharmacy.
- (2) A person who intends to establish a pharmacy shall file for registration of establishment with the head of a *Si/Gun/Gu* (the head of a *Gu* refers to the head of an autonomous *Gu*; hereinafter the same shall apply), as prescribed by Ordinance of the Ministry of Health and Welfare. The same shall apply to any modification of the registered matters. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>
- (3) A person who intends to file for registration under paragraph (2) shall install necessary facilities in conformity with the standards for facilities prescribed by Presidential Decree.
- (4) The Mayor/*Do* Governor may set the standards for registration for establishing a pharmacy by rules of the relevant City/*Do*, according to the standards prescribed by Presidential Decree.
- (5) In any of the following cases, an application for registration of establishment of a pharmacy shall be rejected:
 1. Where six months have not elapsed from the date the registration of establishment of a pharmacy has been revoked pursuant to Article 76;
 2. Where a pharmacy is to be established in a place located within facilities or premises of a medical institution;
 3. Where a pharmacy is established by dividing, altering, or repairing some of facilities or sites of a medical institution;
 4. Where a pathway, such as an exclusive corridor, flight of stairs, or elevator, or a footbridge, is in place or to be constructed between a pharmacy and a medical institution.
- (6) No person shall use the word "pharmacy" or similar names unless he or she is registered for establishment of a pharmacy pursuant to paragraph (2). <Newly Inserted by Act No. 12450, Mar. 18, 2014>

Article 21 (Duties to Manage Pharmacies)

- (1) A pharmacist or oriental medicine pharmacist may establish only one pharmacy.
- (2) A pharmacy founder shall manage his or her pharmacy in person: *Provided*, That where the pharmacy founder is unable to manage the pharmacy, he or she shall designate a pharmacist or oriental medicine pharmacist who manages such pharmacy on his or her behalf.
- (3) A pharmacist or oriental medicine pharmacist who manages a pharmacy shall observe the following matters necessary for managing such pharmacy: *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10788, Jun. 7, 2011; Act No. 11690, Mar. 23, 2013; Act No. 13655, Dec. 29, 2015>*
1. He or she shall manage his or her pharmacy and drugs in a manner not to cause any risk to health and hygiene and not to reduce the efficacy of drugs;
 2. He or she shall thoroughly oversee his or her employees in order to prevent any incident related to health and hygiene;
 3. He or she shall keep any objects likely to cause any risk to health and hygiene off from his or her pharmacy;
 4. He or she shall take necessary safety measures, where any side effect, etc. occur in connection with the use of drugs, etc.;
 5. Where a pharmacist or oriental medicine pharmacist dispenses or distributes drugs, he or she shall wear an identification tag to ensure that patients can identify his or her status, as prescribed by Ordinance of the Ministry of Health and Welfare (including instructing or supervising university students who engage in dispensation or distribution pursuant to the proviso of Article 23 (1) or 44 (1) to wear an identification tag to ensure that patients can identify his or her status, as prescribed by Ordinance of the Ministry of Health and Welfare);
 6. He or she shall observe other matters which correspond to the matters referred to in subparagraphs 1 through 5 and are prescribed by Ordinance of the Ministry of Health and Welfare, following consultation with the Minister of Food and Drug Safety, as deemed necessary to manage the facilities and drugs of pharmacies in a manner not to cause any risk to public health.

Article 21-2 (Succession to Status of Pharmacy Founders)

- (1) Where a pharmacy founder transfers the business operation and the transferee intends to succeed to the status of the former pharmacy founder, the transferee shall file a notification thereof with the head of a *Si/Gun/Gu* within one month from the date of transfer, as prescribed by Ordinance of the Ministry of Health and Welfare.
- (2) Upon receipt of a notification referred to in paragraph (1), the head of a *Si/Gun/Gu* shall examine the details of the notification and accept such notification if in compliance with this Act. In such cases, where the transferee is not a pharmacist or oriental medicine pharmacist, or if the transferee falls under any subparagraph of Article 5, the head of a *Si/Gun/Gu* shall not accept the relevant notification.
- (3) Where the notification referred to in paragraph (1) is accepted, the transferee shall succeed to the status of the former pharmacy founder as of the date of transfer.

[This Article Newly Inserted by Act No. 16250, Jan. 15, 2019]

Article 22 (Notification of Business Closure)

Where a pharmacy founder closes or suspends business of his or her pharmacy or resumes the suspended business, he or she shall file a notification thereof with the head of a *Si/Gun/Gu* having jurisdiction over his or her pharmacy within seven days from the date of business closure or suspension or business resumption, as prescribed by Ordinance of the Ministry of Health and Welfare: *Provided*, That the same shall not apply where the period of business suspension is less than one month. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

SECTION 2 Dispensation of Drugs

Article 23 (Dispensation of Drugs)

- (1) No person, other than pharmacists or oriental medicine pharmacists, shall dispense drugs, and pharmacists or oriental medicine pharmacists shall dispense drugs within the scope of their licenses: *Provided*, That university students majoring in pharmacy may dispense drugs to the extent prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>
- (2) A pharmacist or oriental medicine pharmacist shall dispense drugs at a pharmacy or a dispensary of a medical institution (including a dispensary installed in the Korea Orphan and Essential Drug Center pursuant to the latter part of Article 92 (1) 2): *Provided*, That this shall not apply where he or she has obtained approval from the head of the relevant *Si/Gun/Gu*. <Amended by Act No. 14328, Dec. 2, 2016>
- (3) A physician or dentist may prescribe prescription drugs and over-the-counter drugs, and a pharmacist shall dispense prescription drugs and over-the-counter drugs according to the prescriptions issued by physicians or dentists: *Provided*, That a pharmacist may dispense drugs without prescriptions issued by a physician or dentist in any of the following cases: <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9847, Dec. 29, 2009; Act No. 9932, Jan. 18, 2010>
1. Where he or she dispenses drugs in an area where no medical institution exists;
 2. Where he or she dispenses drugs for disaster relief because medical institutions become essentially nonexistent in the occurrence of a natural disaster;
 3. Where he or she distributes oral vaccines to prevent the spread of an infectious disease after the Minister of Health and Welfare recognizes that such infectious disease is contagious or is likely to cause widespread contagion;
 4. Where he or she dispenses drugs for community service activities.
- (4) Notwithstanding paragraph (1), a physician or dentist may directly dispense drugs, in any of the following cases: <Amended by Act Nos. 8723 & 8728, Dec. 21, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9819, Nov. 2, 2009; Act No. 9847, Dec. 29, 2009; Act No. 9932, Jan. 18, 2010; Act No. 10512, Mar. 30, 2011; Act No. 11251, Feb. 1, 2012; Act No. 13425, Jul. 24, 2015; Act No. 14170, May 29, 2016; Act No. 15534, Mar. 27, 2018>
1. Where he or she dispenses drugs in an area where no pharmacy exists;
 2. Where he or she dispenses drugs for disaster relief because pharmacies become essentially nonexistent in the occurrence of a natural disaster;
 3. Where he or she dispenses drugs for an emergency patient or a mentally ill person suffering from schizophrenia, manic-depressive insanity, etc. who is likely to harm oneself or others;
 4. Where he or she dispenses drugs for an in-patient; a patient suffering from cholera, typhoid, paratyphoid, shigellosis (bacillary dysentery), enterohemorrhagic escherichia coli, or hepatitis A among patients with infectious diseases referred to in subparagraph 13 of Article 2 of the Infectious Disease Control and Prevention Act; or a person admitted to a social welfare facility under the Social Welfare Services Act (where such person is not a ward of such social welfare facility, limited to dispensation of drugs during the period for which he or she uses such facility);
 5. Where he or she administers injections;
 6. Where he or she administers drugs, including vaccines to prevent infectious diseases and drugs for medical diagnosis, prescribed by Ordinance of the Ministry of Health and Welfare;
 7. Where a physician or dentist serving in a public health center or its branch office under the Regional Public Health Act dispenses drugs for patients, in the performance of his or her duties (excluding ambulatory care services for residents within the jurisdiction of a public health center or a public health branch office designated by the Minister of Health and Welfare);
 8. Where he or she dispenses drugs to veterans with disability ratings of 1 through 3 under the

statutes and regulations concerning the honorable treatment and support for persons, etc. of distinguished services to the State; persons with disability ratings of 1 through 4 among those wounded in the May 18 Democratization Movement under the Act on the Honorable Treatment of Persons of Distinguished Service to the May 18 Democratization Movement; persons with severe disabilities under the statutes and regulations concerning assistance, etc. to patients from actual or potential aftereffects of defoliants, etc.; persons with disability ratings of 1 and 2 under the statutes and regulations concerning welfare of persons with disabilities and persons with disabilities equivalent thereto; and patients suffering from Parkinson's disease or Hansen's disease;

9. Where he or she dispenses drugs for the treatment of persons having undergone the surgery for transplant of an internal organ and the treatment of patients suffering from AIDS;
 10. Where he or she dispenses drugs for soldiers in active service, conscripted policemen, and inmates of correctional facilities under the Administration and Treatment of Correctional Institution Inmates Act and the Act on the Execution of Criminal Penalties in the Armed Forces and the Treatment of Military Prison Inmates, protected juvenile admittance facilities under the Act on the Treatment of Protected Juveniles, Etc., and alien detention facilities under the Immigration Act;
 11. Where he or she administers medication for the treatment of tuberculosis under the Tuberculosis Prevention Act (limited to public health centers, public health branch offices, and hospitals affiliated to the Korean National Tuberculosis Association);
 12. Where he or she dispenses drugs for community service activities;
 13. Where he or she is prohibited from disclosing prescriptions for reason of confidentiality of information related to the national security;
 14. Other cases prescribed by Presidential Decree.
- (5) The scope of an area where no medical institution or pharmacy exists under paragraph (3) 1 or (4) 1 shall be determined by the Minister of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>
- (6) An oriental medicine pharmacist shall dispense herbal drugs according to the prescriptions issued by oriental medical doctors: *Provided*, That he or she may dispense herbal drugs without prescriptions issued by oriental medical doctors, according to the category of herbal drug prescriptions or a dispensation method determined by the Minister of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>
- (7) A pharmacist engaging in dispensing drugs at a dispensary of a medical institution shall not dispense drugs for a patient to whom a prescription is issued under Article 18 of the Medical Service Act.

Article 23-2 (Checking Drug Information)

- (1) Where a pharmacist dispenses a drug pursuant to Article 23 (3), he or she shall check the following information (hereinafter referred to as “drug information”) in advance:
 1. Whether the ingredients of the drug are the same as those of the drug prescribed or administered to a patient;
 2. Whether the drug contains the ingredients contraindicated for combined use, for specific age groups, during pregnancy, or for other reasons which have been publicly notified by the Minister of Food and Drug Safety;
 3. Other information prescribed by Ordinance of the Ministry of Health and Welfare.
- (2) Notwithstanding paragraph (1), a pharmacist need not check drug information where there is good cause.
- (3) Methods and procedures for checking drug information under paragraph (1), good cause for which a pharmacist need not check drug information under paragraph (2), etc. shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 13655, Dec. 29, 2015]

Article 23-3 (Establishment and Operation of Information System for Safe Use of Drugs)

- (1) The Minister of Health and Welfare may establish and operate an information system for safe use of drugs (hereinafter referred to as “information system”) to support the check of drug information pursuant to Article 23-2 of this Act and Article 18-2 of the Medical Service Act.
- (2) The Minister of Health and Welfare may entrust the operation of the information system to a specialized institution prescribed by Ordinance of the Ministry of Health and Welfare. In such cases, the Minister of Health and Welfare may support all or part of expenses incurred in operating the information system.
- (3) The Minister of Health and Welfare or the head of the specialized institution entrusted under paragraph (2) may request the physicians, dentists, pharmacists, etc. to provide data prescribed by Ordinance of the Ministry of Health and Welfare as information necessary for operation of the information system (including sensitive information under Article 23 of the Personal Information Protection Act and personally identifiable information pursuant to Article 24 of that Act; in such cases, the relevant information shall be protected pursuant to the Personal Information Protection Act) and handle such information. In such cases, the physicians, dentists, pharmacists, etc. upon receipt of the request shall comply with such request, unless there is a compelling reason not to do so.
- (4) The Minister of Health and Welfare may establish and operate a steering committee for the information system for safe use of drugs (hereafter in this Article, referred to as “steering committee”) for the smooth operation of the information system referred to in paragraph (1).
- (5) Matters necessary for establishment and operation of the information system referred to in paragraph (1), entrustment referred to in paragraph (2), organization and operation of the steering committee referred to in paragraph (4), etc. shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 13655, Dec. 29, 2015]

Article 24 (Duties and Matters to Be Observed)

- (1) No pharmacist or oriental medicine pharmacist engaging in dispensing drugs at a pharmacy shall refuse any request to dispense drugs without good cause.
- (2) A pharmacy founder (including persons employed by the relevant pharmacy; hereafter in this Article, the same shall apply) and a medical institution founder (including persons employed by the relevant medical institution; hereafter in this Article, the same shall apply) shall not engage in any of the following collusive conduct: <Amended by Act No. 15891, Dec. 11, 2018>
 1. A pharmacy founder wholly or partially exempting any person carrying a medical prescription issued by a specific medical institution from paying drug expenses;
 2. A pharmacy founder or a medical institution founder offering, requesting, or promising money, valuables, favors, labor, entertainment, and other economic benefits to or from another pharmacy founder or medical institution founder in return for medical prescriptions arranged to favor such founder, either directly or through a third party, or receiving the same from another pharmacy founder or medical institution founder;
 3. A medical institution founder directing or inducing any person carrying its medical prescription to obtain drugs dispensed at a specific pharmacy (excluding the act of introducing the full names, locations, etc. of pharmacies in the relevant area at the request of any patient);
 4. A physician or dentist repeatedly prescribing other drugs identical in composition to drugs that are included in the list of prescription drugs offered by the branches of the Medical Association or the branches of the Dental Association to the branches of the Pharmaceutical Association pursuant to Article 25 (2) (the same shall apply to any pharmacist who repeatedly dispenses the relevant drugs according to the relevant medical prescription);
 5. Other acts similar to any of those referred to in subparagraphs 1 through 4, prescribed by

Presidential Decree as having the potential for collusion.

- (3) Where a pharmacist or oriental medicine pharmacist working at a dispensary of a medical institution prescribed in Article 23 (2) dispenses drugs, he or she shall observe matters prescribed by Ordinance of the Ministry of Health and Welfare, following consultation with the Minister of Food and Drug Safety. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>*
- (4) Where a pharmacist dispenses drugs to a patient, he or she shall give the patient or his or her protector necessary oral or written medication counselling in which the directions to take medicines (referring to a written direction or electronic document explaining the details of medication counselling in terminology readily comprehensible by the patient) is written. In such cases, necessary matters, such as the form of medication counselling, shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 12450, Mar. 18, 2014>*
- (5) The Minister of Health and Welfare may take necessary measures for pharmacists to conscientiously offer patients the medication counselling referred to in paragraph (4), by allowing pharmacists to dispense a proper number of medical prescriptions. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

Article 25 (Preparation of List of Prescription Drugs)

- (1) A medical institution founder shall submit a list of drugs that the relevant medical institution intends to prescribe to a branch of the Medical Association or a branch of the Dental Association (hereinafter referred to as "branch of the Medical Association, etc."), which has been established pursuant to Article 28 (5) of the Medical Service Act, of the *Si/Gun/Gu* where such medical institution is located.
- (2) A branch of the Medical Association, etc. shall provide the branch of the Pharmaceutical Association of the relevant *Si/Gun/Gu* with a regional list of prescription drugs, the items of which are appropriately adjusted in the list of prescription drugs of each medical institution under paragraph (1) and a list of prescription drugs of each medical institution which are adjusted from the regional list of prescription drugs.
- (3) Upon receipt of the regional list of prescription drugs and the list of prescription drugs of each medical institution from a branch of the Medical Association, etc. under paragraph (2), a branch of the Pharmaceutical Association shall inform pharmacy founders in the relevant area of such lists and require them to secure relevant drugs.
- (4) Where a pharmacy founder finds it difficult to secure drugs according to the list of prescription drugs under paragraph (2) and thus it is necessary to adjust the number of items, a branch of the Medical Association, etc. and a branch of the Pharmaceutical Association may adjust it through consultations. The same shall apply where the numbers of items are added or altered.
- (5) Where a branch of the Medical Association, etc. intends to alter or add the list of prescription drugs referred to in paragraph (2), it shall inform the relevant branch of the Pharmaceutical Association thereof 30 days in advance.

Article 26 (Modification and Revision of Prescriptions)

- (1) No pharmacist or oriental medicine pharmacist shall dispense drugs by modifying or revising prescriptions without the consent of the physician, dentist, oriental medical doctor, or veterinarian who has issued the prescriptions.
- (2) Where the name, quantity, dose regimen, dose, etc. of any of drugs stated in a prescription are suspected to fall under any of the following cases, a pharmacist or oriental medicine pharmacist shall not dispense the drug unless he or she has confirmed any suspicious matters with the physician, dentist, oriental medical doctor, or veterinarian who has issued the prescription, by telephone and fax or through an information and communications network under Article 2 (1) 1 of the Act on Promotion of Information and Communications Network Utilization and Information Protection,

Etc.: <Amended by Act No. 8558, Jul. 27, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11141, Dec. 31, 2011; Act No. 11690, Mar. 23, 2013; Act No. 13655, Dec. 29, 2015>

1. Where a drug, for which permission by item or a notification by item is revoked by the Minister of Food and Drug Safety due to any defect in terms of safety and effectiveness of the drug, is prescribed;
 2. Where it is impracticable to check a product name or ingredient name of a drug;
 3. Where a drug publicly notified by the Minister of Food and Drug Safety as drugs containing ingredients contraindicated for combined use, for specific age groups, or during pregnancy: *Provided*, That the same shall not apply cases prescribed by Ordinance of the Ministry of Health and Welfare, such as where a physician or dentist states the grounds for prescription by using an information system pursuant to Article 18-2 (1) of the Medical Service Act or states such grounds in a prescription.
- (3) Methods and procedures for revising and modifying prescriptions under paragraph (1) or other detailed matters shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

Article 27 (Dispensation of Substitute Drugs)

- (1) When a pharmacist intends to dispense a drug by substituting the drug in a prescription issued by a physician or dentist with another drug of the same ingredients, content, and dosage form, he or she shall obtain prior consent from the physician or dentist who has issued the prescription.
- (2) Notwithstanding paragraph (1), a pharmacist may dispense a substitute drug without obtaining prior consent from the physician or dentist who has issued the prescription, in any of the following cases: <Amended by Act No. 11690, Mar. 23, 2013>
 1. Where the pharmacist dispenses a substitute drug recognized by the Minister of Food and Drug Safety as having bioequivalence (including drugs that prove their bioequivalence through a medical experiment using no living body because of the needlessness to conduct a medical experiment using a living body or of the impossibility to do so): *Provided*, That where the physician or dentist has indicated in the prescription that dispensing a substitute drug is not permissible and has stated in detail the clinical reasons, etc. therefor, such substitute drug shall be excluded herefrom;
 2. Where the pharmacist dispenses a substitute drug with the same prescription dose, which has been manufactured by the same drug manufacturer who also manufactures the drug stated in the prescription, and which is different in content but is of the same ingredients and dosage form: *Provided*, That this shall be limited to cases where a substitute over-the-counter drug is dispensed in place of an over-the-counter drug and a substitute prescription drug is dispensed in place of a prescription drug;
 3. Where the pharmacist dispenses a substitute drug with the same ingredients, content, and dosage form as the drug stated in the prescription, among drugs included in the regional list of prescription drugs of the relevant pharmacy; a drug, which is stated in a prescription issued by a medical institution located in a region other than the *Si/Gun/Gu* in which the relevant pharmacy is located, is not included in the regional list of prescription drugs of the relevant pharmacy; and it is difficult to obtain prior consent of the physician or dentist who has issued the prescription due to any unavoidable reasons.
- (3) Where a pharmacist dispenses a substitute drug for the drug prescribed in a prescription under paragraph (1) or (2), he or she shall immediately inform the person carrying such prescription of the details of such substitute drug that has been dispensed.
- (4) Where a pharmacist dispenses a substitute drug for the drug prescribed in a prescription under paragraph (2), he or she shall inform the physician or dentist who has issued such prescription of the details of such substitute drug that has been dispensed within one day (three days if any unavoidable

reasons exist) from the date of dispensation: *Provided*, That the same shall not apply where there exist grounds prescribed by Ordinance of the Ministry of Health and Welfare, such as where the pharmacist dispenses such substitute drug after obtaining prior consent from the physician or dentist who has issued the prescription or where the telephone or fax number stated in the prescription is found to be incorrect. *<Amended by Act No. 13655, Dec. 29, 2015>*

- (5) Where any pharmacist dispenses a substitute drug for the drug prescribed in a prescription without prior consent of the physician or dentist who has issued such prescription, such physician or dentist shall not be held responsible for any drug accident caused by such substitute drug.
- (6) Matters necessary for the methods, procedures, etc. for obtaining consent and informing under paragraphs (1) and (4) shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

Article 28 (Indication and Recording of Drugs Dispensed)

- (1) A pharmacist or oriental medicine pharmacist shall indicate the relevant patient's name, dose regimen, and dose mentioned in the pertinent prescription and other matters prescribed by Ordinance of the Ministry of Health and Welfare on the containers or packages of drugs dispensed for distribution. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*
- (2) When a pharmacist or oriental medicine pharmacist has dispensed drugs, he or she shall indicate in the prescription, the date of dispensation and other matters prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

Article 29 (Retainment of Prescriptions)

A pharmacist or oriental medicine pharmacist shall retain prescriptions by which he or she has dispensed drugs at his or her pharmacy, for two years from the date of dispensation.

Article 30 (Records of Dispensation)

- (1) Where a pharmacist dispenses drugs (including where he or she dispenses drugs without a prescription in accordance with the proviso of Article 23 (3), with the exception of its subparagraphs, and each subparagraph of that Article; hereafter in this Article, the same shall apply) at his or her pharmacy, he or she shall keep records of dispensation (including electronic records) concerning the personal information of a patient, date of dispensation, the names of drugs prescribed, and the days of taking drugs, details of dispensation, details of medication counselling, and other matters prescribed by Ordinance of the Ministry of Health and Welfare and retain such records for five years. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10512, Mar. 30, 2011>*
- (2) A patient may file a request for perusal of his or her records or issuance of a copy thereof with a pharmacist to verify the details of his or her records. In such cases, the pharmacist upon receipt of such request shall not refuse it without good cause. *<Amended by Act No. 13655, Dec. 29, 2015>*
- (3) No pharmacist shall allow any person other than a patient to verify the details of the patient's records of dispensation, by allowing a perusal of such records or issuing a copy of such records: *Provided*, That he or she may allow any person other than a patient to verify the details of the patient's records, in any of the following cases: *<Newly Inserted by Act No. 13655, Dec. 29, 2015>*
 1. Where the spouse, a lineal ascendant or descendant, a sibling (limited to where the spouse, any of lineal ascendants or descendants, and any of lineal ascendants of the spouse, of a patient do not exist) of a patient, or a lineal ascendant of the spouse of a patient files a request by attaching the written consent of the patient or a certification, etc. verifying the relative relationship or by fulfilling the requirements prescribed by Ordinance of the Ministry of Health and Welfare;
 2. Where a representative designated by a patient files a request by attaching the written consent of the patient or a document evidencing the right of representation or by fulfilling the requirements

- prescribed by Ordinance of the Ministry of Health and Welfare;
3. Where the legal representative (limited to a guardian referred to in Article 928 or 936 of the Civil Act) of a patient files a request by attaching a document evidencing the right of representation or by fulfilling the requirements prescribed by Ordinance of the Ministry of Health and Welfare;
 4. Where the spouse, a lineal ascendant or descendant, a sibling (limited to where the spouse, any of lineal ascendants or descendants, and any of lineal ascendants of the spouse, of a patient do not exist) of a patient, or a lineal ascendant of the spouse of a patient files a request by attaching a certification, etc. verifying the relative relationship or by fulfilling the requirements prescribed by Ordinance of the Ministry of Health and Welfare, since it is impracticable to obtain consent from the patient due to a death or unconsciousness of the patient;
 5. Where records of dispensation are provided to the National Health Insurance Service or the Health Insurance Review and Assessment Service pursuant to Articles 14, 47, 48 and 63 of the National Health Insurance Act for the review and payment of costs of benefits, verification of entitlement to benefits, follow-up management, evaluation of the reasonableness of health care benefits, adjusted payment of health care benefits, etc.;
 6. Where records of dispensation are provided to social security agencies (a *Si/Gun/Gu*), the National Health Insurance Service, or the Health Insurance Review and Assessment Service pursuant to Articles 5, 11, 11-3 and 33 of the Medical Care Assistance Act for the verification of eligible recipients of medical benefits, the review, payment, follow-up management, etc. of costs of benefits, or other medical benefit services;
 7. Where it falls under Article 106, 215 or 218 of the Criminal Procedure Act;
 8. Where a court issues an order to submit records of dispensation pursuant to Article 347 of the Civil Procedure Act.

CHAPTER V Manufacturing and Import of Drugs

SECTION 1 Manufacturing Business of Drugs

Article 31 (Permission for Manufacturing Business)

- (1) A person who intends to manufacture drugs for business purposes shall obtain permission from the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister, after securing the necessary facilities meeting the standards for facilities prescribed by Presidential Decree. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>*
- (2) A manufacturer prescribed in paragraph (1) who intends to distribute drugs manufactured (including cases of entrusting another manufacturer with the manufacture) shall obtain permission for manufacturing and distribution of each item (hereinafter referred to as "permission by item") from the Minister of Food and Drug Safety or file a notification of manufacturing and distribution of each item (hereinafter referred to as "notification by item"), as prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 11690, Mar. 23, 2013>*
- (3) Where a person other than a manufacturer prescribed in paragraph (1) (in cases falling under subparagraph 4, limited to the Korea Orphan and Essential Drug Center referred to in Article 91 (1)) intends to entrust a manufacturer with the manufacturing of any of the following drugs for distribution, he or she shall file a notification of contract manufacturing and distribution business with the Minister of Food and Drug Safety and obtain permission by item, as prescribed by Ordinance of the Prime Minister: *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013; Act No. 13114, Jan. 28, 2015; Act No. 14926, Oct. 24, 2017; Act No. 15891, Dec. 11, 2018>*

1. A drug for which clinical trials (excluding bioequivalence tests; hereafter in this paragraph, the same shall apply) have been conducted after obtaining approval of a clinical trial protocol from the Minister of Food and Drug Safety pursuant to Article 34 (1);
 2. A drug for which clinical trials prescribed by Ordinance of the Prime Minister have been conducted in a foreign country in addition to the clinical trials prescribed in subparagraph 1;
 3. A drug prescribed by Ordinance of the Prime Minister, for which manufacturing technology has been transferred to a domestic manufacturer, among the drugs distributed in foreign countries;
 4. A drug prescribed in each of the subparagraphs of Article 91 (1), which is handled by the Korea Orphan and Essential Drug Center referred to in that paragraph.
- (4) A person who intends to manufacture quasi-drugs for business purposes shall file a notification of manufacturing business with the Minister of Food and Drug Safety after securing the necessary facilities meeting the standards for facilities prescribed by Presidential Decree and shall obtain permission by item or file a notification by item. *<Amended by Act No. 11690, Mar. 23, 2013>*
 - (5) A person who has obtained permission by item or filed a notification by item pursuant to paragraph (2) or (3) (hereinafter referred to as "person obtaining permission by item") may establish a business place, as prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>*
 - (6) Notwithstanding paragraphs (1) through (4), permission for manufacturing business or permission by item need not be granted or a notification by item need not be filed with regard to drugs or quasi-drugs prescribed by Ordinance of the Prime Minister, such as drugs for clinical trials prescribed in Article 34 (hereinafter referred to as "drugs, etc."). *<Newly Inserted by Act. No. 10512, Mar. 30, 2011; Act No. 11690, Mar. 23, 2013>*
 - (7) Notwithstanding paragraphs (2) through (4), in cases of a product or an item for which a drug, etc. and a medical device are combined or complicatedly created and which has been permitted or notified pursuant to the Medical Devices Act as the preeminent function is that of a medical device, permission by item or a notification by item shall be deemed obtained or filed pursuant to paragraphs (2) through (4). *<Newly Inserted by Act. No. 10512, Mar. 30, 2011>*
 - (8) None of the following persons shall obtain permission and file a notification of manufacturing business or contract manufacturing and distribution business of drugs, etc.: *<Amended by Act. No. 10512, Mar. 30, 2011; Act No. 14926, Oct. 24, 2017>*
 1. A person falling under any subparagraph of Article 5;
 2. A person in whose case one year has not elapsed since the revocation of permission for manufacturing business or the closure of a place of contract manufacturing and distribution business or a factory pursuant to Article 76: *Provided*, That the foregoing shall not apply to any of the following cases:
 - (a) A person recognized as capable of performing pharmaceutical affairs by a psychiatrist after being subject to revocation or closure as he or she falls under subparagraph 1 or 3 of Article 5;
 - (b) A person determined for termination of adult guardianship or limited guardianship by a family court after being subject to revocation or closure as he or she falls under subparagraph 2 of Article 5;
 3. A person declared bankrupt and not yet reinstated.
 - (9) In cases falling under paragraphs (1) through (4), where a person intends to modify any matters prescribed by Ordinance of the Prime Minister among matters permitted or notified, he or she shall obtain permission for modification or file a notification of modification, as prescribed by Ordinance of the Prime Minister. *<Amended by Act. No. 10512, Mar. 30, 2011; Act No. 11690, Mar. 23, 2013>*
 - (10) Where an item to be permitted or notified pursuant to paragraphs (2) and (3) is a new drug or a drug designated by the Minister of Food and Drug Safety, the following documents related to safety and effectiveness shall be submitted, as prescribed by Ordinance of the Prime Minister: *Provided*, That subparagraph 2 shall be excluded herefrom, where drug substances have been registered pursuant

to Article 31-2: <Amended by Act No. 10512, Mar. 30, 2011; Act No. 11690, Mar. 23, 2013>

1. Test results and data related thereto;
 2. Data on drug substances;
 3. Relevant documents;
 4. Other necessary data.
- (11) Upon receipt of a notification referred to in paragraphs (2) through (4) and (9), the Minister of Food and Drug Safety shall examine the details of notification and accept such notification if in compliance with this Act. <Newly Inserted by Act No. 16250, Jan. 15, 2019>
- (12) Where permission for or a notification of manufacturing business or contract manufacturing and distribution business of drugs, etc. or manufacturing and distribution of items is granted or filed under paragraphs (1) through (4) and (9), matters necessary for the subject matters, standards, conditions, management, etc. of permission or notifications shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 10512, Mar. 30, 2011; Act No. 11690, Mar. 23, 2013; Act No. 16250, Jan. 15, 2019>

[This Article Wholly Amended by Act No. 8643, Oct. 17, 2007]

Article 31-2 (Registration of Drug Substances)

- (1) A person who intends to manufacture and distribute a drug substance of a new drug or a drug substance determined and publicly notified by the Minister of Food and Drug Safety may file for registration of the matters prescribed by Ordinance of the Prime Minister, such as its ingredients, name, and manufacturing method, with the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013>
- (2) The Minister of Food and Drug Safety shall examine whether the matters registered under paragraph (1) satisfy the standards prescribed by Ordinance of the Prime Minister, inform the relevant applicant of the examination results, and record and keep the details of examination in the drug substance register. In such cases, he or she shall publicly notify the matters prescribed by Ordinance of the Prime Minister, such as the ingredients and manufacturer of the relevant drug substance. <Amended by Act No. 11690, Mar. 23, 2013>
- (3) A person who intends to modify important matters prescribed by Ordinance of the Prime Minister among the matters registered pursuant to paragraphs (1) and (2) shall file for registration of modification with the Minister of Food and Drug Safety: *Provided*, That a person who intends to modify other matters shall report thereon. <Amended by Act No. 11690, Mar. 23, 2013>
- (4) In cases of drug substances registered pursuant to paragraphs (1) through (3), permission by item or a notification by item shall be deemed granted or filed under Article 31 (2).
- (5) Except as provided in paragraphs (1) through (3), matters necessary for registration of or registration of modification of drug substances, reports of modification thereof, public announcement of registered drug substances, and other matters shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013>

[This Article Newly Inserted by Act No. 10512, Mar. 30, 2011]

Articles 31-3 and 31-4 Deleted. <by Act No. 13219, Mar. 13, 2015>

Article 31-5 (Renewal of Permission by Item of Drugs)

- (1) The period of validity of permission by item or a notification by item of drugs under Article 31 (2) and (3) shall be five years: *Provided*, That the period of validity thereof shall not apply to any of the following drugs: <Amended by Act No. 11690, Mar. 23, 2013>
 1. Drug substances;
 2. Drugs for export which are produced only for the purpose of export;
 3. Other drugs prescribed by Ordinance of the Prime Minister, which correspond to those prescribed

in subparagraphs 1 and 2.

- (2) Notwithstanding paragraph (1), the period of validity of permission by item of a drug subject to re-review under Article 32 shall apply after the period of re-review of the relevant drug expires.
- (3) Where a person obtaining permission by item intends to distribute the relevant drug continuously after the expiration of the period of validity prescribed in paragraph (1) or (2), he or she shall obtain renewed permission by item from, or file a renewed notification by item with, the Minister of Food and Drug Safety before the period of validity expires. <Amended by Act No. 11690, Mar. 23, 2013>
- (4) Where any serious problem is deemed to exist in the safety or effectiveness of drugs, where no data necessary for the renewal under paragraph (3) is submitted, or where other similar cases occur, the Minister of Food and Drug Safety need not renew permission by item or accept a renewed notification by item, of the relevant drugs. <Amended by Act No. 11690, Mar. 23, 2013>
- (5) Where a person obtaining permission by item fails to manufacture a drug during the period of validity prescribed in paragraph (1), permission by item or a notification by item of such drug shall not be renewed in accordance with paragraph (3): *Provided*, That the same shall not apply to drugs that have not been manufactured due to any unavoidable causes prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013>
- (6) Matters necessary for the method of calculating the period of validity under paragraphs (1) and (2) and the standards, methods, procedures, etc. for the renewal of permission by item or a notification by item under paragraphs (3) and (4) shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013>

[*This Article Newly Inserted by Act No. 11421, May 14, 2012*]

Article 32 (Re-Review of New Drugs)

- (1) Drugs falling under Article 31 (10) for which permission by item is granted under Article 31 (2) and (3) shall undergo a re-review by the Minister of Food and Drug Safety, within three months after the date on which four to six years have passed depending on items from the date such permission by item has been granted. <Amended by Act No. 8643, Oct. 17, 2007; Act No. 10512, Mar. 30, 2011; Act No. 11690, Mar. 23, 2013>
- (2) Matters necessary for the methods, procedures, timing, etc. for re-review referred to in paragraph (1) shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>

Article 33 (Re-Evaluation of Drugs)

- (1) The Minister of Food and Drug Safety may re-evaluate drugs for which the examination of their safety and effectiveness by efficacy or by ingredient or the verification of drug equivalence is deemed necessary, among drugs, etc. for which permission by item or a notification by item has been granted or filed pursuant to Article 31 (2) through (4). <Amended by Act No. 8643, Oct. 17, 2007; Act No. 11690, Mar. 23, 2013; Act No. 13114, Jan. 28, 2015>
- (2) Matters necessary for the methods, procedures, etc. for re-evaluation referred to in paragraph (1) shall be determined by the Minister of Food and Drug Safety. <Amended by Act No. 11690, Mar. 23, 2013>

Article 34 (Approval for Clinical Trial Protocols)

- (1) A person who intends to conduct a clinical trial of drugs, etc. shall prepare a protocol thereof and obtain approval from the Minister of Food and Drug Safety; and even where such person intends to modify any of the approved matters, he or she shall obtain approval of modification, as prescribed by Ordinance of the Prime Minister: *Provided*, That where such person intends to modify matters prescribed by Ordinance of the Prime Minister from among those in the clinical trial protocol, he or she shall report it to the Minister of Food and Drug Safety. <Amended by Act No. 11690, Mar. 23, 2013>

2013; Act No. 13114, Jan. 28, 2015; Act No. 14926, Oct. 24, 2017>

- (2) Notwithstanding paragraph (1), approval under paragraph (1) need not be granted for clinical trials prescribed by Ordinance of the Prime Minister, such as a trial or test aimed at observing the clinical effects of distributed drugs, etc. and investigating whether any adverse reaction occurs, on condition that permission by item or a notification by item of such drugs is granted. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 14926, Oct. 24, 2017>
- (3) A person who intends to conduct a clinical trial under paragraph (1) shall observe the following matters: <Amended by Act No. 11690, Mar. 23, 2013; Act No. 14926, Oct. 24, 2017; Act No. 15891, Dec. 11, 2018>
 1. A clinical trial shall be conducted at an institution conducting clinical trials or an institution conducting the analysis of clinical trial samples designated under Article 34-2 (1): *Provided*, That the same shall not apply to clinical trials prescribed by Ordinance of the Prime Minister in which participation by a medical institution, other than an institution conducting clinical trials or an institution conducting the analysis of clinical trial samples, is deemed necessary based upon the characteristics of the clinical trials;
 2. The person shall comply with the standards for conducting clinical trials, including the use of drugs, etc. manufactured, or imported after being manufactured, in appropriate manufacturing facilities prescribed by Ordinance of the Prime Minister;
 3. In the public announcement of the recruitment of subjects for conducting a clinical trial, the person shall inform the name, purpose, and method of the clinical trial; the qualifications and selection standards for test subjects; the names (corporate name), addresses, and contact information of a sponsor and a principal investigator; and foreseeable side effects;
 4. Deleted; <by Act No. 14926, Oct. 24, 2017>
 5. Insurance shall be obtained to indemnify or compensate the subjects of a clinical trial for any damage that may occur to their health; and in cases of paying compensation for the occurrence of damage, the person shall comply with the procedures, etc. for compensation explained to the subjects of a clinical trial in advance pursuant to Article 34-2 (3) 2;
 6. The safety information of drugs, etc. for clinical trials shall be evaluated, recorded, retained, and reported, as prescribed by Ordinance of the Prime Minister.
- (4) No drugs, etc. manufactured, or imported after being manufactured, for the purpose of clinical trials (excluding bioequivalence tests; hereafter in this paragraph, the same shall apply) shall be used for any purpose other than for clinical trials: *Provided*, That where approval from the Minister of Food and Drug Safety is obtained as prescribed by Ordinance of the Prime Minister, as the relevant drugs, etc. fall under any of the following cases, they may be used for any purpose other than for clinical trials; and in such cases, Article 34-2 (3) 2 shall apply *mutatis mutandis*: <Amended by Act No. 11690, Mar. 23, 2013; Act No. 14926, Oct. 24, 2017>
 1. Where the relevant drugs, etc. are intended to treat a patient with a serious life-threatening disease, such as terminal cancer or AIDS;
 2. Where the relevant drugs, etc. are intended to treat an emergency patient prescribed by Ordinance of the Prime Minister, such as a patient whose life is threatened and a patient without alternative means of treatment;
 3. Where the relevant drugs, etc. are intended to be used for the purpose of research or analysis (referring to research or analysis conducted without humans as a trial subject).
- (5) Where a clinical trial of pharmaceutical medications, blood pharmaceutical medications, gene remedial agents, cell remedial agents, etc., containing questionable ingredients in light of safety or effectiveness, causes or is likely to cause any risk to the public interest or health and hygiene, the Minister of Food and Drug Safety may provide limitations on such clinical trial which is subject to approval under paragraph (1). <Amended by Act No. 11690, Mar. 23, 2013; Act No. 14926, Oct. 24, 2017>

- (6) Where any clinical trial approved under the former and latter parts of paragraph (1) is conducted in violation of the approved matters or raises serious safety and ethical issues, the Minister of Food and Drug Safety may issue an order to halt the clinical trial, to stop use of drugs, etc. for the clinical trial, to recall or destroy such drugs, etc., or to take other necessary measures. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 14926, Oct. 24, 2017>
- (7) Matters necessary for approval of clinical trial protocols referred to in paragraph (1), matters to be included in the protocols, the standards for conducting clinical trials referred to in paragraph (3) 2, and other necessary matters shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 14926, Oct. 24, 2017>
- [This Article Wholly Amended by Act No. 10788, Jun. 7, 2011]

Article 34-2 (Designation of Institution Conducting Clinical Trials)

- (1) Any of the following institutions shall obtain designation from the Minister of Food and Drug Safety after securing facilities, professional personnel, and organization prescribed by Ordinance of the Prime Minister according to the following classifications, as prescribed by Ordinance of the Prime Minister: <Amended by Act No. 13114, Jan. 28, 2015; Act No. 14926, Oct. 24, 2017>
1. An institution intending to conduct clinical trials [excluding analysis of samples collected or extracted from a human body (hereinafter referred to as "sample analysis")] (limited to a medical institution prescribed in Article 3 of the Medical Service Act);
 2. An institution intending to conduct sample analysis among clinical trials.
- (2) Where an institution conducting clinical trials after obtaining designation pursuant to paragraph (1) 1 (hereinafter referred to as "institution conducting clinical trials") or an institution conducting sample analysis after obtaining designation pursuant to subparagraph 2 of that paragraph (hereinafter referred to as "institution conducting the analysis of clinical trial samples") intends to modify any designated matter, it shall obtain designation of modification from the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister: *Provided*, That where it intends to modify matters prescribed by Ordinance of the Prime Minister, it shall file a report to the Minister of Food and Drug Safety. <Amended by Act No. 13114, Jan. 28, 2015; Act No. 14926, Oct. 24, 2017>
- (3) An institution conducting clinical trials or an institution conducting the analysis of clinical trial samples shall comply with the following matters: *Provided*, That subparagraphs 1 through 4 shall apply only to institutions conducting clinical trials: <Amended by Act No. 14926, Oct. 24, 2017; Act No. 15709, Jun. 12, 2018; Act No. 15891, Dec. 11, 2018>
1. Persons under the custody of any group care facilities prescribed by Ordinance of the Prime Minister, such as social welfare facilities, (hereafter in this subparagraph referred to as "inmate") shall not be selected as the subject of a clinical trial: *Provided*, That an inmate may be selected as the subject of a clinical trial, where the standards prescribed by Ordinance of the Prime Minister are satisfied and where it is inevitable to select an inmate as the subject of a clinical trial in consideration of the characteristics of the clinical trial;
 2. An explanation shall be provided in advance to subjects of a clinical trial regarding clinical trial details, the extent of damage that is expected to occur to the health of the subjects due to the clinical trials, the details of compensation therefor, the procedures for applying for the compensation, and other relevant matters; and a written consent thereto (including electronic documents containing digital signatures prescribed in the Digital Signature Act; hereafter in this Article, the same shall apply) shall be obtained from the subjects;
 3. Notwithstanding subparagraph 2, where consent of a subject of a clinical trial cannot be obtained due to the lack of comprehension and communication or due to other reasons, a written consent shall be obtained from his or her representative prescribed in the following items. In such cases, the consent of a representative shall not be contrary to the intent of the subject of a clinical trial:
 - (a) A legal representative;

- (b) Where no legal representative is appointed, the spouse, a lineal ascendant, or a lineal descendant shall act as a representative for such person in the abovementioned order; and where there exist at least two lineal ascendants or descendants, the representative for such person shall be appointed under agreement by and between such ascendants or descendants, or the eldest person among them shall act as the representative if they fail to reach an agreement;
4. Where any clinical trial is to be conducted on healthy persons, those who have not participated in any clinical trial within six months from the date of the clinical trial shall be selected as the subjects of the clinical trial, as prescribed by Ordinance of the Prime Minister;
5. Upon conducting a clinical trial, the relevant institution shall comply with the matters prescribed by Ordinance of the Prime Minister, such as preparing and issuing a clinical trial report or an analysis report of clinical trial samples, and preparing, keeping, and reporting records on the subjects of the clinical trial (including personally identifiable information referred to in Article 24 of the Personal Information Protection Act); records on adverse reactions that have occurred during the clinical trial; records on the management of drugs used in the clinical trial; and the contract for the clinical trial (hereinafter referred to as "records on a clinical trial").
- (4) The Minister of Food and Drug Safety and an institution conducting clinical trials may handle information on health prescribed in Article 23 of the Personal Information Protection Act and data containing personally identifiable information prescribed in Article 24 of that Act after obtaining consent from the relevant persons, to perform the affairs regarding the selection, management, etc. of subjects of clinical trials. In such cases, the Minister of Food and Drug Safety and the institution conducting clinical trials shall protect the relevant information in accordance with the Personal Information Protection Act. *<Newly Inserted by Act No. 15891, Dec. 11, 2018>*
- (5) Except as provided in paragraphs (1) through (4), matters necessary for the requirements, procedures, and methods for designating institutions conducting clinical trials or institutions conducting the analysis of clinical trial samples, and the operation, management, etc. thereof shall be prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 11690, Mar. 23, 2013; Act No. 14926, Oct. 24, 2017; Act No. 15891, Dec. 11, 2018>*

[This Article Newly Inserted by Act No. 10788, Jun. 7, 2011]

Article 34-3 (Designation of Institutions Conducting Non-Clinical Studies)

- (1) An institution that intends to conduct non-clinical studies determined and publicly notified by the Minister of Food and Drug Safety on non-human subjects with regard to the safety and effectiveness of drugs, etc. shall have facilities, professional personnel, and organizations and obtain designation from the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 13114, Jan. 28, 2015>*
- (2) Where an institution that conducts non-clinical studies after obtaining designation under paragraph (1) (hereinafter referred to as "institution conducting non-clinical studies") intends to modify any designated matter, it shall obtain designation of modification from the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister: *Provided*, That where it intends to modify matters prescribed by Ordinance of the Prime Minister, it shall file a report to the Minister of Food and Drug Safety. *<Amended by Act No. 13114, Jan. 28, 2015>*
- (3) When an institution conducting non-clinical studies has conducted a non-clinical study under paragraph (1), it shall comply with the matters prescribed by Ordinance of the Prime Minister, such as preparing and issuing non-clinical study reports and retaining records on such non-clinical study. *<Amended by Act No. 11690, Mar. 23, 2013>*
- (4) Except as provided in paragraphs (1) through (3), matters necessary for the requirements, procedures, and methods for designating institutions conducting non-clinical studies and the operation, management, etc. thereof shall be prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 11690,*

Mar. 23, 2013>

[This Article Newly Inserted by Act No. 10788, Jun. 7, 2011]

Article 34-4 (Education for Persons Engaged in Clinical Trials)

- (1) The head of an institution conducting clinical trials and a person intending to conduct a clinical trial pursuant to Article 34 (1) shall have the following personnel (hereinafter referred to as "persons engaged in clinical trials") receive education to enhance expertise and protect subjects of clinical trials (hereinafter referred to as "education on clinical trials"): *<Amended by Act No. 14926, Oct. 24, 2017>*
 1. Persons responsible for conducting clinical trials in an institution conducting clinical trials;
 2. Persons monitoring the supervision, verification, and examination of clinical trials;
 3. Persons in charge of conducting clinical trials under the delegation and supervision of the persons responsible under subparagraph 1 in an institution conducting clinical trials;
 4. Persons prescribed by Ordinance of the Prime Minister, who conduct the affairs of protecting the rights and ensuring safety of the subjects of clinical trials participating in the clinical trials.
- (2) The Minister of Food and Drug Safety may order the heads of institutions conducting clinical trials and persons intending to conduct clinical trials to have persons engaged in clinical trials, who are employed thereby, receive education on clinical trials. *<Amended by Act No. 14926, Oct. 24, 2017>*
- (3) The Minister of Food and Drug Safety may designate specialized organizations, institutions, etc. related to clinical trials as an institution to offer education on clinical trials (hereinafter referred to as "institution offering education on clinical trials"). In such cases, the Minister of Food and Drug Safety shall publicly notify the details of designation. *<Amended by Act No. 14926, Oct. 24, 2017>*
- (4) An institution offering education on clinical trials shall observe matters prescribed by Ordinance of the Prime Minister, such as preparing and retaining records on education on clinical trials. *<Amended by Act No. 14926, Oct. 24, 2017>*
- (5) Except as provided in paragraphs (1) through (4), matters necessary for education on clinical trials, such as the details, hours, and methods of education, and education fees, and matters necessary for requirements and procedures for designation of institutions offering education on clinical trials, operation thereof, revocation of designation, etc. shall be prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 14926, Oct. 24, 2017>*

[This Article Newly Inserted by Act No. 13114, Jan. 28, 2015]

Article 35 (Conditional Permission)

- (1) In granting permission under Article 31 (1) and (2), the Minister of Food and Drug Safety may grant permission for drug manufacturing business or items prescribed by Ordinance of the Prime Minister, on condition that the facilities referred to in Article 31 (1) be installed within a fixed period. *<Amended by Act No. 8643, Oct. 17, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>*
- (2) If a person who has obtained permission under paragraph (1) fails to be equipped with proper facilities without good cause within the period referred to in paragraph (1), the Minister of Food and Drug Safety shall revoke such permission. *<Amended by Act No. 11690, Mar. 23, 2013>*

Article 35-2 (Preliminary Examination of Permission by Item of Drugs)

- (1) A person who intends to obtain permission by item or file a notification by item of drugs, etc. pursuant to Article 31 and a person who intends to conduct a clinical trial pursuant to Article 34 may request, in advance, the Minister of Food and Drug Safety to examine standards for preparing data necessary for permission, notifications, approval, etc. *<Amended by Act No. 11690, Mar. 23, 2013 Act No. 14926, Oct. 24, 2017>*
- (2) Upon receipt of a request under paragraph (1), the Minister of Food and Drug Safety shall confirm

such request and inform the applicant of the examination results in writing. <Amended by Act No. 11690, Mar. 23, 2013>

- (3) In granting or filing permission, notifications, approval, etc. referred to in Articles 31 and 34, the Minister of Food and Drug Safety shall take into consideration the examination results referred to in paragraph (2). <Amended by Act No. 11690, Mar. 23, 2013>
- (4) Matters necessary for the subject matters and scope of preliminary examination under paragraph (1), procedures and methods therefor, etc. shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013>

[This Article Newly Inserted by Act No. 10788, Jun. 7, 2011]

Article 36 (Manufacturing Managers of Drugs)

- (1) A manufacturer of drugs, etc. (excluding a quasi-drug manufacturer manufacturing only items falling under subparagraph 7 (a) of Article 2) shall assign the necessary number of pharmacists or oriental medicine pharmacists to each of his or her factories and have them manage manufacturing affairs, as prescribed by Ordinance of the Prime Minister: *Provided*, That in cases of business of manufacturing biological medications, cellular therapy products, or gene therapy products, the manufacturer may have a physician approved by the Minister of Food and Drug Safety or a professional technician with bacteriological knowledge prescribed by Ordinance of the Prime Minister manage the manufacturing affairs. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013; Act No. 13114, Jan. 28, 2015>
- (2) A quasi-drug manufacturer manufacturing only items falling under subparagraph 7 (a) of Article 2 shall assign technicians approved by the Minister of Food and Drug Safety to each of his or her factories and have them manage the manufacturing affairs: *Provided*, That where the manufacturer is a technician approved by the Minister of Food and Drug Safety and manages the manufacturing affairs at his or her factories, he or she need not assign an additional technician to such factories. <Amended by Act No. 11690, Mar. 23, 2013>
- (3) Where a manufacturer of drugs, etc. intends to have a person who manages the manufacturing affairs of drugs, etc. (hereinafter referred to as "manufacturing manager") pursuant to paragraph (1) or (2), he or she shall file a notification with the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister. <Newly Inserted by Act No. 10788, Jun. 7, 2011; Act No. 11690, Mar. 23, 2013>
- (4) Upon receipt of a notification referred to in paragraph (3), the Minister of Food and Drug Safety shall examine the details of the notification and accept such notification if in compliance with this Act. <Newly Inserted by Act No. 16250, Jan. 15, 2019>

Article 37 (Duty to Manage Manufacturing of Drugs)

- (1) A manufacturing manager shall comply with the matters prescribed by Ordinance of the Prime Minister with regard to guidance and supervision of employees engaging in the affairs of manufacturing drugs, etc., quality management, management of manufacturing facilities, and other matters concerning manufacturing management. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10788, Jun. 7, 2011; Act No. 11690, Mar. 23, 2013>
- (2) No manufacturing manager shall engage in affairs, other than management of manufacturing in the relevant factory.
- (3) No manufacturer of drugs, etc. or person who has obtained permission by item shall interfere with the management affairs of a manufacturing manager, nor refuse, without good cause, any request from a manufacturing manager for matters necessary for performing the affairs. <Amended by Act No. 8643, Oct. 17, 2007>

Article 37-2 (Education for Manufacturing Managers)

- (1) A manufacturing manager shall regularly receive education for ensuring safety and effectiveness of drugs, etc. and managing manufacturing and quality thereof.
- (2) If necessary to prevent any risk to public health, the Minister of Food and Drug Safety may order manufacturing managers to receive education referred to in paragraph (1). *<Amended by Act No. 11690, Mar. 23, 2013>*
- (3) A manufacturing manager (including a replaced manufacturing manager where such replacement was notified pursuant to Article 40 (1) 3) shall receive education referred to in paragraph (1) within six months from the date he or she begins the manufacturing management affairs: *Provided*, That the same shall not apply where he or she received the relevant education within two years before becoming a manufacturing manager. *<Amended by Act No. 13655, Dec. 29, 2015; Act No. 14328, Dec. 2, 2016>*
- (4) For the purposes of providing education referred to in paragraphs (1) through (3), the Minister of Food and Drug Safety may designate and publicly notify a relevant specialized organization or institution as an institution offering education. *<Amended by Act No. 11690, Mar. 23, 2013>*
- (5) An institution offering education designated under paragraph (4) (hereinafter referred to as "institution offering education for manufacturing managers") shall observe matters prescribed by Ordinance of the Prime Minister, such as issuing certificates of completion of education, preparing and retaining education records, etc. *<Newly Inserted by Act No. 13114, Jan. 28, 2015>*
- (6) Except as provided in paragraphs (1) through (5), matters necessary for educating manufacturing managers, such as the details, hours, and methods of education, and education fees, and matters necessary for requirements and procedures for designating an institution offering education, operation thereof, revocation of such designation, etc. shall be prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 11690, Mar. 23, 2013; Act No. 13114, Jan. 28, 2015>*

[This Article Newly Inserted by Act No. 10788, Jun. 7, 2011]

Article 37-3 (Post-Marketing Safety Management of Drugs)

- (1) A person who has obtained permission by item shall employ a physician, pharmacist, or oriental medicine pharmacist to perform the affairs of post-marketing safety management, such as re-reviewing new drugs, etc., re-evaluating drugs, and reporting side effects, as prescribed by Ordinance of the Prime Minister: *Provided*, That a person who has obtained permission by item of drugs to be used for animals only may perform the affairs of post-marketing safety management after employing a veterinarian. *<Amended by Act No. 11251, Feb. 1, 2012; Act No. 11690, Mar. 23, 2013; Act No. 13114, Jan. 28, 2015>*
- (2) A person who performs the affairs of safety management under paragraph (1) (hereinafter referred to as "safety manager") shall comply with the matters prescribed by Ordinance of the Prime Minister, regarding the safety management of drugs in distribution. *<Amended by Act No. 11690, Mar. 23, 2013>*

[This Article Newly Inserted by Act No. 8643, Oct. 17, 2007]

Article 37-4 (Education for Safety Managers)

- (1) A safety manager shall regularly receive education on the affairs of safety management under Article 37-3 (1).
- (2) If necessary to prevent any risk to public health, the Minister of Food and Drug Safety may order safety managers to receive occasional education, in addition to receiving regular education pursuant to paragraph (1).
- (3) A safety manager (including a replaced safety manager where such replacement is notified under Article 40 (1) 3) shall receive education prescribed in paragraph (1) within six months from the date

he or she begins the affairs of safety management: *Provided*, That this shall not apply where he or she received the relevant education within two years before becoming a safety manager. <Amended by Act No. 13655, Dec. 29, 2015; Act No. 14328, Dec. 2, 2016>

- (4) The Minister of Food and Drug Safety may designate a relevant specialized organization or institution as an educational institution to provide education prescribed in paragraphs (1) through (3).
- (5) An educational institution prescribed in paragraphs (4) shall issue certificates of completion of education to persons who complete education courses and shall prepare and retain education records, as prescribed by Ordinance of the Prime Minister.
- (6) Except as provided in paragraphs (1) through (4), matters necessary for education, such as the details, hours, and methods of education, and education fees, and matters necessary for the designation and operation of an educational institution, revocation of designation, etc. shall be prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted by Act No. 12450, Mar. 18, 2014]

Article 38 (Duties of Production Management of Drugs and Reporting Thereof)

- (1) A manufacturer of drugs, etc. or a person who has obtained permission by item of drugs shall comply with the matters prescribed by Ordinance of the Prime Minister with respect to the manufacturing and quality management (including self-tests) of drugs, etc. and other production management thereof. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10788, Jun. 7, 2011; Act No. 11690, Mar. 23, 2013>
- (2) A person who has obtained permission by item of drugs or a quasi-drug manufacturer shall report the production performance, etc. of drugs, etc. to the Minister of Food and Drug Safety or the president of the Korea Pharmaceutical Information Service under Article 47-3 (1), as prescribed by Ordinance of the Prime Minister. <Amended by Act No. 8643, Oct. 17, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013; Act No. 14328, Dec. 2, 2016>

Article 38-2 (Drug Identification Mark)

- (1) A person who has obtained permission by item of drugs in dosage form determined and publicly notified by the Minister of Food and Drug Safety shall place a mark on the drugs distinguishable from other drugs (hereinafter referred to as "identification mark") and shall file for registration of the identification mark with the Minister of Food and Drug Safety and distribute such drugs in the market.
- (2) Where a person who had filed for registration of an identification mark pursuant to paragraph (1) modifies the identification mark, he or she shall file for registration of modification with the Minister of Food and Drug Safety.
- (3) The Minister of Food and Drug Safety may entrust a corporation established pursuant to Article 67 or a relevant specialized institution prescribed by Presidential Decree with the affairs of registering identification marks under paragraphs (1) and (2).
- (4) Matters necessary for the operation of the identification mark system, such as the methods of identification marking, and procedures for registration, under paragraphs (1) through (3) shall be prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted by Act No. 13114, Jan. 28, 2015]

Article 39 (Recall of Hazardous Drugs)

- (1) Where any of the following persons becomes aware that drugs, etc. have any issues as to safety and effectiveness, in violation of Article 53 (1), 61 (including cases applicable *mutatis mutandis* in Article 66), or 62 (including cases applicable *mutatis mutandis* in Article 66), he or she shall without delay recall the drugs, etc. in distribution or take necessary measures for recall. In such cases, a person falling under any of the subparagraphs 1 through 3 shall in advance report a recall plan to the

Minister of Food and Drug Safety: <Amended by Act No. 13114, Jan. 28, 2015>

1. A person who has obtained permission by item of drugs;
 2. A quasi-drug manufacturer;
 3. An importer of drugs, etc. prescribed in Article 42 (2);
 4. A distributor of drugs, etc.;
 5. A pharmacy founder;
 6. A medical institution founder;
 7. Other persons prescribed by Ordinance of the Prime Minister, among persons eligible to distribute or handle drugs pursuant to this Act or other statutes.
- (2) The Minister of Food and Drug Safety, the Mayor/Do Governor, or the head of a *Si/Gun/Gu* may reduce or exempt the administrative dispositions issued pursuant to Article 76 for persons who have obtained permission by item of drugs, quasi-drug manufacturers, importers of drugs, etc., pharmacy founders, and drug distributors, who conscientiously perform the recall or take measures necessary for the recall in accordance with paragraph (1), as prescribed by Ordinance of the Prime Minister. <Amended by Act No. 8643, Oct. 17, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>
- (3) Matters necessary for the ranking of risk and standards for risk assessment necessary for the recall of drugs, etc. under paragraph (1), recall plans or procedures for recall, and destruction of and follow-up measures for recalled drugs, etc. shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10788, Jun. 7, 2011; Act No. 11690, Mar. 23, 2013>

Article 40 (Notification of Business Closure)

- (1) Where a manufacturer of drugs, etc. or a person who has obtained permission by item falls under any of the following cases, he or she shall file a notification of such fact with the Minister of Food and Drug Safety within seven days: *Provided*, That he or she need not file a notification, where the period of business suspension is less than one month: <Amended by Act No. 11690, Mar. 23, 2013; Act No. 14328, Dec. 2, 2016>
1. Where he or she closes, or suspends the operation of, a factory or a place of contract manufacturing and distribution business;
 2. Where he or she resumes the operation of a factory or a place of contract manufacturing and distribution business after suspension;
 3. Where a manufacturing manager or a safety manager is replaced, or other matters prescribed by Ordinance of the Prime Minister are modified.
- (2) Where a manufacturer of drugs, etc., or a person who has obtained permission by item intends to file a notification of business closure or business suspension under paragraph (1), he or she shall recall the drugs, etc. in distribution or take the necessary measures for recall under Article 39 or take other necessary measures as prescribed by Ordinance of the Prime Minister. <Newly Inserted by Act No. 14328, Dec. 2, 2016>
- (3) Where a manufacturer of drugs, etc., or a person who has obtained permission by item files a notification of business resumption under paragraph (1) 2, he or she shall attach and submit the documents or data prescribed by Ordinance of the Prime Minister, such as the result of inspecting facilities in factories of drugs, etc. and the status of possession of drugs, etc., to the Minister of Food and Drug Safety: *Provided*, That where a manufacturer of drugs, etc. or a person who has obtained permission by item, whose period of business suspension is less than one year, files a notification of business resumption, the Minister of Food and Drug Safety may exempt the duty to submit documents or data. <Newly Inserted by Act No. 14328, Dec. 2, 2016>
- (4) Upon receipt of a notification referred to in paragraph (1), the Minister of Food and Drug Safety shall examine the details of the notification and accept such notification if in compliance with this

Act. <Newly Inserted by Act No. 16250, Jan. 15, 2019>
 [This Article Wholly Amended by Act No. 8643, Oct. 17, 2007]

Article 41 (Preparation of Pharmacy Medication)

- (1) When pharmacy founders intend to prepare pharmacy medications or dispensaries of medical institutions designated by the Minister of Health and Welfare intend to prepare medications, they shall file a notification of the relevant items with the head of a *Si/Gun/Gu*, as prescribed by Ordinance of the Prime Minister, following consultation with the Minister of Health and Welfare: *Provided*, That where a dispensary of a medical institution, the incorporation of which is permitted by the Mayor/*Do* Governor pursuant to the Medical Service Act, intends to prepare medications, it shall file a notification with the relevant Mayor/*Do* Governor. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>
- (2) Upon receipt of a notification referred to in paragraph (1), the head of a *Si/Gun/Gu* or the Mayor/*Do* Governor shall examine the details of the notification and accept such notification if in compliance with this Act. <Newly Inserted by Act No. 16250, Jan. 15, 2019>
- (3) The scope of pharmacy medications and dispensary medications, facilities of dispensaries, and other necessary matters shall be prescribed by Ordinance of the Prime Minister, following consultation with the Minister of Health and Welfare. <Amended by Act No. 852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013; Act No. 16250, Jan. 15, 2019>

SECTION 2 Permission for Import of Drugs

Article 42 (Permission for Import of Drugs)

- (1) A person who intends to engage in the business of importing drugs, etc. shall file a notification of import business with the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister, and obtain permission from, or file a notification with, the Minister of Food and Drug Safety for each item, as prescribed by Ordinance of the Prime Minister. The same shall also apply where he or she intends to modify the matters permitted or notified. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013; Act No. 13114, Jan. 28, 2015>
- (2) Notwithstanding paragraph (1), the Minister of National Defense or a person who has filed a notification of import business pursuant to the former part of paragraph (1) (hereinafter referred to as "importer") may import drugs, etc. without obtaining permission, or filing a notification, by each item under paragraph (1) in any of following cases: <Amended by Act No. 10512, Mar. 30, 2011; Act No. 11690, Mar. 23, 2013; Act No. 13114, Jan. 28, 2015>
 1. Where the Minister of National Defense intends to import drugs, etc. not produced domestically for any urgent military purpose, following prior-consultation with the Minister of Food and Drug Safety on the items and quantity of the drugs, etc.;
 2. Where an importer intends to import drug substances to manufacture drugs, etc., or to import the drugs, etc. prescribed by Ordinance of the Prime Minister, including drugs, etc. for clinical trials.
- (3) An importer shall secure necessary facilities, such as a business place, in compliance with the standards for facilities prescribed by Presidential Decree. <Amended by Act No. 13114, Jan. 28, 2015>
- (4) None of the following persons shall file a notification of import business under paragraph (1). In cases of corporations, the same shall apply where the representative of a corporation falls under any of the following cases: <Newly Inserted by Act No. 13114, Jan. 28, 2015; Act No. 14926, Oct. 24, 2017>
 1. A person falling under any of the subparagraphs of Article 5;
 2. A person for whom one year has not elapsed since a business place is closed pursuant to Article

76: *Provided*, That the same shall not apply to any of the following cases:

- (a) A person recognized as capable of performing pharmaceutical affairs by a psychiatrist after being subject to closure for falling under subparagraph 1 or 3 of Article 5;
 - (b) A person determined for termination of adult guardianship or limited guardianship by a family court after being subject to closure as he or she falls under subparagraph 2 of Article 5;
3. A person declared bankrupt and not yet reinstated.
- (5) Articles 31 (7), (10) and (12), 31-2, 31-5, 32, 33, 35-2, 36, 37, 37-2 through 37-4, 38, 38-2, 40, 50-2 through 50-10, 69-3 and 75 shall apply *mutatis mutandis* to the drugs, etc. imported pursuant to paragraph (1) or the importers thereof. In such cases, "manufacture" or "production" shall be construed as "import", "manufacturers or persons who have obtained permission by item" as "importers", respectively, and "factory or place of contract manufacturing and distribution business" as "business place", respectively. <Amended by Act No. 8643, Oct. 17, 2007; Act No. 10512, Mar. 30, 2011; Act No. 10788, Jun. 7, 2011; Act No. 11118, Dec. 2, 2011; ; Act No. 11421, May 14, 2012; Act No. 12450, Mar. 18, 2014; Act No. 13114, Jan. 28, 2015; Act No. 13219, Mar. 13, 2015; Act No. 16250, Jan. 15, 2019>
- (6) Upon receipt of a notification referred to in paragraph (1), the Minister of Food and Drug Safety shall examine the details of the notification and accept such notification if in compliance with this Act. <Newly Inserted by Act No. 16250, Jan. 15, 2019>
- (7) An importer who intends to import drugs, etc. prescribed by Ordinance of the Prime Minister among those for which he or she has obtained permission or filed a notification by item pursuant to paragraph (1) shall file for registration of matters prescribed by Ordinance of the Prime Minister, including the name, location, etc. of overseas factories (referring to factories located overseas for the manufacturing and quality management of drugs, etc.; hereinafter the same shall apply), with the Minister of Food and Drug Safety. <Newly Inserted by Act No. 15891, Dec. 11, 2018; Act No. 16250, Jan. 15, 2019>
- (8) An importer who intends to modify any matter prescribed by Ordinance of the Prime Minister, among the matters registered pursuant to paragraph (7), shall file for registration of modification with the Minister of Food and Drug Safety; and where the importer modifies matters other than those prescribed by Ordinance of the Prime Minister, he or she shall file a notification of such modification with the Minister of Food and Drug Safety. <Newly Inserted by Act No. 15891, Dec. 11, 2018; Act No. 16250, Jan. 15, 2019>
- (9) Matters necessary for notifications of import business, and the subject matters, standards, conditions, and management of permission by item or a notification by item prescribed in paragraph (1); and the procedures, methods, etc. for registration, registration of modification, and notifications of modification prescribed in paragraphs (7) and (8) shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10512, Mar. 30, 2011; Act No. 11690, Mar. 23, 2013; Act No. 13114, Jan. 28, 2015; Act No. 15891, Dec. 11, 2018; Act No. 16250, Jan. 15, 2019>

Article 43 (International Trade in Endangered Species of Wild Fauna and Flora)

- (1) A person who intends to export, import, or carry into Korea by sea, drugs made from processed goods of animals and plants prescribed in the Convention on International Trade in Endangered Species of Wild Fauna and Flora shall obtain permission from the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>
- (2) No person shall commit the following acts with respect to the horns of rhinoceroses or the bones of tigers, which are processed goods using endangered species of wild animals:
 - 1. Importing or distributing the horns of rhinoceros or the bones of tigers, or storing or displaying them for distribution;

2. Manufacturing or dispensing drugs using the horns of rhinoceros or the bones of tigers;
3. Distributing any drugs manufactured or dispensed using the horns of rhinoceros or the bones of tigers, or storing or displaying them for distribution.

SECTION 3 Distribution Business of Drugs

Article 44 (Distribution of Drugs)

- (1) No person, other than pharmacy founders (including pharmacists or oriental medicine pharmacists working for the relevant pharmacy; the same shall also apply in Articles 47, 48, and 50), shall distribute or obtain drugs for distribution: *Provided*, That the same shall not apply where a person who has obtained permission by item of drugs, or an importer, distributes drugs manufactured or imported to a person eligible to manufacture or distribute drugs according to this Act or where university students majoring in pharmacy dispense drugs to the extent prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8643, Oct. 17, 2007; Act No. 13655, Dec. 29, 2015>
- (2) Notwithstanding paragraph (1), any of the following persons may distribute or obtain drugs for distribution: <Amended by Act No. 11421, May 14, 2012; Act No. 14328, Dec. 2, 2016>
 1. The Korea Orphan and Essential Drug Center established pursuant to Article 91;
 - 1-2. A distributor of safe and readily available drugs who has been registered under Article 44-2 (limited to cases of distributing safe and readily available drugs referred to in Article 44-2 (1));
 2. An herb druggist or drug wholesaler who has obtained permission pursuant to Article 45.

Article 44-2 (Registration of Distributors of Safe and Readily Available Drugs)

- (1) A person who intends to distribute safe and readily available drugs (referring to drugs which, among over-the-counter drugs, are emergently used mainly for minor symptoms at the sole discretion of patients and are prescribed and publicly notified by the Minister of Health and Welfare within the limit of 20 items taking into consideration the ingredients, side effects, content, dosage form, awareness, purchase availability, etc. of the relevant items; hereinafter the same shall apply) at a place which is not a pharmacy shall file for registration as a distributor of safe and readily available drugs with the head of the competent *Si/Gun/Gu*.
- (2) A person who intends to file for registration as a distributor of safe and readily available drugs under paragraph (1) shall have a year-round shop that opens 24 hours a day and shall meet the standards for registration prescribed by Ordinance of the Ministry of Health and Welfare, in consideration of the convenience in use by local residents, the availability of recall of hazardous drugs, and other matters.
- (3) If a distributor of safe and readily available drugs intends to modify any matter prescribed by Ordinance of the Ministry of Health and Welfare among the matters registered, he or she shall file for registration of modification with the head of the competent *Si/Gun/Gu*.
- (4) Where a distributor of safe and readily available drugs closes or suspends the business of distribution of safe and readily available drugs or resumes the suspended business, he or she shall file a notification thereof with the head of the competent *Si/Gun/Gu*: *Provided*, That the same shall not apply where the period of business suspension is less than one month.
- (5) Matters necessary for filing for registration and filing for registration of modification pursuant to paragraphs (1) through (3) and those necessary for the methods, procedures, etc. for filing a notification of business closure, suspension, and resumption under paragraph (4) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 11421, May 14, 2012]

Article 44-3 (Education for Distributors of Safe and Readily Available Drugs)

- (1) A person who intends to file for registration as a distributor of safe and readily available drugs under

Article 44-2 (1) shall receive education in advance on safety assurance and quality management of safe and readily available drugs.

- (2) If deemed necessary to prevent any risk to public health, the Minister of Health and Welfare may order a distributor of safe and readily available drugs (including his or her employees) to receive education on the safety assurance and quality management of safe and readily available drugs.
- (3) In order to provide education referred to in paragraphs (1) and (2), the Minister of Health and Welfare may designate a relevant organization or institution as an educational institution.
- (4) Matters necessary for the curricula, time, methods, procedures, fees, etc. of education under paragraph (1) and (2) and matters necessary for the designation, operation, revocation of designation, etc. of an educational institution under paragraph (3) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 11421, May 14, 2012]

Article 44-4 (Matters to Be Observed by Distributors of Safe and Readily Available Drugs)

A distributor of safe and readily available drugs shall observe the following matters:

1. The distributor shall manage his or her facilities and safe and readily available drugs to ensure that such drugs do not cause any risk to health and hygiene and their efficacy is not undermined;
2. The distributor shall thoroughly supervise his or her employees in order to prevent any incident related to health and hygiene;
3. The distributor shall observe the matters prescribed by Ordinance of the Ministry of Health and Welfare, such as the limit of quantity to distribute at one time, and age restriction on distribution;
4. The distributor shall observe other matters corresponding to subparagraphs 1 through 3 and prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 11421, May 14, 2012]

Article 44-5 (Application Mutatis Mutandis)

- (1) Articles 39 (1), 47 (1), 50 (1) and (3), 56 (2), 68-7, 69, 71, and 72 (2) shall apply *mutatis mutandis* to distributors of safe and readily available drugs registered under Article 44-2 (1). In such cases, "pharmacy founder" shall be construed as "distributor of safe and readily available drugs registered under Article 44-2 (1)", and "over-the-counter drugs" referred to in Article 50 (3) as "safe and readily available drugs under Article 44-2 (1)".
- (2) Article 47-3 (2) shall apply *mutatis mutandis* to distributors of safe and readily available drugs registered under Article 44-2 (1). In such cases, "pharmacy" shall be construed as "distributor of safe and readily available drugs". *<Amended by Act No. 14328, Dec. 2, 2016>*

[This Article Newly Inserted by Act No. 11421, May 14, 2012]

Article 45 (Permission for Drug Distribution Business)

- (1) A person who intends to become an herb druggist or drug wholesaler pursuant to Article 44 (2) 2 shall obtain permission from the head of a *Sil/Gun/Gu*, as prescribed by Ordinance of the Ministry of Health and Welfare. The same shall apply to the modification of any permitted matters. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10788, Jun. 7, 2011>*
- (2) An herb druggist or drug wholesaler who intends to obtain permission pursuant to paragraph (1) shall have facilities classified as follows: *<Amended by Act No. 10512, Mar. 30, 2011; Act No. 12450, Mar. 18, 2014; Act No. 13114, Jan. 28, 2015>*
 1. In cases of an herb druggist, a business place and other facilities meeting the standards for facilities prescribed by Presidential Decree;
 2. In cases of a drug wholesaler, a business place, a warehouse, and other facilities meeting the standards for facilities prescribed by Presidential Decree. In such cases, the area of the warehouse shall be at least 165 square meters: *Provided*, That where he or she handles only imported drugs,

reagents, or drug substances, the area of the warehouse shall be at least 66 square meters; where he or she handles only animal drugs, the area of the warehouse shall be at least 33 square meters; where he or she handles only herbal drugs, high pressure gases for medical purposes, and radiopharmaceuticals, the standards for the area of warehouses shall not be applied.

- (3) Permission for an herb druggist under paragraph (1) shall be granted to a person who has passed the examination for herb druggists prescribed by Presidential Decree only in districts prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>
- (4) An herb druggist permitted under paragraph (1) may distribute herbal drugs after mixing them in accordance with a prescription recorded in an established herbal drug book or with a prescription of an oriental medical doctor, at the request of a patient.
- (5) A drug wholesaler permitted under paragraph (1) shall employ a pharmacist to manage the relevant affairs, and an herbal drug wholesaler shall employ any of the following persons to manage the relevant affairs: *Provided*, That the same shall not apply where the drug wholesaler who is a pharmacist directly manages the relevant affairs or where any of the following herbal drug wholesalers directly manages the relevant affairs: <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>
1. A pharmacist;
 2. An oriental medicine pharmacist;
 3. An herb druggist;
 4. A person who has completed an herbal drug related course in a college or university accredited by the Minister of Health and Welfare.
- (6) Where a drug wholesaler or herbal drug wholesaler intends to employ a person who manages the relevant affairs pursuant to paragraph (5), he or she shall file a notification with the head of a *Si/Gun/Gu*, as prescribed by Ordinance of the Ministry of Health and Welfare. In such cases, the head of a *Si/Gun/Gu* shall examine the details of the notification and accept such notification if in compliance with this Act. <Newly Inserted by Act No. 10788, Jun. 7, 2011; Act No. 16250, Jan. 15, 2019>
- (7) Matters necessary for the standards for and conditions and management of permission under paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10788, Jun. 7, 2011>
- (8) Notwithstanding paragraph (5), in cases of entrusting the affairs of distribution and management, such as storage and delivery of drugs, to any other drug wholesaler who meets the requirements prescribed by Ordinance of the Ministry of Health and Welfare, a drug wholesaler need not employ a person who manages the relevant affairs pursuant to paragraph (5): *Provided*, That in such cases, a person to whom distribution and management affairs are entrusted shall employ a person who manages the relevant affairs pursuant to paragraph (5), as prescribed by Ordinance of the Ministry of Health and Welfare. <Newly Inserted by Act No. 13655, Dec. 29, 2015>

Article 46 (Grounds for Disqualification of Permission for Herb Druggists or Drug Wholesalers)

None of the following persons shall be permitted as an herb druggist or drug wholesaler: <Amended by Act No. 10788, Jun. 7, 2011>

1. A person falling under any of the subparagraphs of Article 5;
2. A person for whom one year has not passed after his or her permission was revoked pursuant to Article 76;
3. A medical institution founder (where the medical institution is a corporation, the executive officers and staff thereof) or a pharmacy founder;
4. A person declared bankrupt and not yet reinstated.

Article 47 (Order in Distribution of Drugs)

- (1) Any of the following persons shall comply with the following matters to establish a distribution system of drugs, etc. and to maintain order in distribution: *<Amended by Act No. 13655, Dec. 29, 2015>*
1. A person who has obtained permission by item of drugs, an importer, or a drug wholesaler (hereinafter referred to as "drug provider") shall not engage in the following activities:
 - (a) Retailing Drugs;
 - (b) Distributing drugs to persons other than pharmacy founders; distributors of safe and readily available drugs; herb druggists; druggists or drug sellers referred to in Article 5 of the Addenda to the Pharmaceutical Affairs (Act No. 8365) (hereinafter referred to as "founder of pharmacy, etc."); other drug wholesalers; and other persons entitled to distribute drugs pursuant to this Act;
 2. Notwithstanding subparagraph 1, a drug provider may retail or distribute drugs where he or she falls under any ground prescribed by Presidential Decree, such as cases for public interests;
 3. A drug wholesaler or a founder of pharmacy, etc. shall comply with the following matters:
 - (a) A drug wholesaler or a founder of pharmacy, etc. shall not purchase drugs from a person other than a drug provider: *Provided*, That this shall not apply where he or she purchases drugs from the founder of pharmacy, etc. who closed his or her business or where a founder of pharmacy, etc. purchases drugs from other founders of pharmacy, etc. urgently since no drug prescribed by a physician or dentist exists in his or her pharmacy;
 - (b) A drug wholesaler shall store drugs in the warehouses meeting the requirements of Article 45 (2);
 4. A drug wholesaler, a founder of pharmacy, etc., and other persons entitled to distribute drugs pursuant to this Act shall comply with the following matters:
 - (a) Matters regarding distribution management on safety and quality of drugs, etc. prescribed by Ordinance of the Prime Minister, such as prohibition of the distribution of unsanitary or hazardous drugs, and compliance by drug wholesalers with the standards for quality management of drugs in distribution;
 - (b) Matters regarding distribution management and maintenance of order in distribution of drugs prescribed by Ordinance of the Ministry of Health and Welfare, such as prohibition of disturbing the market order, including cornering of the market; prohibition of enticing consumers by the name, etc. of a pharmacy; or prohibition of dispensing or distributing drugs in excess of the limits.
- (2) No drug provider (including the representative, directors, or other employees of a corporation, or the employees of a non-corporation; hereafter in this Article, the same shall apply) shall offer any money, articles, convenience, labor, entertainment, or other economic benefits (hereinafter referred to as "economic benefits, etc.") to pharmacists, oriental medicine pharmacists (including persons employed by the relevant pharmacy; hereafter in this Article, the same shall apply), medical personnel, medical institution founders (including the representative, directors, and other workers of a corporation; hereafter in this Article, the same shall apply), or persons employed by a medical institution for the purpose of sales promotion, such as adoption of drugs, inducement of prescription, and maintenance of transactions, nor have pharmacists, oriental medicine pharmacists, medical personnel, medical institution founders, or persons working for a medical institution provide economic benefits, etc. to the relevant pharmacy or medical institution: *Provided*, That the same shall not apply to the economic benefits, etc. within the extent prescribed by Ordinance of the Ministry of Health and Wealth, following consultation with the Minister of Food and Drug Safety, such as the provision of samples, support for symposiums, support for clinical trials, product presentation, discount in price and payment terms, and post-marketing survey (hereinafter referred

to as "provision of samples, etc."). <Newly Inserted by Act No. 10324, May 27, 2010; Act No. 11690, Mar. 23, 2013; Act No. 13655, Dec. 29, 2015; Act No. 13598, Dec. 22, 2015>

- (3) No pharmacist or oriental medicine pharmacist shall receive any economic benefits, etc. provided by a drug provider for sales promotion, such as adoption of drugs, inducement of prescription, and maintenance of transactions, nor assist the relevant pharmacy, etc. to acquire such economic benefits, etc.: *Provided*, That the same shall not apply to the economic benefits, etc. within the extent prescribed by Ordinance of the Ministry of Health and Welfare, following consultation with the Minister of Food and Drug Safety, such as provision of samples, etc. <Newly Inserted by Act No. 10324, May 27, 2010; Act No. 11690, Mar. 23, 2013; Act No. 13655, Dec. 29, 2015; Act No. 13598, Dec. 22, 2015>
- (4) No drug wholesaler shall distributes drugs, directly or through another drug wholesaler, to the medical institution or pharmacy with which he or she has any of the following affiliations: *Provided*, That the same shall not apply to herbal drugs: <Newly Inserted by Act No. 10788, Jun. 7, 2011>
1. Where a person who has any of the following affiliations with a drug wholesaler (hereinafter referred to as "affiliated person") is a medical institution founder or a pharmacy founder, the relevant medical institution or pharmacy:
 - (a) If a drug wholesaler is an individual, his or her relatives within the second degree of consanguinity or affinity (referring to relatives defined in Article 767 of the Civil Act; hereinafter the same shall apply);
 - (b) If a drug wholesaler is a corporation, an executive officer of the relevant corporation, and his or her relatives within the second degree of consanguinity or affinity;
 - (c) If a drug wholesaler is a corporation, a person who *de facto* controls the relevant corporation (referring to a person who has contributed or owns the share exceeding 50/100 of the total amount of contributions, the total issued stock, or the total contributed shares of the relevant corporation, and a person who exercises a dominant influence over an organization of executive officers or business operation, etc.; hereinafter the same shall apply);
 - (d) If an affiliated person referred to in item (c) is a corporation, an executive officer of the relevant corporation or a person who *de facto* controls the relevant corporation;
 - (e) If an affiliated person referred to in item (c) or (d) is an individual, his or her relatives within the second degree of consanguinity or affinity;
 - (f) A corporation which *de facto* controls drug wholesalers;
 - (g) A corporation *de facto* controlled by an affiliated person under this subparagraph;
 - (h) An employee of a drug wholesaler or of an affiliated person under this subparagraph (referring to an executive officer in cases of a corporation, and commercial employees and employees by an employment contract in cases of individuals; hereafter in this Article, the same shall apply);
 2. Where a person who has any of the following affiliations with a medical institution founder or a pharmacy founder is a drug wholesaler, the relevant medical institution or pharmacy:
 - (a) If a medical institution founder or a pharmacy founder is an individual, his or her relatives within the second degree of consanguinity or affinity;
 - (b) If a medical institution founder is a corporation, an executive officer of the relevant corporation, and his or her relatives within the second degree of consanguinity or affinity;
 - (c) If a medical institution founder is a corporation, a person who *de facto* controls the relevant corporation;
 - (d) If an affiliated person under item (c) is a corporation, an executive officer of the relevant corporation, and a person who *de facto* controls the relevant corporation;
 - (e) If an affiliated person under item (c) or (d) is an individual, his or her relatives within the second degree of consanguinity or affinity;
 - (f) A corporation which *de facto* controls a corporate medical institution;

- (g) A corporation *de facto* controlled by an affiliated person under this subparagraph;
 - (h) Employees of a medical institution founder, a pharmacy founder, or an affiliated person under this subparagraph.
- (5) Where a pharmacy founder or medical institution founder is to pay the purchase price of drugs to a drug provider, the payment shall be made within six months from the date of receiving the relevant drugs: *Provided*, That the same shall not apply to cases prescribed by Ordinance of the Ministry of Health and Welfare in consideration of the scale of the drug transactions, etc. where a pharmacy founder or medical institution founder is not deemed to have a superior bargaining position against a drug provider. <Newly Inserted by Act No. 13598, Dec. 22, 2015>
- (6) Where a pharmacy founder or medical institution founder pays the purchase price of drugs to a drug provider after the period specified in paragraph (5), the interest shall be paid for the overdue period at an interest rate prescribed by the Minister of Health and Welfare within the limit of 20/100 per annum in consideration of economic situations, such as overdue interest rates applied by banks referred to in the Banking Act. <Newly Inserted by Act No. 13598, Dec. 22, 2015>
- (7) Where the purchase price of drugs referred to in paragraph (5) is paid with a bill or by a means of payment in place of a bill prescribed in the Fair Transactions in Subcontracting Act, Article 13 of that Act shall apply *mutatis mutandis*. In such cases, “prime contractor” shall be construed as “pharmacy founder or medical institution founder”, “subcontractor” as “drug provider”, “subcontract consideration” as “purchase price of drugs”, “60 days” as “six months”, “40/100” as “20/100”, and the “Fair Trade Commission” as the “Ministry of Health and Welfare”. <Newly Inserted by Act No. 13598, Dec. 22, 2015>

Article 47-2 (Submission of Expense Report on Details of Providing Economic Benefits)

- (1) A drug provider shall prepare an expense report on economic benefits, etc. which he or she provided to pharmacists, oriental medicine pharmacists, medical personnel, medical institution founders, or persons working for a medical institution, within three months after the termination of each fiscal year, as prescribed by Ordinance of the Ministry of Health and Wealth, and shall retain the relevant expense report, books related thereto, and evidentiary data for five years.
- (2) Where deemed necessary, the Minister of Health and Wealth may request the submission of the expense report, books related thereto, and evidentiary data under paragraph (1). In such cases, a drug provider shall comply therewith unless there is good cause.

[This Article Newly Inserted by Act No. 14328, Dec. 2, 2016]

Article 47-3 (Designation and Operation of Korea Pharmaceutical Information Service)

- (1) The Minister of Health and Welfare may designate a relevant specialized institution or organization as an institution for information management of distribution of drugs (hereinafter referred to as the "Korea Pharmaceutical Information Service"), as prescribed by Presidential Decree, for collection, investigation, processing, utilization, and provision of drug distribution information, such as manufacturing, import, supply, and details of use of drugs and require it to perform such affairs. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>
- (2) Where a person who has obtained permission by item of drugs, an importer, or a drug wholesaler has supplied medical institutions, pharmacies, and drug wholesalers with drugs, he or she shall submit the details of such supply to the Korea Pharmaceutical Information Service, as prescribed by Ordinance of the Ministry of Health and Welfare: *Provided*, That the submission of details of supply may be omitted when he or she has supplied drugs in a manner that details of supply can be verified, as prescribed by Ordinance of the Ministry of Health and Welfare.
- (3) The Korea Pharmaceutical Information Service may request the State, local governments, other public organizations, etc. to provide necessary data for efficient management of drug distribution information, and the State, local governments, other public organizations, etc. upon receipt of such

request shall comply with such request, unless there is a compelling reason not to do so. In such cases, such data provided to the Korea Pharmaceutical Information Service shall be utilized free of royalties, fees, etc.

- (4) The Minister of Health and Welfare and the Minister of Food and Drug Safety may order the president of the Korea Pharmaceutical Information Service to report the current status of distribution and management of drugs. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>
- (5) The Minister of Health and Welfare may fully or partially subsidize expenses incurred in operation of the Korea Pharmaceutical information Service. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>
- (6) Matters necessary for operation, etc. of the Korea Pharmaceutical Information Service shall be prescribed by Presidential Decree.

[This Article Newly Inserted by Act No. 8643, Oct. 17, 2007]

Article 48 (Prohibition of Distribution of Unsealed Drugs)

No person shall remove the seal on a container or package of drugs affixed by a manufacturer of the drugs, etc., a person who has obtained permission by item of the drugs, etc., or an importer pursuant to Article 63 for the purpose of distribution of such drugs: *Provided*, That the same shall not apply to any of the following cases: <Amended by Act No. 8643, Oct. 17, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

1. Where a pharmacy founder dispenses and distributes drugs according to prescriptions made by a physician, dentist, or oriental medical doctor, or pursuant to the proviso of Article 23 (3), the proviso of paragraph (6) of that Article, or to Article 4 of the Addenda to the amended Pharmaceutical Affairs Act (Act No. 4731);
2. Where a pharmacy founder opens and distributes herbal medications;
3. Where a person designated by the Minister of Health and Welfare opens and distributes drugs within the scope prescribed by Ordinance of the Ministry of Health and Welfare.

Article 49 (Restrictions on Products for Distribution by Drug Sellers)

No drug seller shall distribute drugs, other than those designated separately by the Minister of Health and Welfare, nor store or display them for distribution. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

Article 50 (Distribution of Drugs)

- (1) No pharmacy founder or drug distributor shall distribute drugs at a place, other than his or her pharmacy or shop: *Provided*, That the same shall not apply where approval therefor is obtained from the head of a *Si/Gun/Gu*.
- (2) No pharmacy founder shall distribute any prescription drugs without prescriptions issued by a physician or dentist: *Provided*, That the same shall not apply where prescription drugs are distributed to any person who has opened a veterinary hospital under the Veterinarians Act, as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>
- (3) A pharmacy founder may distribute over-the-counter drugs without prescriptions issued by a physician or a dentist.
- (4) Where a pharmacy founder distributes over-the-counter drugs, he or she may provide medication counselling therefor, if deemed necessary.

CHAPTER V-2 Registration of Drug Patent and Prevention of Distribution

SECTION 1 Registration of Drug Patent

Article 50-2 (Registration of Drug Patent)

- (1) A person who has obtained permission by item referred to in Article 31 (2) and (3) or permission for modification referred to in paragraph (9) of the same Article (hereinafter referred to as “permission by item or permission for modification”) shall file an application for registration of a drug patent in the drug patent list (hereinafter referred to as “patent list”) in which the Minister of Food and Drug Safety registers and manages patents on drugs for which permission by item or permission for modification is granted (hereinafter referred to as “drug patent”).
- (2) A person who intends to file an application for registration of a drug patent in the patent list pursuant to paragraph (1) shall submit an application for registration, stating the following matters, to the Minister of Food and Drug Safety, along with a copy of the patent register, a written consent of a patentee or exclusive licensee under the Patent Act (hereinafter referred to as “patentee, etc.”), and other documents prescribed by Ordinance of the Prime Minister, within 30 days from the date permission by item or permission for modification is granted or from the date the grant of the patent is registered pursuant to Article 87 of the Patent Act:
 1. The name of a drug;
 2. Personal information of a registration applicant;
 3. Personal information of a patentee, etc. (where a patentee does not reside or have a business place within Korea, referring to the personal information of a representative of the patentee who resides or has a business place within Korea);
 4. Patent number;
 5. Expiration date of the term of a patent;
 6. Claim to be protected (hereinafter referred to as "claim");
 7. Other matters prescribed by Ordinance of the Prime Minister.
- (3) A person who has filed an application for registration of a drug patent pursuant to paragraph (1), may file an application for modification of the details of a registration application specified in paragraph (2) before the decision on such application is made: *Provided*, That in cases of adding claims, he or she shall file an application within the period for application referred to in paragraph (2).
- (4) Where a drug patent, for which registration has been applied pursuant to paragraph (1) or the modification of the registration application has been applied pursuant to paragraph (3), meets all of the following subject matters and requirements, the Minister of Food and Drug Safety shall register in the patent list the matters prescribed by Ordinance of the Prime Minister, such as the drug name, personal information of the patentee, etc., the patent registration number, and the term of the patent, and post them on the website for the public:
 1. The drug patent shall pertain to any of the following:
 - a. Substance;
 - b. Dosage form;
 - c. Composition;
 - d. Medical usage;
 2. The drug patent shall be directly related to matters for which permission by item or permission for modification of the relevant drug is granted;
 3. An application for the drug patent shall be filed pursuant to Article 42 of the Patent Act before the date permission by item or permission for modification of the relevant drug is granted;
 4. The drug patent shall not have expired by the expiration of the term of the patent, invalidation, relinquishment, etc.;
 5. Permission by item or permission for modification of the relevant drug shall be effective.

- (5) Where it is necessary to examine whether to meet the subject matters and requirements referred to in the subparagraphs of paragraph (4), the Minister of Food and Drug Safety may order a person filing an application for registration of a drug patent to submit additional data.
- (6) Matters necessary for procedures, methods, etc. for filing applications for registration of drug patents pursuant to paragraph (1) or applications for modification of the details of registration applications pursuant to paragraph (3) shall be prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted by Act No. 13219, Mar. 13, 2015]

Article 50-3 (Modification of Registered Information)

- (1) A person who has a drug patent registered in the patent list after filing an application for registration of the drug patent pursuant to Article 50-2 (1) (hereinafter referred to as “registered patentee”) may file an application for modification or deletion of the patent information registered in the patent list pursuant to Article 50-2 (4) (hereinafter referred to as “registered information”) with the Minister of Food and Drug Safety.
- (2) An application for modification of the expiration date of the term of a patent registered in the patent list (hereinafter referred to as “registered patent”) among the registered information shall be filed within 30 days from the date of such modification: *Provided*, That the Minister of Food and Drug Safety may grant a further period of up to 30 days for the modification upon application of the registered patentee.
- (3) The Minister of Food and Drug Safety may modify or delete the registered information, where he or she checks the details of an application filed under paragraph (1) and such details are deemed appropriate. In such cases, the Minister of Food and Drug Safety shall in advance seek the opinions of interested parties, such as a patentee of a drug (hereinafter referred to as “patentee, etc. of a listed drug”), the drug patent of which is registered in the patent list (hereinafter referred to as “listed drug”), or a person who has filed an application for permission by item or permission for modification of a drug, based on data about the safety and effectiveness of a listed drug.
- (4) In any of the following cases, the Minister of Food and Drug Safety may modify or delete, *ex officio*, the registered information. In such cases, the Minister of Food and Drug Safety shall seek the opinions of the registered patentee in advance:
 1. Where a patentee, etc. withdraws his or her consent;
 2. Where the subject matters and requirements referred to in Article 50-2 (4) cease to be met;
 3. Where a drug patent is registered by fraud or other improper means.
- (5) Where the Minister of Food and Drug Safety modifies or deletes the registered information pursuant to paragraphs (3) and (4), he or she shall post it on the website for the public.
- (6) Matters necessary for procedures, methods, etc. for filing applications for modification or deletion of the registered information pursuant to paragraph (1) shall be prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted by Act No. 13219, Mar. 13, 2015]

SECTION 2 Informing of Application for Permission by Item and Prohibition of Distribution

Article 50-4 (Informing of Application for Permission by Item)

- (1) A person who has filed an application for permission by item of a drug pursuant to Article 31 (2) or (3) based on the data on safety and effectiveness of a listed drug or a person who has filed an application for permission of modification of the efficacy and effectiveness pursuant to paragraph (9) of that Article shall inform the registered patentee and the patentee, etc. of a listed drug of the matters prescribed by Ordinance of the Prime Minister, such as the fact that the application for permission has been filed and the date of filing such application: *Provided*, That this shall not apply

to any of the following cases:

1. Where the term of a registered patent expires;
 2. Where an application for permission by item or permission for modification of a drug is filed to distribute the drug after the term of a registered patent expires;
 3. Where a registered patentee and a patentee, etc. of a listed drug consent to not giving information;
 4. Cases prescribed by Presidential Decree, corresponding to subparagraphs 1 through 3.
- (2) Notwithstanding the proviso of paragraph (1), if the causes referred to in paragraph 1 (2) through (4) cease to exist, information shall be given under the main clause of paragraph (1).
- (3) Information referred to in paragraph (1) or (2) shall be deemed to be given when the notice arrives at the domestic domicile of the patentee, etc. or his or her agent stated in the patent list.
- (4) Information referred to in paragraph (1) or (2) shall be given within 20 days from the date an application for permission by item or permission for modification is filed. If the notice is not given within such period, the date a person who has filed an application for permission by item or permission for modification informs a registered patentee or a patentee, etc. of a listed drug, whichever occurs later, shall be deemed the date of filing an application for permission by item or permission for modification.
- (5) A person who has given information pursuant to paragraph (1) or (2) shall without delay submit a document evidencing the fact of giving such information to the Minister of Food and Drug Safety. In such cases, the Minister of Food and Drug Safety shall post the matters prescribed by Ordinance of the Prime Minister, such as the date of filing an application for permission, main ingredients, and dosage form of the informed drug (hereinafter referred to as “informed drug”), on the website for the public.
- (6) Where information referred to in paragraph (1) or (2) is not given, the Minister of Food and Drug Safety shall not grant the relevant permission by item or permission for modification.
- (7) Matters necessary for the methods, procedures, etc. for giving information under paragraph (1) shall be prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted by Act No. 13219, Mar. 13, 2015]

Article 50-5 (Application for Prohibition of Distribution)

- (1) A patentee, etc. of a listed drug may file an application for the prohibition of distribution of an informed drug with the Minister of Food and Drug Safety by attaching a statement including the following, within 45 days from the date of receipt of information pursuant to Article 50-4:
1. An application for prohibition of distribution shall have been filed based on the patent registered lawfully;
 2. A petition for trial or litigation referred to in paragraph (2) shall have been filed in good faith; there shall be a prospect of winning a case; and the trial or litigation shall not be delayed unreasonably.
- (2) A patentee, etc. of a listed drug shall institute any of the following patent-related litigations or file or take a petition for any of the following patent-related trials regarding an informed drug before filing an application for prohibition of distribution:
1. A litigation to seek injunction against, or prevention of, infringement of patent rights pursuant to Article 126 of the Patent Act;
 2. A trial to confirm the scope of patent rights pursuant to Article 135 of the Patent Act.
- (3) Notwithstanding paragraph (1), an application for prohibition of distribution of the drug whose distribution has already been prohibited pursuant to Article 50-6 (1) shall not be additionally filed: *Provided*, That this shall not apply to an application for prohibition of distribution of an informed drug after an application for modification of the efficacy and effectiveness is filed pursuant to Article 31 (9).
- (4) The Minister of Food and Drug Safety shall not grant permission by item or permission for

modification of an informed drug until the period for filing an application for prohibition of distribution under paragraph (1) expires: *Provided*, That this shall not apply to any of the following cases:

1. Where there is a trial ruling under Article 162 of the Patent Act or a ruling under Article 189 of that Act that the drug for which prohibition of distribution was applied does not fall within the scope of the registered patent;
 2. Where there is a trial ruling under Article 162 of the Patent Act or a ruling under Article 189 of that Act that the registered patent is invalid;
 3. Where there is a decision under Article 43 of the Administrative Appeals Act and a ruling of a court against a litigation instituted under Article 3 of the Administrative Litigation Act that registration of a drug patent is illegal.
- (5) Where there is a trial ruling or ruling against the trial ruling, decision, or ruling referred to in each subparagraph of paragraph (4) after such trial ruling, decision, or ruling, the Minister of Food and Drug Safety shall not grant permission by item or permission for modification of the informed drug, notwithstanding the proviso of paragraph (4).
- (6) Matters necessary for the methods, procedures, etc. for filing applications for prohibition of distribution shall be prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted by Act No. 13219, Mar. 13, 2015]

Article 50-6 (Prohibition of Distribution)

- (1) Where the Minister of Food and Drug Safety upon receipt of an application for prohibition of distribution under Article 50-5 (1) grants permission by item or permission for modification of the drug for which the application for prohibition of distribution was filed, he or she shall prohibit the distribution of such drug for nine months from the date the patentee, etc. of a listed drug is informed pursuant to Article 50-4 (hereinafter referred to as “date of receipt of information”), except in any of the following cases:
1. Where an application is filed after the filing period referred to in Article 50-5 (1) expires;
 2. Where an application is filed, based on the patent which have expired by the expiration of the term of the patent, relinquishment, etc.;
 3. Where an application is filed without having instituted a litigation or having filed or taken a petition for trial pursuant to each subparagraph of Article 50-5 (2);
 4. Where a drug patent is registered by fraud or other improper means;
 5. Where at least two drugs are informed under Article 50-4 and an application for prohibition of distribution is filed only for some of the drugs, of which the following matters are same with those of the informed drugs (hereinafter referred to as “same drug”):
 - (a) Main ingredients and the content thereof;
 - (b) Dosage form;
 - (c) Dose regimen and dose;
 - (d) Efficacy and effectiveness;
 6. Where the same drug with the drug for which an application for prohibition of distribution is filed can be distributed after permission by item or permission for modification has already been granted, based on the data on the safety and effectiveness of the listed drug;
 7. Where a trial ruling, decision, or ruling falling under the subparagraphs of Article 50-5 (4) is made;
 8. Where a registered patent falls under Article 106 (1) or 106-2 (1) of the Patent Act or is subject to a petition for adjudication under Article 107 of that Act.
- (2) Where a trial ruling or ruling (including a ruling for retrial made under Article 178 of the Patent Act) to revoke or reverse the trial ruling, decision, or ruling referred to in paragraph (1) 7 is made before granting permission by item or permission for modification of the informed drug, the Minister of

Food and Drug Safety shall prohibit the distribution of such drug for nine months from the date of receipt of information, notwithstanding paragraph (1).

- (3) Prohibition of distribution referred to in paragraph (1) shall remain in effect by one of the following dates, whichever comes first:
1. The date a trial ruling or ruling is made that the drug for which an application for prohibition of distribution has been filed does not fall within the scope of rights of the registered patent;
 2. The date a ruling is made that the drug for which an application for prohibition of distribution has been filed does not infringe the registered patent;
 3. The date a trial ruling or ruling is made that the registered patent is invalid;
 4. The date a decision or ruling is made that the registration of the drug patent is illegal;
 5. The date any trial or litigation referred to in the subparagraphs of Article 50-5 (2) ended by the withdrawal or consent to withdrawal of a patentee, etc., reconciliation, rejection, etc.;
 6. The date the arbitration or mediation regarding any trial or litigation referred to in the subparagraphs of Article 50-5 (2) is completed;
 7. The date the period for permission by item or permission for modification of the listed drug expires;
 8. The expiration date of the term of the registered patent;
 9. The date a decision by the Fair Trade Commission or a trial ruling by a court is made that the patentee, etc. of a listed drug has violated Article 3-2 (1), 19 (1), or 23 (1) of the Monopoly Regulation and Fair Trade Act in connection with prohibition of distribution or permission for preferential distribution of items referred to in Article 50-7;
 10. The date it is found that an application for prohibition of distribution has been filed by fraud or other improper means.
- (4) Matters necessary for prohibition of distribution, procedure of extinction, etc. under paragraphs (1) through (3) shall be prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted by Act No. 13219, Mar. 13, 2015]

SECTION 3 Permission for Preferential Distribution of Items

Article 50-7 (Application for Permission for Preferential Distribution of Items)

- (1) Where a person who shall give information pursuant to Article 50-4 files an application for permission by item or permission for modification of a drug, he or she may also file an application for permission to preferentially distribute drugs over the drugs meeting all of the following requirements (hereinafter referred to as “permission for preferential distribution of items”), with the Minister of Food and Drug Safety:
1. A drug shall be the same drug with the drug for which an application for permission for preferential distribution of items is filed;
 2. A drug shall be the drug, the effective ingredients of which are identical to those of the listed drug, among the drugs for which an application for permission by item or permission for modification has been filed based on the data on safety and effectiveness of the listed drug.
- (2) A person who intends to obtain permission for preferential distribution of items shall file a petition for any of the following trials before filing an application under paragraph (1):
1. A trial on invalidity of a patent pursuant to Article 133 of the Patent Act;
 2. A trial to invalidate registration for extension of a patent pursuant to Article 134 of the Patent Act;
 3. A trial to confirm the scope of rights pursuant to Article 135 of the Patent Act.
- (3) A person who files a petition for a trial under the subparagraphs of paragraph (2) shall without delay inform the Minister of Food and Drug Safety of the matters prescribed by Ordinance of the Prime Minister, such as the patent trial number. The Minister of Food and Drug Safety may post the matters informed on the website for the public.

(4) A person who intends to obtain permission for preferential distribution of items shall submit an application for permission for preferential distribution of items, stating the following matters, to the Minister of Food and Drug Safety, along with the documents prescribed by Ordinance of the Prime Minister, such as a petition for trial referred to in the subparagraphs of paragraph (2):

1. Personal information of an applicant;
2. Patent registration number;
3. Patent trial number;
4. The date of filing a petition for trial;
5. Other matters prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted by Act No. 13219, Mar. 13, 2015]

Article 50-8 (Permission for Preferential Distribution of Items)

(1) Upon receipt of an application for permission for preferential distribution of items pursuant to Article 50-7, the Minister of Food and Drug Safety shall grant permission for preferential distribution of items together with permission by item or permission for modification of a drug, where the applicant meets all of the following requirements:

1. The applicant shall be the first applicant among those who have filed an application for permission by item or permission for modification of the drug required to be informed pursuant to Article 50-4 (where several persons have filed applications on the same day, the same priority shall be given to all of them);
2. The applicant shall file a petition for a trial under Article 50-7 (2) and then receive a trial ruling or ruling that the registered patent is invalid; the registration for extension of the registered patent is invalid; or the relevant drug does not fall in the scope of rights in the patent: *Provided*, That a person who received a trial ruling or ruling after nine months have passed from the date of receipt of information shall be excluded therefrom;
3. The applicant shall meet any of the following requirements and receive a trial ruling or ruling pursuant to subparagraph (2):
 - a. The applicant shall be the first one who files a petition for trial under the subparagraphs of Article 50-7 (2) (hereafter in this subparagraph, referred to as “first trial”);
 - b. The applicant shall file a petition for trial within 14 days from the date of filing the first trial;
 - c. The applicant shall receive a trial ruling or ruling under subparagraph 2, prior to a person who meets the requirements under item (a) or (b).

(2) Where the Minister of Food and Drug Safety grants permission for preferential distribution of items pursuant to paragraph (1), he or she shall post the matters prescribed by Ordinance of the Prime Minister, such as the main ingredients or dosage form of the drug for which permission for preferential distribution of items is granted, or the date of permission, on the website for the public.

[This Article Newly Inserted by Act No. 13219, Mar. 13, 2015]

Article 50-9 (Prohibition of Distribution of Same Drugs)

(1) Where the Minister of Food and Drug Safety grants permission for preferential distribution of items pursuant to Article 50-8 (1), he or she may prohibit the distribution of the drugs meeting all of the following requirements during the period referred to in paragraph (2) when granting permission by item or permission for modification of such drugs:

1. A drug shall be the same drug with the drug for which permission for preferential distribution of items is granted;
2. A drug shall be the drug, the effective ingredients of which are identical to those of the listed drug, among the drugs for which an application for permission by item or permission for modification has been filed, based on the data on safety and effectiveness of the listed drug.

(2) The period of prohibition of distribution under paragraph (1) shall be nine months from the date a

person who has obtained first permission for preferential distribution of items of a drug may distribute the drug: *Provided*, That in cases of a drug for which an application for health care benefits has been filed pursuant to Article 41 (1) 2 of the National Health Insurance Act, the period may be extended by up to two months.

- (3) Matters necessary for the methods, procedures, etc. for prohibition of distribution referred to in paragraphs (1) and (2) shall be prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted by Act No. 13219, Mar. 13, 2015]

Article 50-10 (Extinction of Effect of Prohibition of Distribution of Same Drug)

- (1) Prohibition of distribution referred to in Article 50-9 (1) shall cease to be effective on any of the following dates, whichever comes earlier:

1. The date permission by item or permission for modification of a drug for which permission for preferential distribution of items is granted ceases to be effective;
2. The date a registered patent ceases to be effective due to the expiration of the registered patent or the finalization, etc. of a trial ruling or ruling that the registered patent is invalid (excluding the petition for a trial or litigation filed by the person who has obtained permission for preferential distribution of items).

- (2) The Minister of Food and Drug Safety shall terminate the effect of prohibition of distribution under Article 50-9 (1) in any of the following cases. In such cases, the Minister of Food and Drug Safety shall hear in advance the opinions of the person who has obtained permission for preferential distribution of items:

1. Where a ruling to revoke or reverse a trial ruling or ruling referred to in Article 50-8 (1) 2 is made (including a ruling for retrial referred to in Article 178 of the Patent Act);
2. Where a person fails to distribute the drug for which permission for preferential distribution of items is granted, within two months from the date such drug may be distributed, without good cause;
3. Where a decision by the Fair Trade Commission or a trial ruling by a court is made that a person who has obtained permission for preferential distribution of items violates Articles 3-2 (1), 19 (1), or 23 (1) of the Monopoly Regulation and Fair Trade Act in connection with prohibition of distribution or permission for preferential distribution of items;
4. Where a person has obtained permission for preferential distribution of items by fraud or other improper means.

- (3) A person who has filed an application for permission by item or permission for modification of the same drug with those for which permission for preferential distribution of items is granted, or any other interested party may provide the information that permission for preferential distribution of items falls under paragraph (1) or (2) to the Minister of Food and Drug Safety.

- (4) Matters necessary for the extinction of the effect of prohibition of distribution and the methods, procedures, etc. for providing information by the interested parties pursuant to paragraphs (1) through (3) shall be prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted by Act No. 13219, 3Mar. 13, 2015]

SECTION 4 Impact Assessment

Article 50-11 (Impact Assessment)

- (1) The Minister of Food and Drug Safety shall analyze and assess the impact of the matters prescribed in this Chapter, such as prohibition of distribution and permission for preferential distribution of items under Article 50-6, on the domestic pharmaceutical industry, health policies, fluctuations of employment, etc.
- (2) Where deemed necessary for the impact assessment referred to in paragraph (1), the Minister of

Food and Drug Safety may request the relevant administrative agencies, education and research institutions, etc. to provide necessary data. In such cases, the heads of the relevant administrative agencies, education and research institutions, etc. upon receipt of the request for the provision of data shall comply therewith, unless there is good cause.

- (3) Where the impact assessment is conducted pursuant to paragraph (1), overseas cases shall be analyzed.
- (4) The Minister of Food and Drug Safety shall disclose the result of the impact assessment conducted under paragraph (1) and report it to the National Assembly.
- (5) Matters necessary for the standards, methods, procedures, etc. for the impact assessment referred to in paragraphs (1) through (4) shall be prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted by Act No. 13219, Mar. 13, 2015]

Article 50-12 (Management of Listed Drugs)

- (1) The Minister of Food and Drug Safety shall implement the following business regarding drug patents:
 1. Collecting information on market trends and prices of listed drugs;
 2. Supporting small and medium enterprises to conduct affairs regarding registration in the patent list, permission for preferential distribution of items, etc.;
 3. Providing education to pharmaceutical companies to enhance their competency related to drug patents;
 4. Analyzing and providing patent information on listed drugs;
 5. Researching overseas cases and policies regarding the matters prescribed in this Chapter, and producing and analyzing statistics thereof;
 6. Other business deemed necessary by the Minister of Food and Drug Safety.
- (2) The Minister of Food and Drug Safety may entrust the implementation of the business referred to in paragraph (1) to other institutions.
- (3) Where deemed necessary to implement the business referred to in paragraph (1), the Minister of Food and Drug Safety may request any of the following institutions to provide data regarding drug patents, etc., and the institutions upon receipt of such request shall comply therewith, unless there is good cause:
 1. The State or local governments;
 2. Public institutions or public organizations.

[This Article Newly Inserted by Act No. 13219, Mar. 13, 2015]

CHAPTER VI Handling of Drugs

SECTION 1 Standards and Verification

Article 51 (The Korean Pharmacopoeia)

- (1) In order to ensure the appropriateness in the nature, state, quality, and storing method of drugs, etc. and similar matters, the Minister of Food and Drug Safety shall enact and publicly announce the Korean Pharmacopoeia following deliberation by the Central Pharmaceutical Affairs Advisory Committee. *<Amended by Act No. 10788, Jun. 7, 2011; Act No. 11690, Mar. 23, 2013>*
- (2) The Korean Pharmacopoeia shall consist of Parts I and II: Drug substances that are frequently used and the primary medications shall be mainly listed in Part I, and the mixed medications of drugs and the drugs, etc. not listed in Part I shall be mainly listed in Part II. *<Amended by Act No. 10788, Jun. 7, 2011>*

Article 52 (Standards for Drugs)

- (1) With regard to biological medications and drugs which are not listed in the Korean Pharmacopoeia, the Minister of Food and Drug Safety may determine the nature, state, quality and storing methods, and other necessary standards after hearing the opinion of the Central Pharmaceutical Affairs Advisory Committee. <Amended by Act No. 10788, Jun. 7, 2011; Act No. 11690, Mar. 23, 2013>
- (2) Where deemed necessary to prevent any risk to health and hygiene, the Minister of Food and Drug Safety may determine the manufacturing method, properties, performance, quality, and storing method of quasi-drugs and other necessary standards therefor after hearing the opinion of the Central Pharmaceutical Affairs Advisory Committee. <Amended by Act No. 11690, Mar. 23, 2013>

Article 52-2 (Fact-Finding Surveys and Research on Safe Use of Drugs by Specific Groups)

- (1) The Minister of Health and Welfare and the Minister of Food and Drug Safety may conduct a fact-finding survey on safe use of drugs by a group prescribed by Ordinance of the Prime Minister, which requires special attention, such as seniors, children, or pregnant women (hereinafter referred to as “specific group”), as prescribed by Ordinance of the Ministry of Health and Welfare.
- (2) For the survey referred to in paragraph (1), the Minister of Food and Drug Safety may instruct the manufacturers of the relevant drugs or the persons who have obtained permission by item of the relevant drugs to investigate and research the impact of such drugs on the relevant specific group. In such cases, the manufacturers or persons who have obtained permission by item, upon receipt of such instruction, shall comply therewith.

[This Article Newly Inserted by Act No. 13655, Dec. 29, 2015]

Article 53 (Drugs under National Lot Release)

- (1) A person who intends to distribute or to display, keep, or store, for distribution, the drugs prescribed by Ordinance of the Prime Minister, among the following drugs, shall obtain lot release approval from the Minister of Food and Drug Safety after undergoing the examination, verification, etc. of the data on manufacturing and quality management of the drugs: <Amended by Act No. 11690, Mar. 23, 2013>
 1. Biological medications;
 2. Drugs liable to be altered or spoiled in quality;
 3. Deleted. <by Act No. 15891, Dec. 11, 2018>
- (2) Matters necessary for the procedures and methods for lot release approval under paragraph (1) and other necessary matters shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013>

[This Article Wholly Amended by Act No. 10788, Jun. 7, 2011]

Article 54 (Radiopharmaceuticals)

The Minister of Food and Drug Safety may determine matters necessary for manufacturing, import, etc. of radiopharmaceuticals after consultation with the Minister of Science and ICT. <Amended by Act No. 10788, Jun. 7, 2011; Act No. 11690, Mar. 23, 2013; Act No. 14839, Jul. 26, 2017>

Article 55 (Addictive and Habit-Forming Drugs)

Matters necessary for the manufacturing, management, etc. of drugs that might affect the human body and thus lead to addiction or habit-forming, shall be separately prescribed by statutes.

SECTION 2 Handling of Drugs**Article 56 (Labeling on Drug Containers)**

- (1) A person who has obtained permission by item of drugs and an importer shall indicate the following

information on the containers or packages of drugs: *Provided*, That in cases of the containers or packages prescribed by Ordinance of the Prime Minister, part of the following information may be omitted or only part of the following information may be indicated, as prescribed by Ordinance of the Prime Minister: <Amended by Act No. 11421, May 14, 2012; Act No. 11690, Mar. 23, 2013; Act No. 14328, Dec. 2, 2016>

1. The trade name and address of a person who has obtained permission by item of drugs or an importer (in cases of contract manufacturing, including the trade name and address of a factory);
 2. The product name;
 3. The manufacturing number and the user-by date or expiration date;
 4. The weight, capacity, or number of articles;
 5. Labeling on containers or packages prescribed by the Korean Pharmacopoeia;
 6. As for drugs, the standards for which are determined under Article 52 (1), the storing methods and other labeling on the containers or packages of such drugs in accordance with such standards;
 7. The name of all ingredients, quantity of active ingredients (if active ingredients are not clear, referring to the essence thereof and outline of manufacturing methods), and quantity of preservatives stated in the certificate of permission by item and certificate of notification by item: *Provided*, That ingredients prescribed by Ordinance of the Prime Minister, such as ingredients included in small quantity except preservatives, may be excluded;
 8. The letter "prescription drug" or "over-the-counter drug" [in cases of safe and readily available drugs, letters of "over-the-counter (safe and readily available) drugs"];
 9. Information provided for in subparagraphs 1 through 3 of Article 58;
 10. Other information prescribed by Ordinance of the Prime Minister.
- (2) A person who distributes drugs directly to consumers, such as a pharmacy founder, shall indicate the prices of drugs on the containers or packages of such drugs, as prescribed by the Minister of Health and Welfare.

[This Article Wholly Amended by Act No. 10788, Jun. 7, 2011]

Article 57 (Labeling on Outside Packages)

If information listed in the subparagraphs of Article 56 (1) and paragraph (2) of that Article, which has been indicated on the immediate containers or packages of drugs, is not visible because it is obstructed by the outside containers or packages, the same information shall be also indicated on the outside containers or packages. <Amended by Act No. 10788, Jun. 7, 2011>

Article 58 (Labeling on Package Inserts)

The following information shall be indicated in package inserts for drugs: <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10788, Jun. 7, 2011; Act No. 11690, Mar. 23, 2013>

1. Dose regimen, dose, and other precautions necessary for use or handling;
2. As for drugs listed in the Korean Pharmacopoeia, labeling on the package inserts, containers, or packages of drugs prescribed by the Korean Pharmacopoeia;
3. As for drugs, the standards for which are determined under Article 52 (1), labeling on the package inserts, containers, or packages of drugs in accordance with such standards;
4. Other information prescribed by Ordinance of the Prime Minister.

Article 59 (Precautions in Indications)

Information provided for in Articles 56 through 58 shall be indicated on places which are more easily seen than other letters, news articles, pictures, or designs, and such information shall be indicated precisely in easy and understandable terms, as prescribed by Ordinance of the Prime Minister. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>

Article 60 (Information Prohibited from Labeling)

None of the following information shall be indicated in package inserts for drugs or labels of containers or packages of drugs: <Amended by Act No. 8643, Oct. 17, 2007; Act No. 15891, Dec. 11, 2018>

1. False or misleading information with regard to the relevant drug;
2. Efficacy or effectiveness for which permission or permission for modification has not been obtained or a notification or a notification of modification has not been filed under Article 31 (2), (3) or (9) or 41 (1);
3. Dose regimen, dose, or period of use which is dangerous to health and hygiene.

Article 61 (Prohibition of Distribution)

(1) No one shall distribute, or store or display the following drugs for distribution: <Amended by Act No. 8643, Oct. 17, 2007; Act No. 10788, Jun. 7, 2011; Act No. 15891, Dec. 11, 2018>

1. Drugs in violation of Articles 56 through 60 or fake drugs;
 2. Drugs manufactured or imported in violation of Articles 31 (1) through (3) and (9), 41 (1), 42 (1) and (3), and 43 (1).
- (2) No one shall indicate information that leads to misunderstandings about medical efficacy, effectiveness, etc. in containers, packages, or package inserts for articles, other than drugs, shall advertise such information, or shall distribute, or store or display for distribution, articles in which such information is indicated or advertised.

Article 61-2 (Prohibition against Arranging and Advertising Illegal Distribution of Drugs)

(1) No one shall arrange or advertise the distribution of drugs in violation of Article 44 or 50 (1) and (2) and shall arrange or advertise the distribution of drugs referred to in the subparagraphs of Article 61 (1) or products carrying misleading indication or advertisement prescribed in paragraph (2) of that Article.

(2) Where it is necessary to investigate the distribution of drugs using the information and communications network under Article 2 (1) 1 of the Act on Promotion of Information and Communications Network Utilization and Information Protection, Etc. (hereafter in this Article, referred to as “information and communications network”) or any violation of paragraph (1), the Minister of Food and Drug Safety may request submission of the necessary data from providers of information and communications services defined in Article 2 (1) 3 of the Act on Promotion of Information and Communications Network Utilization and Information Protection, Etc. or mail order brokers referred to in Article 20 of the Act on the Consumer Protection in Electronic Commerce, Etc. (hereafter in this Article referred to as “information and communications service providers, etc.”). In such cases, information and communications service providers, etc. upon receipt of a request for submission of data shall comply with such request, unless there is good cause.

(3) Upon discovering the distribution of drugs using the information and communications network or any violation of paragraph (1), information and communications service providers, etc. shall immediately inform the Minister of Food and Drug Safety of such fact.

(4) Matters necessary for the scope of and procedures for a request for data submission referred to in paragraph (2), the methods for informing referred to in paragraph (3), etc. shall be prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted by Act No. 15891, Dec. 11, 2018]

Article 62 (Prohibition of Manufacturing)

No one shall distribute any of the following drugs nor shall manufacture, import, store, or display them for the purpose of distribution: <Amended by Act No. 8643, Oct. 17, 2007; Act No. 10788, Jun. 7, 2011; Act No. 11690, Mar. 23, 2013; Act No. 15891, Dec. 11, 2018>

1. Drugs listed in the Korean Pharmacopoeia, whose properties, performance, or quality does not meet

- the standards specified in the Korean Pharmacopoeia;
2. Drugs for which permission or permission for modification has been obtained or a notification or a notification of modification has been filed under Articles 31 (2), (3), or (9) or 41 (1), but whose ingredients or quantities (if active ingredients are unclear, the essence thereof or the outline of manufacturing methods) are different from the contents for which permission or permission for modification has been obtained or a notification or a notification of modification has been filed;
 3. Drugs the standards for which are determined under Article 52 (1), but which do not meet such standards;
 4. Drugs, all or part of which are made from unclean, or degenerated or spoiled materials;
 5. Drugs which are tainted or deemed to have been tainted by germs that may cause a disease;
 6. Drugs to which alien substances are mixed or adhered;
 7. Drugs in which tar pigment other than that determined by the Minister of Food and Drug Safety is used;
 8. Drugs which are manufactured under unsanitary circumstances that may cause any risk to health and hygiene, or which are manufactured at a place where the manufacturing facilities fail to meet the standards prescribed by Presidential Decree;
 9. Drugs which are likely to cause any risk to health and hygiene, due to unsanitary containers or packages;
 10. Drugs whose containers or packages may lead users to misunderstand the method of using them;
 11. Drugs falling under Article 76 (1) 4.

Article 63 (Sealing)

If a manufacturer of drugs, a person who has obtained permission by item, or an importer distributes drugs manufactured or imported by oneself, he or she shall seal the containers or packages of such drugs, as prescribed by Ordinance of the Prime Minister: *Provided*, That this shall not apply where he or she distributes them to a drug manufacturer, or a person who has obtained permission by item. <Amended by Act No. 8643, Oct. 17, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>

Article 64 (Safety Containers or Packages)

- (1) Where a person who has obtained permission by item of drugs or an importer distributes drugs manufactured or imported by oneself, he or she shall use safety containers or packages in order to prevent the accidents of drugs by children due to misuses: *Provided*, That the same shall not apply where the drugs are distributed to drug manufacturers or persons who have obtained permission by item. <Amended by Act No. 8643, Oct. 17, 2007>
- (2) The scope of items for which safety containers or packages shall be used and the standards, etc. for safety containers or packages shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>

SECTION 3 Quasi-Drugs

Article 65 (Labeling on Containers of Quasi-Drugs)

- (1) A manufacturer or importer of quasi-drugs shall indicate the following information on the containers or packages of quasi-drugs: *Provided*, That part of the following matters may not be stated or only part of the following matters may be indicated, as prescribed by Ordinance of the Prime Minister: <Amended by Act No. 11690, Mar. 23, 2013; Act No. 14328, Dec. 2, 2016; Act No. 14926, Oct. 24, 2017>
 1. Names of quasi-drugs;
 2. The trade name and address of a manufacturer or importer;

3. Capacity or weight (capacity, weight, or number, in cases of products under subparagraph 7 (a) of Article 2);
 4. The manufacturing number and the expiration date;
 5. The name of all ingredients stated in the certificate of permission by item and certificate of notification by item: *Provided*, That ingredients prescribed by Ordinance of the Prime Minister, such as ingredients included in small quantity except preservatives, may be excluded;
 6. For products, the standards for which are determined under Article 52 (2), the storing methods and other labeling on containers or packages in accordance with such standards;
 7. The letter "quasi-drug";
 8. Other information prescribed by Ordinance of the Prime Minister.
- (2) A person who distributes quasi-drugs directly to consumers, such as a pharmacy founder, shall indicate the prices of quasi-drugs on the containers or packages, as prescribed by the Minister of Health and Welfare.

[*This Article Wholly Amended by Act No. 10788, Jun. 7, 2011*]

Article 65-2 (Labeling on Outside Packages)

Where the information referred to in the subparagraphs of Article 65 (1) and paragraph (2) of that Article, which has been indicated on the immediate containers or packages of quasi-drugs, is not visible on the outside containers or packages, the same information shall be also indicated on such outside containers or packages.

[*This Article Newly Inserted by Act No. 14926, Oct. 24, 2017*]

Article 65-3 (Labeling on Package Inserts)

Where there are package inserts for quasi-drugs, the following information shall be indicated thereon:

1. Dose regimen, dose, and other precautions for use or handling;
2. For quasi-drugs listed in the Korean Pharmacopoeia, labeling on the package inserts, containers, or packages of quasi-drugs prescribed by the Korean Pharmacopoeia;
3. For quasi-drugs, the standards for which are determined under Article 52 (2), labeling on the package inserts, containers, or packages of quasi-drugs in accordance with such standards;
4. Other information prescribed by Ordinance of the Prime Minister, which are necessary to ensure the safe use of quasi-drugs.

[*This Article Newly Inserted by Act No. 14926, Oct. 24, 2017*]

Article 65-4 (Precautions in Indications)

Information provided for in Articles 65, 65-2, and 65-3 shall be indicated on places which are readily visible compared to other letters, articles, pictures, or designs, and such information shall be indicated precisely in easy and understandable terms, as prescribed by Ordinance of the Prime Minister.

<Amended by Act No. 11690, Mar. 23, 2013; Act No. 14926, Oct. 24, 2017>

[*This Article Newly Inserted by Act No. 11251, Feb. 1, 2012*]

Article 66 (Application Mutatis Mutandis)

@Articles 60, 61, 62 and 63 (Articles 60, 61, and 62, in cases of products falling under subparagraph 7 (a) of Article 2 among quasi-drugs) shall apply *mutatis mutandis* to quasi-drugs. In such cases, "drugs" shall be construed as "quasi-drugs"; "Article 31 (1) through (3) and (9)" as "Article 31 (4) and (9)"; "Article 31 (2), (3) and (9)" respectively as "Article 31 (4) and (9)"; "Article 52 (1)" as "Article 52 (2)"; and "Articles 56 through 60" as "Articles 65 and 65-2 through 65-4, and Article 60 which is applied *mutatis mutandis* pursuant to Article 66". <Amended by Act No. 11251, Feb. 1, 2012; Act No. 14926, Oct. 24, 2017; Act No. 15891, Dec. 11, 2018>

SECTION 4 Pharmaceutical Organizations

Article 67 (Organization)

Manufacturers of drugs, etc., persons who have obtained permission by items, importers, or drug distributors may incorporate an association, respectively, in order to ensure independent activities and common interests and to contribute to the improvement of the national public health. <Amended by Act No. 8643, Oct. 17, 2007>

SECTION 5 Advertisement of Drugs

Article 68 (Prohibition of Exaggerated Advertisement)

- (1) Names, manufacturing methods, efficacy, or performance of drugs, etc. shall not be advertised falsely or unduly.
- (2) No news article shall be used for drugs to make people misunderstand that physicians, dentists, oriental medical doctors, veterinarians, or other persons guarantee the efficacy or performance of drugs, etc.
- (3) Drugs, etc. shall not be advertised by news articles, photographs, or designs that suggest efficacy or performance, or other suggestive methods.
- (4) Documents or designs which suggest induced abortion shall not be used with respect to drugs.
- (5) Names, manufacturing methods, efficacy, or performance of drugs, etc. shall not be advertised without obtaining permission or permission for modification or filing a notification or a notification of modification under Article 31 (2) through (4) and (9) or 42 (1). <Amended by Act No. 8643, Oct. 17, 2007; Act No. 15891, Dec. 11, 2018>
- (6) None of the following drugs shall be advertised: *Provided*, That the same shall not apply to cases prescribed by Ordinance of the Prime Minister, including advertising drugs for preventing infectious diseases defined in subparagraphs 2 through 12 of Article 2 of the Infectious Disease Control and Prevention Act and placing advertisements on professional medical media targeting professionals, etc. in medicine and pharmacy: <Newly Inserted by Act No. 14926, Oct. 24, 2017>
 1. Prescription drugs;
 2. Over-the-counter drugs with the same dosage form, administration route, and content of active ingredient per unit dosage form as prescription drugs;
 3. Drug substances.
- (7) The methods of advertisement of drugs, etc. and other necessary matters shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013; Act No. 14926, Oct. 24, 2017>

Article 68-2 (Deliberation on Advertisement)

- (1) Where a drug manufacturer, a person who has obtained permission by item, or an importer intends to advertise drugs manufactured or imported by oneself, he or she shall undergo deliberation by the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013>
- (2) The Minister of Food and Drug Safety may entrust an association incorporated pursuant to Article 67 with the affairs concerning deliberation on advertisement of drugs under paragraph (1). <Amended by Act No. 11690, Mar. 23, 2013>
- (3) Matters necessary for procedures and method for deliberation on advertisement under paragraph (1), raising of an objection against the results of deliberation, modification of the details of deliberation, indication of the results of deliberation, etc. shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 10788, Jun. 7, 2011; Act No. 11690, Mar. 23, 2013>

[This Article Newly Inserted by Act No. 8643, Oct. 17, 2007]

SECTION 6 The Korea Institute of Drug Safety and Risk Management

Article 68-3 (Establishment)

- (1) The Korea Institute of Drug Safety and Risk Management (hereinafter referred to as the "Institute of Drug Safety and Risk Management") shall be established to efficiently and systematically perform the duties of collecting, managing, analyzing, assessing, and providing a variety of information on drug safety, such as side effects of drugs, etc., information on permission by item, and information on notification by item (hereinafter referred to as "drug safety information").
- (2) The Institute of Drug Safety and Risk Management shall be a corporation.
- (3) The articles of association of the Institute of Drug Safety and Risk Management shall include the following matters: *<Newly Inserted by Act No. 15891, Dec. 11, 2018>*
 1. Purposes;
 2. The name;
 3. The location of the principal office;
 4. Matters concerning assets;
 5. Matters concerning the executive officers and employees;
 6. Operation of the board of directors;
 7. The scope, contents, and execution of business;
 8. Accounting;
 9. The methods of public announcement;
 10. Modification of the articles of association;
 11. Other important matters concerning the operation of the Institute of Drug Safety and Risk Management.
- (4) Where the Institute of Drug Safety and Risk Management intends to modify any matter stated in the articles of association, it shall obtain authorization therefor from the Minister of Food and Drug Safety. *<Newly Inserted by Act No. 15891, Dec. 11, 2018>*
- (5) Except as provided in this Act, the provisions concerning incorporated foundations under the Civil Act shall apply *mutatis mutandis* to the Institute of Drug Safety and Risk Management. *<Amended by Act No. 15891, Dec. 11, 2018>*
- (6) Other matters necessary for the organization, operation, etc. of the Institute of Drug Safety and Risk Management shall be prescribed by Presidential Decree. *<Amended by Act No. 15891, Dec. 11, 2018>*
[This Article Newly Inserted by Act No. 10788, Jun. 7, 2011]

Article 68-4 (Projects)

The Institute of Drug Safety and Risk Management shall conduct the following projects entrusted by the Minister of Food and Drug Safety pursuant to Article 84 or other statutes and regulations; projects for the relief of injury from side effects of drugs entrusted pursuant to Article 86 (5); and for-profit projects prescribed by Presidential Decree with regard to drug safety information: *<Amended by Act No. 11690, Mar. 23, 2013; Act No. 12450, Mar. 18, 2014; Act No. 13320, May 18, 2015>*

1. Investigating and identifying the causal relationship of side effects of drugs, such as pharmaceutical mishaps;
2. Establishing a drug safety information management system to collect and manage drug safety information;
3. Collecting, analyzing, assessing, managing, and providing drug safety information;
4. Conducting investigation, research, education, and publicity aimed at developing and utilizing drug safety information;
5. Other projects entrusted under this Act or other statutes and regulations.

[This Article Newly Inserted by Act No. 10788, Jun. 7, 2011]

Article 68-5 (Financial Resources for Operation)

The Institute of Drug Safety and Risk Management shall be operated by contributions from the Government and persons, other than the Government, and other gains.

[This Article Newly Inserted by Act No. 10788, Jun. 7, 2011]

Article 68-6 (Submission of Business Plans)

(1) The business year of the Institute of Drug Safety and Risk Management shall coincide with the fiscal year of the Government.

(2) The Institute of Drug Safety and Risk Management shall prepare a business plan and a budget bill for each fiscal year, as prescribed by Presidential Decree, and obtain approval from the Minister of Food and Drug Safety. The same shall apply to modifications to such business plan and budget bill.

<Amended by Act No. 11690, Mar. 23, 2013>

[This Article Newly Inserted by Act No. 10788, Jun. 7, 2011]

Article 68-7 (Requests for Provision of Data)

(1) If deemed necessary for performing the duties, such as collection and assessment of drug safety information, the president of the Institute of Drug Safety and Risk Management may request any of the following institutions or persons to provide data regarding drug safety information. In such cases, an institution or a person upon receipt of a request shall comply with such request, unless there is good cause: *<Amended by Act No. 13114, Jan. 28, 2015>*

1. The State or a local government;
2. A public institution or public organization;
3. A research institute;
4. A pharmacy founder or a medical institution founder;
5. A person who may handle drugs in accordance with this Act, including a manufacturer of drugs, etc., a person who has obtained permission by item of a drug, an importer, or a drug distributor.

(2) Where the president of the Institute of Drug Safety and Risk Management makes a request to provide necessary data pursuant to paragraph (1), he or she may request the provision of data including personal information, such as sensitive information prescribed in Article 23 of the Personal Information Protection Act and personally identifiable information (including resident registration numbers) prescribed in Article 24 of that Act. In such cases, the institution or person upon receipt of such request shall provide data after deleting the parts by which individual identification is possible. *<Amended by Act No. 13114, Jan. 28, 2015>*

(3) Notwithstanding paragraph (2), where the Minister of Food and Drug Safety approves that it is deemed necessary to combine and analysis data possessed by multiple number of institutions and persons, the president of the Institute of Drug Safety and Risk Management may collect data including the parts by which individual identification is possible for the combination of data. In such cases, the president shall, without delay, delete the parts by which personal identification is possible, after the combination of data, and shall make the deleted parts not restored or regenerated. *<Newly Inserted by Act No. 13114, Jan. 28, 2015>*

(4) No data provided pursuant to paragraphs (1) through (3) shall be used for any purpose other than that of such request. *<Newly Inserted by Act No. 13114, Jan. 28, 2015>*

(5) The Minister of Food and Drug Safety may regularly check whether the president of the Institute of Drug Safety and Risk Management complies with paragraphs (3) and (4) and may take necessary measures, such as dismissal, if he or she fails to comply with the paragraphs. *<Newly Inserted by Act No. 13114, Jan. 28, 2015>*

[This Article Newly Inserted by Act No. 10788, Jun. 7, 2011]

Article 68-8 (Reporting Side Effects)

- (1) Where a manufacturer of drugs, etc., a person who has obtained permission by item of drugs, an importer, or a drug wholesaler becomes aware of an hazardous event suspected of having been caused by drugs, etc. such as a disease, disability, death, or other event relating to the safety and effectiveness of drugs, etc. prescribed by Ordinance of the Prime Minister, he or she shall report such events to the president of the Institute of Drug Safety and Risk Management, as determined by the Minister of Food and Drug Safety. <Amended by Act No. 11690, Mar. 23, 2013>
- (2) Where a pharmacy founder and a medical institution founder becomes aware of an adverse event suspected of having been caused by drugs, etc. such as a serious disease, disability, or death prescribed by Ordinance of the Prime Minister, he or she shall report such events to the president of the Institute of Drug Safety and Risk Management, as prescribed by the Minister of Food and Drug Safety. <Amended by Act No. 11690, Mar. 23, 2013>
- (3) The president of the Institute of Drug Safety and Risk Management shall report to the Minister of Food and Drug Safety the matters reported under paragraphs (1) and (2), as prescribed by the Minister of Food and Drug Safety. <Amended by Act No. 11690, Mar. 23, 2013>

[This Article Newly Inserted by Act No. 10788, Jun. 7, 2011]

Article 68-9 (Duty of Confidentiality)

No person who is or was an executive officer or employee of the Institute of Drug Safety and Risk Management shall divulge any confidential information he or she has become aware of in the course of performing the duties.

[This Article Newly Inserted by Act No. 10788, Jun. 7, 2011]

Article 68-10 (Prohibition against Use of Similar Names)

Any person, other than the Institute of Drug Safety and Risk Management, shall be prohibited from using the name "Institute of Drug Safety and Risk Management" or any other similar name.

[This Article Newly Inserted by Act No. 10788, Jun. 7, 2011]

Article 68-11 (Establishment of Deliberative Council on Side Effects of Drugs)

- (1) In order to deliberate on the following matters, the Deliberative Council on Side Effects of Drugs (hereinafter referred to as the "Deliberative Council") shall be established under the jurisdiction of the Ministry of Food and Drug Safety: <Amended by Act No. 11690, Mar. 23, 2013; Act No. 12450, Mar. 18, 2014>
 1. Matters concerning judgment, etc. of side effects and risk probabilities of drugs, etc.;
 2. Matters concerning identification of the causal relationship of side effects of drugs, etc. and identification of the causes of pharmaceutical mishaps, etc.;
 3. Matters concerning the relief of injury caused by drugs, such as benefits for relief of injury, under Article 86-3 (1).
- (2) The Deliberative Council shall be comprised of at least 10 but less than 15 members, including one chairperson, and the chairperson shall be elected by and from among its members.
- (3) The members shall be appointed or commissioned by the Minister of Food and Drug Safety, as prescribed by Presidential Decree, and shall include at least one person, respectively, from among the following persons: <Amended by Act No. 11690, Mar. 23, 2013>
 1. A person with expertise in public health care and drugs;
 2. A person recommended by a non-profit, non-governmental organization prescribed in Article 2 of the Assistance for Non-Profit, Non-Governmental Organizations Act;
 3. An expert prescribed in the Medical Service Act and in forensic medicine who is qualified as a judge, prosecutor, or attorney-at-law;
 4. A public official of a relevant central administrative agency prescribed by Presidential Decree.

(4) Deleted. <by Act No. 12450, Mar. 18, 2014>

(5) The Deliberative Council may establish a working committee under its control to deliberate on matters prescribed in the subparagraphs of paragraph (1) from a professional perspective. <Amended by Act No. 12450, Mar. 18, 2014>

(6) The organization and operation of the Deliberative Council and working committees and other necessary matters shall be prescribed by Presidential Decree.

[This Article Newly Inserted by Act No. 10788, Jun. 7, 2011]

Article 68-12 (Drug Epidemiological Investigators)

(1) Where deemed necessary to perform the project prescribed in subparagraph 1 of Article 68-4, the president of the Institute of Drug Safety and Risk Management may appoint or commission an investigator for the epidemiological investigation of drugs (hereinafter referred to as "drug epidemiological investigator") from among employees of the Institute or persons with expertise and experience in the relevant field.

(2) When the president of the Institute of Drug Safety and Risk Management appoints or commissions a drug epidemiological investigator, he or she shall report such fact to the Minister of Food and Drug Safety without delay.

(3) The president of the Institute of Drug Safety and Risk Management may have a drug epidemiological investigator enter a pharmacy, a medical institution, a factory, warehouse, shop, or office in which drugs, etc. are manufactured, stored, or handled, and other places that it is deemed necessary to investigate, to investigate relevant books, documents, or other articles, or make inquiries to relevant persons about drugs, etc. In such cases, the drug epidemiological investigator shall carry an identification indicating his or her authority and documents stating the matters prescribed by Presidential Decree, such as the period and scope of an investigation, persons in charge of the investigation, and relevant statutes and regulations, and show them to relevant persons. <Amended by Act No. 13655, Dec. 29, 2015>

(4) The qualifications and scope of duties of a drug epidemiological investigator and other necessary matters shall be prescribed by Ordinance of the Prime Minister.

(5) The procedures, methods, etc. for investigations or inquiries under paragraph (3) shall be prescribed by the Framework Act on Administrative Investigations, except as provided in this Act or other statutes and regulations concerning epidemiological investigations of drugs. <Newly Inserted by Act No. 13655, Dec. 29, 2015>

[This Article Newly Inserted by Act No. 12450, Mar. 18, 2014]

CHAPTER VII Supervision

Article 69 (Reporting and Inspections)

(1) The Minister of Health and Welfare, the Minister of Food and Drug Safety, the Mayor/Do Governor, or the head of a *Si/Gun/Gu* may give any of the following directions: <Amended by Act No. 8643, Oct. 17, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10788, Jun. 7, 2011; Act No. 11690, Mar. 23, 2013; Act No. 11985, Jul. 30, 2013; Act No. 13219, Mar. 13, 2015; Act No. 14926, Oct. 24, 2017>

1. Requesting the submission of necessary documents or other data from pharmacy founders; medical institution founders; manufacturers of drugs, etc.; persons who have obtained permission by item of drugs; importers; distributors; registered patentees; patentees, etc. of a listed drug; persons who have obtained permission for preferential distribution of items; persons who have obtained approval for clinical trial protocols; institutions conducting clinical trials; institutions

- conducting the analysis of clinical trial samples; institutions conducting non-clinical studies; and other persons engaged in handling drugs, etc.;
2. Having the relevant public officials access pharmacies; medical institutions; factories, warehouses, shops, or offices that manufacture, store, or handle drugs, etc.; institutions conducting clinical trials; institutions conducting the analysis of clinical trial samples; institutions conducting non-clinical studies; places where registered patentees, patentees, etc. of a listed drug, or persons who have obtained permission for preferential distribution of items conduct the relevant affairs; places where drugs, etc. are handled for clinical trials; or other places where drugs, etc. are handled for business, to inspect the relevant facilities, relevant books or documents, or other articles, or to inquire of the relevant persons;
 3. Collecting articles in a minimum quantity necessary for quality inspections of articles and drugs, etc. which are suspected to fall under Article 71 (1).
- (2) A public official who has access and conducts an inspection under paragraph (1) shall carry an identification indicating such authority and documents stating the matters prescribed by Presidential Decree, such as the period and scope of an investigation, persons in charge of the investigation, and relevant statutes and regulations, and shall show them to relevant persons. *<Amended by Act No. 13655, Dec. 29, 2015>*
- (3) The authority and the scope of duties of pertinent public officials and other necessary matters under paragraph (2) shall be prescribed by Ordinance of the Prime Minister, following consultation with the Minister of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>*
- (4) The procedures, methods, etc. for inspections or inquiries under paragraph (1) 2 shall be prescribed by the Framework Act on Administrative Investigations, except as provided in this Act. *<Newly Inserted by Act No. 13655, Dec. 29, 2015>*

Article 69-2 (Informing Relevant Agencies)

The Minister of Food and Drug Safety shall inform the head of the relevant central administrative agency prescribed by Presidential Decree of the following matters:

1. The disposition of prohibiting the distribution of drugs pursuant to Article 50-6 (1) and (2) and the extinction of the effect of prohibition of distribution under paragraph (3) of that Article;
2. Permission for preferential distribution of items and the extinction of the effect of prohibition of distribution of the same drug under Article 50-10 (1) and (2);
3. Initiation and termination of a patent trial or litigation related to subparagraph 1 or 2.

[This Article Newly Inserted by Act No. 13219, Mar. 13, 2015]

Article 69-3 (Reporting Matters of Agreement)

Where both parties agree as follows, they shall report the matters prescribed by Ordinance of the Prime Minister, such as the parties to the agreement, details of the agreement, and timing for agreement, to the Minister of Food and Drug Safety and the Fair Trade Commission within 15 days from the date of conclusion of the agreement:

1. The agreement on the manufacturing or distribution of the relevant drug between a person who has obtained permission by item or permission for modification of the listed drug or a patentee, etc. of the listed drug, and a person who has filed an application for permission by item or permission for modification of the informed drug;
2. The agreement on acquisition and extinction of permission for preferential distribution of items between a person who has obtained permission by item or permission for modification of the listed drug or a patentee, etc. of the listed drug, and a person who has filed an application for permission by item or permission for modification of the informed drug;
3. The agreement on acquisition and extinction of permission for preferential distribution of items

among the persons who have filed an application for permission by item or permission for modification of the informed drug.

[This Article Newly Inserted by Act No. 13219, Mar. 13, 2015]

Article 69-4 (Corrective Order)

Where pharmacy founders, persons who have obtained permission by item of drugs, importers, drug distributors, and other persons entitled to distribute drugs under this Act fall under any of the following cases, the Minister of Health and Welfare, the Minister of Food and Drug Safety, or the head of the relevant *Si/Gun/Gu* may order them to correct any violation for a specified period: *<Amended by Act No. 14328, Dec. 2, 2016; Act No. 14926, Oct. 24, 2017>*

1. Where they fail to comply with the matters necessary for management of a pharmacy under Article 21 (3);
2. Where they fail to comply with the matters necessary for the establishment of distribution systems of drugs, etc. and maintenance of order in distribution under Article 47 (1);
3. Where they fail to prepare an expense report under Article 47-2 (1) or fail to retain the relevant expense report, books related thereto, or evidentiary data;
4. Where they fail to indicate the prices of drugs on the containers or packages, in violation of Article 56 (2) (including cases applied *mutatis mutandis* pursuant to Article 44-5 (1)) or 65 (2).

[This Article Newly Inserted by Act No. 13655, Dec. 29, 2015]

Article 69-5 (On-Site Inspections at Overseas Manufacturing Factories)

- (1) The Minister of Food and Drug Safety may access and inspect overseas manufacturing factories (hereafter in this Article, referred to as “on-site inspection”) after undergoing prior consultation with the relevant importer, the manager of the overseas manufacturing factories, or the government of the exporting country, in any of the following cases:
 1. Where the Minister of Food and Drug Safety deems it necessary to conduct an on-site inspection to prevent any risk of imported drugs, etc. (hereafter in this Article, referred to as "imported drugs, etc.");
 2. Where the Minister of Food and Drug Safety deems it necessary to verify the safety information on imported drugs, etc. collected domestically and internationally.
- (2) Where overseas manufacturing factories refuse an on-site inspection without good cause or where the findings of an on-site inspection indicate potential risk of imported drugs, etc., the Minister of Food and Drug Safety may suspend import, order an inspection, or requests correction regarding the imported drugs, etc. of the relevant overseas manufacturing factories, or may revoke the registration of the relevant overseas manufacturing factories (hereafter in this Article, referred to as “suspension, etc. of import”).
- (3) For imported drugs, etc. that become subject to any measure prescribed in paragraph (2), such as suspension, etc. of import, where the relevant importer, the manager of the overseas manufacturing factory, or the government of the exporting country identifies the causes of potential risk and suggests improvement measures or where it is deemed that the relevant imported drugs, etc. cause no risk as a result of an on-site inspection, etc., the Minister of Food and Drug Safety may revoke any measure that has been taken, such as suspension, etc. of import. In such cases, an on-site inspection may be conducted if it is necessary to verify matters subject to improvement.
- (4) Matters necessary for on-site inspections, measures such as suspension, etc. of import, and the procedures, methods, etc. for revocation thereof under paragraphs (1) through (3) shall be prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted by Act No. 15891, Dec. 11, 2018]

Article 70 (Order to Commence Business)

- (1) If it is recognized that drug manufacturers, persons who have obtained permission by item of drugs,

pharmacy founders, or drug distributors cause or are likely to cause remarkable impediment in the purchase of drugs through joint suspension of production and distribution of drugs, or collective business suspension or closure, the Minister of Health and Welfare, the Minister of Food and Drug Safety, the Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* may order them to produce drugs or commence their business. <Amended by Act No. 8643, Oct. 17, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>

- (2) No drug manufacturer, person who has obtained permission by item of drugs, pharmacy founder, or drug distributor shall refuse an order issued under paragraph (1) without good cause. <Amended by Act No. 8643, Oct. 17, 2007>

Article 71 (Order of Destruction)

- (1) The Minister of Food and Drug Safety, the Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* may order persons who have obtained permission by item of drugs, quasi-drug manufacturers, importers or distributors of drugs, etc., pharmacy founders, medical institution founders, or other persons prescribed by Ordinance of the Prime Minister among persons eligible to distribute or handle drugs pursuant to this Act or other statutes to destroy the drugs, etc. which have been distributed, stored, displayed, manufactured, or imported in violation of Articles 53 (1), 61 (including cases applied *mutatis mutandis* in Article 66), and 62 (including cases applied *mutatis mutandis* in Article 66) or bad drugs, etc. or the raw materials and materials thereof, etc. in a manner that prevents risk to public health or to take other necessary measures. <Amended by Act No. 8643, Oct. 17, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>
- (2) When it is deemed that any drug, etc. actually causes or is likely to cause any risk to public health, the Minister of Food and Drug Safety, the Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* may order persons who have obtained permission by item of drugs, quasi-drug manufacturers, importers or distributors of drugs, etc., pharmacy founders, medical institution founders, or other persons prescribed by Ordinance of the Prime Minister among persons eligible to distribute or handle drugs pursuant to this Act or other statutes, to recall and destroy such drug, etc. in distribution or to take other necessary measures. <Amended by Act No. 8643, Oct. 17, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>
- (3) Where any person upon receipt of an order pursuant to paragraph (1) or (2) fails to comply with such order, or in cases of emergency for public health, the Minister of Food and Drug Safety, the Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* may require relevant public officials to recall and destroy the relevant articles or to take other necessary measures. <Amended by Act No. 11690, Mar. 23, 2013>
- (4) The provisions of Article 69 (2) shall apply *mutatis mutandis* to paragraph (2).
- (5) Matters necessary for the ranking of risk and standards for risk assessment of drugs, etc., recall and destruction thereof, and other measures under paragraph (2) shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>

Article 72 (Announcement of Recall of Drugs)

- (1) Upon receipt of a report on a plan for recall of drugs, etc. under the latter part of Article 39 (1), the Minister of Food and Drug Safety may order persons who have obtained permission by item of drugs, quasi-drug manufacturers, or importers of drugs, etc. to announce the recall plan: *Provided*, That he or she shall issue an order for announcement if the use of a relevant drug, etc. causes risk prescribed by Ordinance of the Prime Minister, such as serious side effects impossible to cure completely or side effects temporarily or medically possible to cure completely. <Amended by Act No. 8643, Oct. 17, 2007; Act No. 11251, Feb. 1, 2012; Act No. 11690, Mar. 23, 2013>
- (2) Where the Minister of Food and Drug Safety, the Mayor/*Do* Governor, or the head of a *Si/Gun/Gu*

has issued an order to recall and destroy drugs, etc. in distribution or to take other necessary measures pursuant to Article 71 (2), he or she shall order persons who have obtained permission by item of drugs, quasi-drug manufacturers, importers or distributors of drugs, etc., pharmacy founders, medical institution founders, or other persons prescribed by Ordinance of the Prime Minister from among persons eligible to distribute or handle drugs pursuant to this Act or other statutes, to announce such fact. *<Amended by Act No. 8643, Oct. 17, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>*

- (3) A person upon receipt of an order for announcement under paragraphs (1) and (2) shall make an announcement by any of the following methods, depending upon the ranking of risk under Article 71 (5): *<Newly Inserted by Act No. 11251, Feb. 1, 2012>*
1. Broadcasting, daily newspapers, or their equivalents;
 2. Medical or pharmaceutical journals, or their equivalents;
 3. The relevant company's website, or its equivalents.
- (4) Matters necessary for announcement referred to in paragraphs (1) through (3) shall be prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 11251, Feb. 1, 2012; Act No. 11690, Mar. 23, 2013>*

Article 73 (Inspection Orders and Test and Inspection Institutions)

- (1) The Minister of Food and Drug Safety or the Mayor/*Do* Governor may order manufacturers of drugs, etc., persons who have permission by item of drugs, or importers to undergo an inspection of drugs, etc. which are manufactured or imported or for which permission by item or a notification by item is granted or filed, from a testing and inspection institution of drugs, etc. designated by the Minister of Food and Drug Safety pursuant to Article 6 (2) 3 of the Act on Testing and Inspection in the Food and Drug Industry (hereinafter referred to as "testing and inspection institution"). *<Amended by Act No. 11690, Mar. 23, 2013; Act No. 11985, Jul. 30, 2013>*
- (2) through (4) Deleted. *<by Act No. 11985, Jul. 30, 2013>*
[This Article Wholly Amended by Act No. 10788, Jun. 7, 2011]

Articles 73-2 and 73-3 Deleted. *<by Act No. 11985, Jul. 30, 2013>*

Article 74 (Order for Improvement)

Where a facility fails to meet the standards for facilities prescribed in Articles 20 (3), 31 (1) and (4), 34-2 (1), 34-3 (1), 42 (3), and 45 (2) or becomes deteriorated, unclean, or damaged so that the drugs, etc. manufactured by using such facility are likely to fall under any of the subparagraphs of Article 62 (including cases applied *mutatis mutandis* in Article 66), the Minister of Food and Drug Safety, the Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* may order pharmacy founders, manufacturers of drugs, etc., persons who have obtained permission by item of drugs, importers, distributors, institutions conducting clinical trials, institutions conducting the analysis of clinical trial samples, and institutions conducting non-clinical studies to improve such facility or to suspend the use of all or part of such facility until the improvements have been completed. *<Amended by Act No. 8643, Oct. 17, 2007; Act No. 10788, Jun. 7, 2011; Act No. 11690, Mar. 23, 2013; Act No. 11985, Jul. 30, 2013; Act No. 13114, Jan. 28, 2015; Act No. 14926, Oct. 24, 2017>*

Article 75 (Order to Replace Managers)

If a manager of manufacturing business of drugs, etc. or a manager of a pharmacy violates this Act or an order issued pursuant to this Act, or if such manager is considered inappropriate as a manager, the Minister of Food and Drug Safety may order the relevant manufacturer to replace the manager of the manufacturing business, and the head of a *Si/Gun/Gu* may order the relevant pharmacy founder to replace the manager of the pharmacy. *<Amended by Act No. 11690, Mar. 23, 2013>*

Article 75-2 (Corrective Orders)

Where a pharmacy founder violates Article 47 (5) through (7), the Minister of Health and Welfare and the head of a *Si/Gun/Gu* may order him or her to correct the relevant violation by a specified period of up to three months, as prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 13598, Dec. 22, 2015]

Article 76 (Revocation of Permission and Suspension of Business)

(1) If a manufacturer of drugs, etc.; a person who has obtained permission by item of a drug; a person who has filed for registration of drug substances; an importer; a person who has obtained approval of a clinical trial protocol; a pharmacy founder; or a drug distributor falls under any of the following cases, the Minister of Food and Drug Safety may revoke permission, approval, or registration held by the manufacturer of drugs, etc., person who has obtained permission by item of a drug, person who has filed for registration of drug substances, importer, or person who has obtained approval of a clinical trial protocol; close his or her place of contract manufacturing and distribution business or factory (limited only to where a notification has been filed pursuant to Article 31 (4); hereafter the same shall apply in subparagraph 1 of Article 77); close his or her business place (limited only to where a notification has been filed pursuant to Article 42 (1); hereafter the same shall apply in subparagraph 1 of Article 77); issue an order to prohibit the manufacturing or import of items; or issue an order to fully or partially suspend the business for a period of up to one year; and the head of a *Si/Gun/Gu* may impose the same on the pharmacy founder or drug distributor: *Provided*, That in cases falling under subparagraph 4, if it is deemed that the relevant business entity is not liable and the purpose of permission or a notification is attainable by modifying the ingredients, prescription, etc. of the relevant drugs, etc., only the modification of ingredients, prescription, etc. may be ordered: *<Amended by Act No. 8643, Oct. 17, 2007; Act No. 10324, May 27, 2010; Act No. 10512, Mar. 30, 2011; Act No. 10788, Jun. 7, 2011; Act No. 11251, Feb. 1, 2012; Act No. 11690, Mar. 23, 2013; Act No. 12074, Aug. 13, 2013; Act No. 13114, Jan. 28, 2015; Act No. 13219, Mar. 13, 2015; Act No. 13598, Dec. 22, 2015; Act No. 14926, Oct. 24, 2017; Act No. 15891, Dec. 11, 2018; Act No. 16250, Jan. 15, 2019>*

1. Where he or she falls under any of the subparagraphs of Article 5 (limited to an importer in cases falling under subparagraph 5): *Provided*, That the same shall not apply where the representative of a corporation falls under any of such provisions and is replaced within six months;
2. Where it is found that he or she falls under any of the subparagraphs of Article 20 (5), or under Article 31 (8) 2 or 42 (4) 2 or 3: *Provided*, That the same shall not apply where the representative of a corporation falls under any of such provisions and is replaced within six months;
- 2-2. Where he or she fails to obtain permission by item or to file a notification by item, in violation of Article 31 (2) or (3);
- 2-3. Where he or she fails to obtain permission for modification or to file a notification of modification, in violation of Article 31 (9);
- 2-4. Where he or she files for registration of drug substances under Article 31-2 (1) and (3) (including cases applied *mutatis mutandis* pursuant to Article 42 (5)), files for registration of modification, or files a report on modification, by fraud or other improper means;
- 2-5. Where he or she fails to file for registration of modification of, or to file a report on modification of, drug substances under Article 31-2 (3) (including cases applied *mutatis mutandis* pursuant to Article 42 (5));
3. Where he or she violates this Act or any order issued under this Act;
4. Where he or she manufactures, imports, or distributes drugs, etc. which caused or are likely to cause any risk to the public health, or drugs, etc. which are regarded as having no efficacy;
5. Where he or she fails to recall or take the measures necessary for recall, or fails to report, or

- falsely reports, a recall plan pursuant to Article 39 (1);
- 5-2. Where he or she fails to obtain permission or permission for modification for each item or to file a notification or a notification of modification for each item, in violation of Article 42 (1);
- 5-3. Where he or she files for registration or registration of modification or files a notification of modification regarding overseas manufacturing factories referred to in Article 42 (7) or (8), by fraud or other improper means;
- 5-4. Where he or she fails to file for registration or registration of modification or files a notification of modification, in violation of Article 42 (7) or (8);
- 5-5. Where he or she offers any economic benefits, etc., in violation of Article 47 (2);
- 5-6. Where a person who has filed an application for permission by item or permission for modification distributes a drug before the expiration of the term of a registered patent, in order to distribute such drug after the registered patent expires, in violation of Article 50-4 (1) 2;
- 5-7. Where he or she distributes drugs, the distribution of which has been prohibited under Article 50-6 (1) or (2) or 50-9 (1);
- 5-8. Where he or she indicates any information prescribed in the subparagraphs of Article 60 on the package inserts, containers, or packages of drugs, in violation of that Article;
- 5-9. Where he or she distributes any drug prescribed in the subparagraphs of Article 62 or manufactures, imports, stores, or displays such drug for distribution purposes, in violation of that Article;
- 5-10. Where he or she violates an order prescribed in Articles 71 (1) and (2) and 72 (1) and (2);
6. Where a pharmacy founder receives a disposition of suspension of qualifications as a pharmacist or oriental medicine pharmacist under Article 79 (2);
7. Where he or she fails to comply with a corrective order referred to in Article 75-2.
- (2) Paragraph (1) shall also apply where the facilities of a person prescribed in paragraph (1) are not in compliance with the standards for facilities provided for in Articles 20 (3), 31 (1) and (4), 42 (3), and 45 (2). <Amended by Act No. 8643, Oct. 17, 2007>
- (3) Among the standards for administrative dispositions under paragraphs (1) and (2), the standards for administrative dispositions, including the revocation of permission, notifications, registration, and approval, and the suspension of business, against a manufacturer of drugs, etc., a person who has obtained permission by item of a drug, a person who has filed for registration of drug substances, an importer, and a person who has obtained approval of clinical trial protocols shall be prescribed by Ordinance of the Prime Minister; and the standards for administrative dispositions, including the revocation of licenses, registration, and permission, and the suspension of qualifications or business, against a pharmacist, an oriental medicine pharmacist, a pharmacy founder, or a drug distributor shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 14926, Oct. 24, 2017>

Article 76-2 (Revocation of Designation of Institutions Conducting Clinical Trials)

- (1) If an institution conducting clinical trials, an institution conducting the analysis of clinical trial samples, or an institution conducting non-clinical studies prescribed in Article 34-2 or 34-3 (hereinafter referred to as "inspection institution, etc.") falls under any of the following subparagraphs, the Minister of Food and Drug Safety may revoke the designation of such institution or order it to fully or partially suspend business for up to nine months: *Provided*, That in cases falling under subparagraphs 1, 2, 2-2, or 5 (in cases falling under subparagraphs 2 and 2-2, limited to cases of intention or gross negligence), he or she shall revoke the designation of such institution: <Amended by Act No. 11690, Mar. 23, 2013; Act No. 11985, Jul. 30, 2013; Act No. 13114, Jan. 28, 2015; Act No. 14926, Oct. 24, 2017; Act No. 15709, Jun. 12, 2018; Act No. 15891, Dec. 11, 2018>
1. Where designation has been made by fraud or other improper means;
 2. Where a clinical trial report or an analysis report of clinical trial samples referred to in Article

- 34-2 (3) 5 has been falsely prepared or issued, or the records on clinical trials have been falsely prepared;
- 2-2. Where a non-clinical study report referred to in Article 34-3 (3) has been falsely prepared or issued;
3. Where the requirements for designation referred to in Article 34-2 (1) and (5) or 34-3 (1) and (4) have not been satisfied;
4. Where matters to be observed referred to in Article 34-2 (3) or 34-3 (3) have not been observed;
5. Where business has been performed during a business suspension period.
- (2) No person whose designation has been revoked pursuant to paragraph (1) shall be re-designated within two years from the date the designation is revoked.
- (3) The standards for administrative dispositions prescribed in paragraph (1) shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013>
 [This Article Newly Inserted by Act No. 10788, Jun. 7, 2011]

Article 76-3 (Revocation of Registration of Distributors of Safe and Readily Available Drugs)

- (1) The head of a *Si/Gun/Gu* may revoke the registration of a distributor of safe and readily available drugs in any of the following cases: *Provided*, That he or she shall revoke the registration in cases falling under any of subparagraphs 1 and 3 through 6: <Amended by Act No. 13655, Dec. 29, 2015>
1. Where the distributor has filed for registration by fraud or other improper means;
 2. Where the distributor fails to recall, or take measures necessary to recall, drugs, in violation of the former part of Article 39 (1);
 3. Where the distributor fails to meet the standards for registration referred to in Article 44-2 (2);
 4. Where the distributor fails to file for registration of modification, in violation of Article 44-2 (3), or has filed for such registration by fraud or other improper means;
 5. Where the distributor fails to receive education, in violation of Article 44-3 (1);
 6. Where the distributor fails to observe the matters to be observed by distributors of safe and readily available drugs, in violation of Article 44-4 (limited to cases where such violations are committed at least three times a year);
 7. Where the distributor fails to abide by matters necessary to establish a distribution system and to maintain order in distribution even after having received the correction order pursuant to Article 69-4, in violation of Article 47 (1);
 8. Where the distributor distributes drugs at a non-designated place, in violation of Article 50 (1);
 9. Where the distributor fails to comply with a request to submit documents or data prescribed in Article 69 (1) 1 or rejects, interferes with, or evades the access, inspection, inquiry, or collection under Article 69 (1) 2 or 3;
 10. Where the distributor fails to comply with an order of destruction, etc. issued under Article 71 (1) or an order for recall and destruction issued under paragraph Article 71 (2), or rejects, obstructs, or evades the measures taken for recall, destruction, etc. under paragraph (3) of that Article;
 11. Where the distributor fails to comply with an order for announcement prescribed in Article 72 (2).
- (2) A person whose registration has been revoked under paragraph (1) shall be not be re-registered as a distributor of safe and readily available drugs within one year from the date his or her registration was revoked under paragraph (1).

[This Article Newly Inserted by Act No. 11421, May 14, 2012]

Article 77 (Hearings)

The Minister of Health and Welfare, the Minister of Food and Drug Safety, the Mayor/Do Governor, or the head of a *Si/Gun/Gu* who intends to take any of the following dispositions shall hold a hearing: <Amended by Act No. 8643, Oct. 17, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010;

Act No. 10788, Jun. 7, 2011; Act No. 11421, May 14, 2012; Act No. 11690, Mar. 23, 2013; Act No. 13114, Jan. 28, 2015>

1. Revocation of permission, approval, and registration, closure of a place of contract manufacturing and distribution business, factory, or business place, or issuance of orders to prohibit the manufacturing or import of items prescribed in Article 76;
- 1-2. Revocation of registration prescribed in Article 76-3;
2. Revocation of designation prescribed in Article 76-2 (1);
3. Revocation of a license prescribed in Article 79 (1) or (2).

Article 78 (Pharmaceutical Inspectors)

- (1) Pharmaceutical inspectors shall be assigned to the Ministry of Health and Welfare, the Ministry of Food and Drug Safety, Cities/Dos, or Sis/Guns/Gus (Gus refer to autonomous Gus of the Special Metropolitan City and Metropolitan Cities) in order to perform the duties of pertinent public officials under Articles 69 (1) and 71 (2). *<Amended by Act No. 11690, Mar. 23, 2013>*
- (2) Pharmaceutical inspectors shall be appointed by the Minister of Health and Welfare, the Minister of Food and Drug Safety, the Mayor/Do Governor, or the head of a *Si/Gun/Gu* from among the members of the Ministry of Health and Welfare, the Ministry of Food and Drug Safety, Cities/Dos, or Sis/Guns/Gus. *<Amended by Act No. 11690, Mar. 23, 2013>*
- (3) Qualifications and appointment of pharmaceutical inspectors and other necessary matters shall be prescribed by Ordinance of the Prime Minister following consultation with the Minister of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>*

Article 79 (Revocation of Pharmacist or Oriental Medicine Pharmacist Licenses)

- (1) If a pharmacist or oriental medicine pharmacist falls under any of subparagraphs 1 through 4 of Article 5, the Minister of Health and Welfare shall revoke his or her license. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*
- (2) If a pharmacist or oriental medicine pharmacist falls under any of the following cases, the Minister of Health and Welfare may revoke his or her license or order the suspension of qualifications as a pharmacist or oriental medicine pharmacist for a specified period of up to one year: *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 14926, Oct. 24, 2017>*
 1. When he or she violates the statutes and regulations concerning pharmaceutical affairs or violates the standards for ethics prescribed by Ordinance of the Ministry of Health and Welfare;
 2. When he or she forges or alters relevant documents or demands drug expenses by fraud or other improper means;
 3. When he or she fails to comply with an order referred to in Article 79-2 (2) without good cause.
- (3) Where a pharmacist or oriental medicine pharmacist falls under any of the following cases, the Minister of Health and Welfare may order the suspension of qualifications as a pharmacist or oriental medicine pharmacist for a specified period of up to one year: *<Amended by Act No. 10324, May 27, 2010>*
 1. Where he or she has been employed by a person disqualified as a pharmacy founder and performs the affairs of a pharmacist or oriental medicine pharmacist;
 2. Where he or she receives any economic benefit, etc. in violation of Article 47 (3).
- (4) Even though a pharmacist or oriental medicine pharmacist license is revoked under paragraphs (1) and (2), if a ground for the revocation ceases to exist, the Minister of Health and Welfare may regrant the license, as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9123, Jun. 13, 2008; Act No. 9932, Jan. 18, 2010>*
- (5) A disposition of suspension of qualifications under paragraph (2) or (3) shall not be issued after five years (seven years in cases of the suspension of qualifications under paragraph (2) 2) from the date

any ground therefor occurs: *Provided*, That where a criminal complaint under Article 246 of the Criminal Procedure Act is filed for such ground, the period from the date the criminal complaint is filed to the date the trial of the relevant case is finalized shall not be included in the period of prescription. <Newly Inserted by Act No. 14328, Dec. 2, 2016>

Article 79-2 (Requests for Disposition of Revocation of License or Suspension of Qualifications by the Pharmaceutical Association and the Oriental Pharmacy Association)

- (1) Where a pharmacist or oriental medicine pharmacist is deemed to fall under any of the following subparagraphs, the head of the Pharmaceutical Association or the head of the Oriental Pharmacy Association may request any of the following dispositions by the Minister of Health and Welfare, after undergoing deliberations and decisions by the Ethics Committee of the Pharmaceutical Association or the Oriental Pharmacy Association:
1. In cases of falling under any ground for disqualification prescribed in subparagraphs 1 and 3 of Article 5: Revocation of a license;
 2. In cases of violating the standards for ethics prescribed in Article 79 (2) 1: Suspension of qualifications.
- (2) Where the head of the Pharmaceutical Association or the head of the Oriental Pharmacy Association requests a disposition of revocation of a license against any pharmacist or oriental medicine pharmacist pursuant to paragraph (1) 1, the Minister of Health and Welfare may order the relevant pharmacist or oriental medicine pharmacist to undergo inspections by a medical specialist regarding whether he or she falls under any ground for disqualification prescribed in subparagraphs 1 and 3 of Article 5.

[This Article Wholly Amended by Act No. 14926, Oct. 24, 2017]

Article 80 (Renewal of License, Permit, and Certificate of Registration)

A person who has obtained a pharmacist license or an oriental medicine pharmacist license, a person who has filed registration of establishment of a pharmacy, a distributor of safe and readily available drugs, or a person who has obtained permission for drug distribution business shall renew his or her license, permit, certificate of registration, etc. as prescribed by Ordinance of the Ministry of Health and Welfare; and a person who has obtained permission for manufacturing business of drugs, etc. or has filed a notification of contract manufacturing and distribution business shall renew such certificate, as prescribed by Ordinance of the Prime Minister.

[This Article Wholly Amended by Act No. 11690, Mar. 23, 2013]

Article 81 (Disposition of Penalty Surcharges Imposed in Lieu of Disposition of Business Suspension)

- (1) If a manufacturer of drugs, etc., a person who has obtained permission by item of a drug, an importer, a pharmacy founder, or a drug distributor is subject to a disposition of business suspension prescribed in Article 76, the Minister of Food and Drug Safety, the Mayor/Do Governor, or the head of a *Si/Gun/Gu* may impose a penalty surcharge not exceeding one billion won (100 million won for a pharmacy founder or herb druggist) in lieu of such disposition, as prescribed by Presidential Decree. In such cases, if a pharmacy founder who has been ordered to suspend qualifications as a pharmacist or oriental medicine pharmacist prescribed in Article 79 (2) 2 is subject to a disposition of business suspension under Article 76 (1) 5, the penalty surcharge in lieu thereof shall be imposed to not exceed three times the amount. <Amended by Act No. 8643, Oct. 17, 2007; Act No. 10788, Jun. 7, 2011; Act No. 11690, Mar. 23, 2013; Act No. 16250, Jan. 15, 2019>
- (2) The amount of penalty surcharges according to the types, degree, etc. of violations for which penalty surcharges are imposed pursuant to paragraph (1) and other necessary matters shall be prescribed by Presidential Decree.
- (3) If necessary to impose penalty surcharges, the Minister of Food and Drug Safety, the Mayor/Do Governor, or the head of a *Si/Gun/Gu* may request the head of the competent tax office to provide

taxation information by submitting documents stating the following matters: <Amended by Act No. 11690, Mar. 23, 2013; Act No. 15891, Dec. 11, 2018>

1. Taxpayers' personal information;
 2. The purpose of use;
 3. Data on sales that forms the standards for imposing penalty surcharges.
- (4) If a person required to pay a penalty surcharge prescribed in paragraph (1) fails to pay it by the deadline for payment, the Minister of Food and Drug Safety, the Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* shall revoke the disposition to impose penalty surcharges under paragraph (1) and impose a disposition to suspend business under Article 76 (1) or (2) or collect them in the same manner as delinquent national taxes are collected or pursuant to the Act on the Collection, etc. of Local Non-Tax Revenue, as prescribed by Presidential Decree: *Provided*, That where it is impracticable to impose a disposition to suspend business pursuant to Article 76 (1) or (2) due to business closure, etc. under Article 40, the penalty surcharges shall be collected in the same manner as delinquent national taxes are collected or pursuant to the Act on the Collection, etc. of Local Non-Tax Revenue. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 11998, Aug. 6, 2013>
- (5) In order to collect a penalty surcharge in arrears pursuant to paragraph (4), the Minister of Food and Drug Safety, the Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* may request the submission of any of the following data from the relevant person prescribed in the following. In such cases, a person upon receipt of such request shall comply with it, unless there is a compelling reason not to do so: <Newly Inserted by Act No. 15891, Dec. 11, 2018>
1. A certified copy of a building register referred to in Article 38 of the Building Act: The Minister of Land, Infrastructure and Transport;
 2. A certified copy of a cadastre referred to in Article 71 of the Act on the Establishment, Management, etc. of Spatial Data: The Minister of Land, Infrastructure and Transport;
 3. A certified copy of a motor vehicle register referred to in Article 7 of the Motor Vehicle Management Act: The Mayor/*Do* Governor.
- (6) The amount collected as a penalty surcharge under paragraphs (1) and (4) shall revert to the State or to the local government to which the collection agency belongs. <Amended by Act No. 15891, Dec. 11, 2018>

Article 81-2 (Imposition of Penalty Surcharges for Manufacturing of Harmful Drugs)

- (1) With respect to a manufacturer of drugs, a person who has obtained permission by item, or an importer, who is subject to a disposition of revocation of permission; an order to close a place of contract manufacturing and distribution business or a business place; an order to fully suspend business for at least three months; or an order to partially suspend business for at least six months pursuant to Article 76 (1) for violating Article 31 (2), (3) or (9) or 42 (1), subparagraph 3 of Article 60, or Article 62, the Minister of Food and Drug Safety may impose a penalty surcharge of not more than 5/100 of the production or import amount.
- (2) The Minister of Food and Drug Safety shall take into account each of the following matters when imposing a penalty surcharge pursuant to paragraph (1):
 1. The details and severity of violations;
 2. The duration and frequency of violations;
 3. The amount of profits acquired from violations.
- (3) The standards and procedures for imposing penalty surcharges prescribed in paragraphs (1) and (2), and other necessary matters shall be prescribed by Presidential Decree.
- (4) Where a person required to pay a penalty surcharge prescribed in paragraph (1) fails to pay the penalty surcharge by the payment deadline, the Minister of Food and Drug Safety shall collect an additional charge equivalent to 3/100 per annum of the penalty surcharge in arrears starting from the day following the payment deadline.

- (5) Where a person required to pay a penalty surcharge prescribed in paragraph (1) fails to pay the penalty surcharge by its payment deadline, the Minister of Food and Drug Safety shall demand the payment by specifying a period; and where the person fails to pay the penalty surcharge and the additional charge prescribed in paragraph (4) within the specified period, the Minister of Food and Drug Safety shall collect them in the same manner as delinquent national taxes are collected.
- (6) Article 81 (3) and (5) shall apply *mutatis mutandis* to a request for provision of information and data necessary to impose and collect penalty surcharges prescribed in paragraph (1).

[This Article Newly Inserted by Act No. 15891, Dec. 11, 2018]

Article 82 (Fees)

- (1) Each of the following persons shall pay a fee, as prescribed by Ordinance of the Ministry of Health and Welfare. The same shall also apply to the modification of matters prescribed by Ordinance of the Ministry of Health and Welfare, such as licenses, registration, and permission: *<Amended by Act No. 14560, Feb. 8, 2017>*
1. A person who intends to obtain a pharmacist or oriental medicine pharmacist license under Article 3 or 4;
 2. A person who intends to file for registration for establishment of a pharmacy under Article 20;
 3. A person who intends to file for registration as a distributor of safe and readily available drugs under Article 44-2;
 4. A person who intends to obtain permission for drug distribution business under Article 45;
 5. A person who intends to apply for the provision of drug distribution information;
 6. A person who intends to apply for the national examinations for a pharmacist license or an oriental medicine pharmacist license, preliminary examinations for a pharmacist license, etc.;
 7. A person who requests other matters prescribed by Ordinance of the Ministry of Health and Welfare.
- (2) Where a person intends to perform the following activities in connection with the affairs under the jurisdiction of the Ministry of Food and Drug Safety, he or she shall pay a fee as prescribed by Ordinance of the Prime Minister. The same shall also apply to permission, renewal, registration, notification, or approval, or the modification of the matters prescribed by Ordinance of the Prime Minister: *<Amended by Act No. 13219, Mar. 13, 2015>*
1. Applying for permission, renewal, registration, notification, approval, designation, or a preliminary examination;
 2. Determining the standards for new products;
 - 2-2. Filing an application for registration of a drug patent, modification of the registered matters, prohibition of distribution, or permission for preferential distribution of items under Article 50-2, 50-3, 50-5 or 50-7;
 - 2-3. Filing an application for modification of the registered matters during the extension period referred to in the proviso of Article 50-3 (2);
 3. Requesting other matters prescribed by Ordinance of the Prime Minister.

[This Article Wholly Amended by Act No. 11690, Mar. 23, 2013]

Article 82-2 (Registration Fees)

- (1) A registered patentee shall pay a registration fee calculated, on a yearly basis, from the date of registration of a drug patent, as prescribed by Ordinance of the Prime Minister.
- (2) Where a registration fee referred to in paragraph (1) is not paid, the Minister of Food and Drug Safety shall delete the relevant drug patent from the patent list.
- (3) Matters necessary for the amount, method of payment, period of payment, etc. of registration fees referred to in paragraph (1) shall be prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted by Act No. 13219, Mar. 13, 2015]

CHAPTER VIII Supplementary Provisions

Article 83 (Subsidization from National Treasury)

The Minister of Health and Welfare and the Minister of Food and Drug Safety may subsidize research funds for the manufacturers of drugs, etc. who have contributed to export, or for institutions, etc. that contribute to the national health by performing research projects on the safety of drugs, etc., as prescribed by Presidential Decree. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>*

Article 83-2 (Training of Professional Personnel)

- (1) For the enhancement of national health and the promotion of the pharmaceutical industry, the Minister of Health and Welfare and the Minister of Food and Drug Safety shall endeavor to train professional personnel.
- (2) In order to train professional personnel prescribed in paragraph (1), the Minister of Health and Welfare and the Minister of Food and Drug Safety may designate institutions or organizations with appropriate personnel, facilities, etc., such as universities and research institutions, as a professional training institution and have them provide necessary education and training, as prescribed by Presidential Decree.
- (3) The Minister of Health and Welfare and the Minister of Food and Drug Safety may fully or partially subsidize expenses incurred in training for the professional training institutions designated pursuant to paragraph (2) within budgetary limits, as prescribed by Presidential Decree.
- (4) Standards, procedures, etc. for designation of professional training institutions under paragraph (2) shall be prescribed by Presidential Decree.

[This Article Newly Inserted by Act No. 13114, Jan. 28, 2015]

Article 83-3 (Establishing Stable Supply Base of National Essential Drugs)

- (1) The Minister of Health and Welfare and the Minister of Food and Drug Safety shall perform the following affairs regarding national essential drugs:
 1. Formulating and implementing comprehensive policies for stable supply of national essential drugs;
 2. Supporting the establishment of stable supply base of national essential drugs, research and development thereof, and safe use thereof;
 3. Other necessary affairs related to stable supply of national essential drugs.
- (2) If necessary for national essential drugs, the Minister of Health and Welfare and the Minister of Food and Drug Safety may provide administrative, financial, and technical support.
- (3) In order to consult matters necessary for national essential drugs with the head, etc. of the relevant central administrative agency, the Council for Stable Supply of National Essential Drugs shall be established in the Ministry of Food and Drug Safety.
- (4) Matters necessary for the organization, operation, etc. of the council for stable supply of national essential drugs under paragraph (3) shall be prescribed by Presidential Decree.

[This Article Newly Inserted by Act No. 14328, Dec. 2, 2016]

Article 83-4 (Comprehensive Drug Safety Management Plans)

- (1) The Minister of Food and Drug Safety shall formulate a comprehensive plan for drug safety management (hereinafter referred to as "comprehensive plan") for the safe management of drugs every five years in consultation with the heads of the relevant central administrative agencies.
- (2) A comprehensive plan shall contain each of the following matters:
 1. The basic objectives of and direction for implementation of drug safety management policies;
 2. A business plan for drug safety management, and the methods of financing;
 3. Education and public campaign necessary for drug safety management;

4. Investigation, research, and development regarding drug safety management;
 5. Other matters deemed necessary by the Minister of Food and Drug Safety for drug safety management.
- (3) In order to implement a comprehensive plan, the Minister of Food and Drug Safety shall formulate an implementation plan for drug safety management (hereinafter referred to as "implementation plan") each year in consultation with the heads of the relevant central administrative agencies.
 - (4) Where the Minister of Food and Drug Safety formulates a comprehensive plan or an implementation plan, he or she shall inform the heads of the relevant central administrative agencies and the heads of local governments.
 - (5) Where necessary to formulate a comprehensive plan or an implementation plan, the Minister of Food and Drug Safety may request the provision of necessary data from the heads of the relevant central administrative agencies, the heads of local governments, or the heads of relevant institutions or organizations.
 - (6) Matters necessary to formulate and implement a comprehensive plan or an implementation plan shall be prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted by Act No. 15891, Dec. 11, 2018]

Article 83-5 (Establishment and Operation of Integrated Drug Information System)

- (1) The Minister of Food and Drug Safety shall establish and operate an integrated drug information system (hereinafter referred to as "integrated information system") to comprehensively manage the affairs necessary for safety management with respect to the clinical trials, permission by item, manufacturing, import, distribution, use, etc. of drugs, etc.
- (2) The Minister of Food and Drug Safety may request the provision of information necessary to establish and operate an integrated information system (including sensitive information prescribed in Article 23 of the Personal Information Protection Act and personally identifiable information prescribed in Article 24 of that Act; In such cases, the relevant information shall be protected in accordance with the Personal Information Protection Act) from the following institutions, organizations, or persons. In such cases, any institution, organization, or person upon receipt of such request shall comply with it, unless there is good cause:
 1. The State or local governments;
 2. Public institutions or public organizations;
 3. Pharmacy founders; medical institution founders; manufacturers of drugs, etc., persons who have obtained permission by item, importers, or distributors; registered patentees; patentees, etc. of listed drugs; persons who have obtained permission for preferential distribution of items; persons who have obtained approval of clinical trial protocols; institutions conducting clinical trials; institutions conducting the analysis of clinical trial samples; institutions conducting non-clinical studies; and other persons prescribed by Ordinance of the Prime Minister who are engaged in handling drugs, etc.
- (3) The Minister of Food and Drug Safety may entrust the affairs necessary for maintaining and managing an integrated information system to the Institute of Drug Safety and Risk Management. In such cases, the Minister of Food and Drug Safety may fully or partially subsidize the expenses incurred in maintaining and managing the integrated information system.
- (4) Matters necessary for establishment and operation of an integrated information system, requests for the provision of information, entrustment, etc. under paragraphs (1) through (3) shall be prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted by Act No. 15891, Dec. 11, 2018]

Article 84 (Delegation and Entrustment of Authority)

- (1) The Minister of Health and Welfare may delegate part of his or her authority under this Act to the

Director of the Korea Centers for Disease Control and Prevention or the Mayor/*Do* Governor, as prescribed by Presidential Decree.

- (2) The Minister of Food and Drug Safety may delegate part of his or her authority under this Act to the heads of the regional offices of food and drug safety, the Director General of the National Institute of Food and Drug Safety Evaluation, or the Mayor/*Do* Governor, as prescribed by Presidential Decree.
- (3) The Minister of Food and Drug Safety and the Mayors/*Do* Governor may delegate part of their authority under this Act to the heads of Sis/Guns/Gus or the heads of public health clinics, as prescribed by Presidential Decree.
- (4) The heads of Sis/Guns/Gus may delegate part of their authority under this Act to the heads of public health clinics, as prescribed by Presidential Decree.
- (5) The Minister of Health and Welfare and the Minister of Food and Drug Safety may entrust an organization under Article 67 or the Institute of Drug Safety and Risk Management with part of the pharmaceutical affairs under this Act, as prescribed by Presidential Decree.

[This Article Wholly Amended by Act No. 11690, Mar. 23, 2013]

Article 85 (Special Cases concerning Animal Drugs)

- (1) Drugs, etc., the purpose of which is to be used exclusively for animals, among the matters under the jurisdiction of the Minister of Health and Welfare or the Minister of Food and Drug Safety under this Act, shall be controlled by the Minister of Agriculture, Food and Rural Affairs or the Minister of Oceans and Fisheries, and the "Minister of Health and Welfare" or "Minister of Food and Drug Safety" in the corresponding provisions of this Act shall be construed as the "Minister of Agriculture, Food and Rural Affairs" or "Minister of Oceans and Fisheries", and "Ordinance of the Ministry of Health and Welfare" or "Ordinance of the Prime Minister" shall be construed as "Ordinance of the Ministry of Agriculture, Food and Rural Affairs" or "Ordinance of the Ministry of Oceans and Fisheries". In such cases, when the Minister of Agriculture, Food and Rural Affairs issues Ordinance of the Ministry of Agriculture, Food and Rural Affairs or the Minister of Oceans and Fisheries issues Ordinance of the Ministry of Oceans and Fisheries, he or she shall consult with the Minister of Health and Welfare or the Minister of Food and Drug Safety. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 15891, Dec. 11, 2018>
- (2) The Minister of Agriculture, Food and Rural Affairs or the Minister of Oceans and Fisheries may determine standards for use, such as animals for which such drugs are used, dose regimen, dose, and the period for prohibiting its use, regarding any of the following medications that are animal drugs, etc. used to treat or prevent animal diseases: <Amended by Act No. 15891, Dec. 11, 2018>
 1. Medications designated as ones that may remain in an animal's body and cause any risk to human health;
 2. Medications designated to be administered or used for the purpose of preventing infectious diseases in livestock or aquatic animals.
- (3) A person who intends to use animal drugs, etc., the standards for use of which have been determined under paragraph (2), shall observe such standards: *Provided*, That where the person uses them in accordance with the treatment or prescription of a veterinarian or an aquatic organism disease inspector, he or she need not observe such standards. <Amended by Act No. 15891, Dec. 11, 2018>
- (4) Notwithstanding Article 44, a person who has opened a veterinary hospital under the Veterinarians Act may distribute animal drugs to any person who cares for animals or may purchase animal drugs for the purpose of treating animals from any pharmacy founder under the proviso of Article 50 (2). In such cases, the person who has opened a veterinary hospital shall prepare and retain distribution and purchase records, as prescribed by Ordinance of the Ministry of Agriculture, Food and Rural Affairs or Ordinance of the Ministry of Oceans and Fisheries. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 11690, Mar. 23, 2013>
- (5) Notwithstanding Article 44, a person who has established an aquatic organism disease inspection

center under the Aquatic Life Disease Control Act may distribute drugs for aquatic organisms to any aquaculture business entity. <Amended by Act No. 8852, Jul. 21, 2011>

- (6) No person who has been permitted as a wholesaler of animal drugs under this Act shall distribute any of the following animal drugs, which are determined and publicly notified by the Minister of Agriculture, Food and Rural Affairs or the Minister of Oceans and Fisheries, without a prescription issued by a veterinarian or an aquatic organism disease inspector: *Provided*, That the same shall not apply to where such drugs are distributed among a person who has opened a veterinary hospital, a person who has established an aquatic organism disease inspection center, a pharmacy founder, or a wholesaler of animal drugs: <Newly Inserted by Act No. 11251, Feb. 1, 2012; Act No. 11690, Mar. 23, 2013>
1. Animal drugs which are likely to cause any risk to human and animal health if misused or abused;
 2. Animal drugs which require the expertise of a veterinarian or an aquatic organism disease inspector;
 3. Animal drugs deemed likely to cause disorder in the dosage form and pharmacological actions.
- (7) A pharmacy founder may distribute animal drug under the subparagraphs of paragraph (6) without a prescription issued by a veterinarian or an aquatic organism disease inspector: *Provided*, That the same shall not apply to any of the following animal drugs prescribed by the Minister of Agriculture, Food and Rural Affairs or the Minister of Oceans and Fisheries: <Newly Inserted by Act No. 11251, Feb. 1, 2012; Act No. 11690, Mar. 23, 2013>
1. An antibiotic substance medication for injection;
 2. A biological medication for injection.
- (8) Notwithstanding paragraphs (6) and (7), a person who distributes animal drugs pursuant to this Act may distribute animal drugs under the subparagraphs of paragraph (6) without a prescription issued by a veterinarian or an aquatic organism disease inspector, where he or she falls under any of the following cases. In such cases, the methods for distribution, the management of records, the scope of purchasers and matters to be observed, and other necessary matters shall be prescribed by Ordinance of the Ministry of Agriculture Food and Rural Affairs or Ordinance of the Ministry of Oceans and Fisheries: <Newly Inserted by Act No. 11251, Feb. 1, 2012; Act No. 11690, Mar. 23, 2013>
1. Where such drugs are distributed to a livestock farmer or an aquaculture household on an island or remote area determined by the Minister of Agriculture, Food and Rural Affairs or the Minister of Oceans and Fisheries;
 2. Where the use of animal drugs has been ordered by the Minister of Agriculture, Food and Rural Affairs, the Minister of Oceans and Fisheries, the Mayor/Do Governor, or the head of a *Sil/Gun/Gu* for purposes of emergent control pursuant to Article 15 of the Act on the Prevention of Contagious Animal Diseases or Article 13 of the Aquatic Life Disease Control Act.
- (9) A person who distributes animal drugs, etc. pursuant to this Act shall comply with each of the following matters: <Amended by Act No. 15891, Dec. 11, 2018>
1. Matters prescribed by Ordinance of the Ministry of Agriculture Food and Rural Affairs or Ordinance of the Ministry of Oceans and Fisheries to establish the distribution system of animal drugs, etc. and to maintain order in distribution, such as prohibition against an act of collusion, designation of distribution places, and management of records;
 2. Matters prescribed by Ordinance of the Ministry of Agriculture Food and Rural Affairs or Ordinance of the Ministry of Oceans and Fisheries to ensure the safe use of animal drugs, etc., such as preventing any abuse or misuse thereof.
- (10) Where a person who distributes animal drugs, etc. pursuant to this Act distributes animal drugs, etc. for which Ordinance of the Ministry of Agriculture Food and Rural Affairs or Ordinance of the Ministry of Oceans and Fisheries provides that it is necessary to restrict the distribution due to the potential risk to humans or animals, he or she shall prepare and retain records on the transactions of such drugs, etc. <Newly Inserted by Act No. 15891, Dec. 11, 2018>

- (11) A person who manages the affairs of a wholesaler of animal drugs pursuant to this Act shall receive education on safety assurance and quality management of animal drugs, as prescribed by Ordinance of the Ministry of Agriculture, Food and Rural Affairs or Ordinance of the Ministry of Oceans and Fisheries. <Newly Inserted by Act No. 13655, Dec. 29, 2015; Act No. 15891, Dec. 11, 2018>
- (12) Notwithstanding Article 47 (1), a person who has been permitted as a wholesaler of animal drugs may distribute animal drugs to persons who care for animals or aquaculture business entities, as prescribed by Ordinance of the Ministry of Agriculture, Food and Rural Affairs or Ordinance of the Ministry of Oceans and Fisheries. <Newly Inserted by Act No. 13655, Dec. 29, 2015; Act No. 15891, Dec. 11, 2018>

Article 85-2 (Special Cases concerning Prophylactic Drugs and Therapeutic Drugs in Cases of National Emergencies)

- (1) In order to properly address a pandemic of infectious diseases spread through bioterrorism prescribed in the Infectious Disease Control and Prevention Act and other infectious diseases or to address radiation emergencies prescribed in Article 2 (1) 7 of the Act on Physical Protection and Radiological Emergency, the Minister of Food and Drug Safety may perform any of the following acts at the request of the heads of relevant ministries:
1. Notwithstanding Article 31 (2), an act of requiring a drug manufacturer to manufacture a drug for which permission by item or a notification by item has not been granted or filed;
 2. Notwithstanding Article 42 (1), an act of requiring an importer to import a drug for which permission by item or a notification by item has not been granted or filed;
 3. An act of requiring a drug manufacturer or an importer to manufacture or import a drug other than a drug for which permission by item or a notification by item has already been granted or filed, by specifying other dose regimen, dose, efficacy, effect, period of use, etc. inconsistent with the details permitted or notified.
- (2) Where the Minister of Health and Welfare intends to extend the expiration date of a drug stored pursuant to Article 40 (1) of the Infectious Disease Control and Prevention Act, he or she may request the Minister of Food and Drug Safety to extend the expiration date.
- (3) Matters necessary for the types and subjects of drugs for which extension of the expiration date can be requested pursuant to paragraph (2), procedures for requesting the extension of the expiration date, and the condition, methods, standards, etc. for storage may be prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted by Act No. 13114, Jan. 28, 2015]

Article 85-3 (Special Cases concerning Ginseng Varieties under the Ginseng Industry Act)

- (1) A ginseng varieties inspection agency specified in Article 17 (1) of the Ginseng Industry Act (hereafter in this Article, referred to as “ginseng varieties inspection agency”) may file an application for permission for drug manufacturing business pursuant to Article 31 (1) and may file an application for permission by item or file a notification by item under Article 31 (2) of the red ginseng and white ginseng inspected by the relevant ginseng varieties inspection agency (referring to red ginseng and white ginseng defined in subparagraphs 3 and 5 of Article 2 of the Ginseng Industry Act, excluding imported ones; hereinafter the same shall apply).
- (2) A person who has filed a notification under Article 12 (1) of the Ginseng Industry Act (hereafter in this Article, referred to as “ginseng varieties manufacturer”) may distribute the red ginseng and white ginseng for which permission by item or a notification by item has been obtained or filed pursuant to paragraph (1), to any of the following persons, notwithstanding Article 44:
1. Herb druggists;
 2. Drug wholesalers;
 3. Pharmacy founders;

4. Medical institution founders handling herbal drugs.

- (3) Articles 47, 69, 71, 94, 94-2, 95, 96, and 97 shall apply to any ginseng varieties manufacturer who distributes red ginseng and white ginseng pursuant to paragraph (2). In such cases, a ginseng varieties manufacturer shall be construed as a “manufacturer of drugs, etc.” and “person who obtained permission by item of a drug”, and the “factory, warehouse, store, or office of a ginseng varieties manufacturer” shall be construed as a “factory, warehouse, store, or office where drugs are manufactured, stored, or handled”.

[This Article Newly Inserted by Act No. 13320, May 18, 2015]

Article 85-4 (Special Cases concerning Obligation to Preserve and Retain Records)

Where any record to be preserved and retained under this Act is destroyed due to a natural disaster or other *force majeure* circumstances, the person obliged to preserve and retain such record shall be exempt from the relevant obligation prescribed in this Act.

[This Article Newly Inserted by Act No. 15709, Jun. 12, 2018]

Article 86 (Projects for Relief of Injury from Side Effects of Drugs)

- (1) The Minister of Food and Drug Safety shall relieve injury from the side effects of drugs, and an organization consisting of drug manufacturers, persons who have obtained permission by item of a drug, or importers shall conduct research projects to facilitate the improvement of safety of drugs and the development of new drugs. *<Amended by Act No. 8643, Oct. 17, 2007; Act No. 12450, Mar. 18, 2014>*
- (2) Drug manufacturers, persons who have obtained permission by item, or importers shall bear necessary expenses incurred in conducting projects prescribed in paragraph (1). *<Amended by Act No. 8643, Oct. 17, 2007>*
- (3) The Government may subsidize projects referred to in paragraph (1), within budgetary limits.
- (4) Matters necessary for projects referred to in paragraph (1) shall be prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>*
- (5) The Minister of Food and Drug Safety may entrust the Institute of Drug Safety and Risk Management with the project to relieve injury from the side effects of drugs. *<Newly Inserted by Act No. 12450, Mar. 18, 2014>*

Article 86-2 (Charges for Relief of Injury from Side Effects of Drugs)

- (1) For the relief of injury prescribed in Article 86 (1), the Minister of Food and Drug Safety shall impose and collect charges for relief of injury from the side effects of drugs (hereinafter referred to as “charges”) on and from drug manufacturers, persons who have obtained permission by item of drugs, or importers. In such cases, the Minister of Food and Drug Safety may entrust the president of the Institute of Drug Safety and Risk Management with such imposition and collection.
- (2) Charges shall consist of basic charges imposed in proportion to the amount of production or import of drugs classified as prescription drugs or over-the-counter drugs under this Act and additional charges imposed on drugs in need of relief of injury from the side effects as recognized by the Minister of Food and Drug Safety after deliberation by the Deliberative Committee, and such charges shall be prescribed by Presidential Decree to the extent not exceeding any of the following amounts:
1. Basic charges: 1/1,000 of the amount of production or import of drugs for the preceding year;
 2. Additional charges: 25/100 of the amount paid for relief of injury from the relevant drugs of the preceding year: *Provided*, That no additional charge shall exceed 1/100 of the amount of production or import of the drugs for the preceding year.
- (3) The president of the Institute of Drug Safety and Risk Management entrusted with the imposition

and collection of charges pursuant to the latter part of paragraph (1) shall determine the amount to be collected as basic charges under paragraph (2) 1 with approval from the Minister of Food and Drug Safety based upon expected expenses for relief of injury, earnings from the operation of charges, government subsidies, etc. within five years, as prescribed by Presidential Decree.

- (4) The president of the Institute of Drug Safety and Risk Management entrusted with the imposition and collection of charges pursuant to the latter part of paragraph (1) shall keep accounting records of charges separately from other accounting records and shall organize and operate a financial operations committee for the imposition, collection, and operation of charges, as prescribed by Presidential Decree. *<Amended by Act No. 15891, Dec. 11, 2018>*
- (5) Where a person obligated to pay a charge fails to make payment by the payment deadline, the Minister of Food and Drug Safety or the president of the Institute of Drug Safety and Risk Management entrusted with the imposition and collection of charges pursuant to the latter part of paragraph (1) shall demand such payment by specifying a period of at least 30 days. In such cases, a surcharge corresponding to a period from the day following the payment deadline until the day before the date payment is made shall be imposed within the scope not exceeding 3/100 of the unpaid charge, and the rate of surcharge shall be prescribed by Presidential Decree.
- (6) Where a person demanded to make payment pursuant to paragraph (5) fails to pay a charge and a surcharge, they shall be collected in the same manner as delinquent national taxes are collected.
- (7) Methods of collecting charges under paragraph (1), deadline for payment, procedures for payment, raising of an objection, and other matters necessary for the imposition, collection, etc. of charges shall be prescribed by Presidential Decree.

[This Article Newly Inserted by Act No. 12450, Mar. 18, 2014]

Article 86-3 (Benefits for Relief of Injury from Side Effects of Drugs)

- (1) If a person who uses a drug suffers from a disease or disability or dies due to the side effects of the drug, the president of the Institute of Drug Safety and Risk Management shall pay him or her any of the following benefits for relief of injury (hereinafter referred to as "benefits for relief of injury"):
 1. Medical expenses;
 2. Lump-sum compensation for disability;
 3. Lump-sum compensation for death;
 4. Funeral expenses.
- (2) Notwithstanding paragraph (1), no benefit for relief of injury shall be paid in any of following cases:
 1. Where the drugs are those determined by the Minister of Food and Drug Safety, which are used for cancer or specific diseases;
 2. Where a disease, disability, or death due to the side effects of a drug has been caused by vaccinations prescribed in the Infectious Disease Control and Prevention Act;
 3. Where a disease, disability, or death has been caused by intention or gross negligence of the injured;
 4. Where a disease, disability, or death has been caused by a medical accident prescribed in the Act on Remedies for Injuries from Medical Malpractice and Mediation of Medical Dispute;
 5. Where money and valuables equivalent to the relief benefits have already been paid according to the Civil Act or other statutes and regulations on the grounds of the same disease, disability, or death;
 6. Other cases prescribed by Ordinance of the Prime Minister.
- (3) The standards for and scope of the payment of benefits for relief of injury, and other matters necessary for payment, etc. shall be prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted by Act No. 12450, Mar. 18, 2014]

Article 86-4 (Procedures for Relief of Injury from Side Effects of Drugs, etc.)

- (1) A person who intends to receive benefits for relief of injury shall file an application for payment of

benefits for relief of injury with the president of the Institute of Drug Safety and Risk Management, along with documents prescribed by Ordinance of the Prime Minister.

- (2) The president of the Institute of Drug Safety and Risk Management upon receipt of an application for benefits for relief of injury shall, without delay, investigate the details of side effects or injury, verify whether the case corresponds to a medical accident, identify the causal relationship with drugs, investigate whether aftereffects of disability occur, and conduct an investigation, appraisal, etc. of the scope of indemnity for injury, restrictions on the payment of benefits for relief of injury, etc.
- (3) The president of the Institute of Drug Safety and Risk Management shall file a request for deliberation with the Deliberative Committee, along with findings of an investigation prescribed in paragraph (2) and an opinion on appraisal within 90 days from the date of receipt of a request for benefits for relief of injury: *Provided*, That where it is impracticable to conduct the investigation and appraisal due to new side effects, etc., the period may be extended by up to 30 days only one time.
- (4) Where the Deliberative Committee decides to pay benefits for relief of injury as a result of deliberation, the president of the Institute of Drug Safety and Risk Management shall pay the benefits for relief of injury within 30 days from the date of such decision.
- (5) Where payment of benefits for relief of injury is not made as payment is restricted on an applicant pursuant to Article 86-3 (2) as a result of deliberation under paragraph (4), the president of the Institute of Drug Safety and Risk Management shall inform the applicant of the fact and grounds for restriction. In such cases, if the president of the Institute of Drug Safety and Risk Management judges that the applicant is eligible for indemnity pursuant to the Civil Act or other statutes and regulations, the president may guide him or her as to the method for obtaining such indemnity, as prescribed by Ordinance of the Prime Minister.
- (6) An application for the payment of benefits for relief of injury shall be filed within the following periods:
 1. Article 86-3 (1) 1: Five years from the date the relevant medical treatment is provided;
 2. Article 86-3 (1) 2 through 4: Five years from the date any disability or death occurs.
- (7) Where the results of deliberation by the Deliberative Committee conflict with the results of deliberation by the Medical Dispute Mediation and Arbitration Committee prescribed in the Act on Remedies for Injuries from Medical Malpractice and Mediation of Medical Dispute, the Minister of Food and Drug Safety and the president of the Institute of Drug Safety and Risk Management shall hold consultation for mediation, as prescribed by Presidential Decree.
- (8) Where the president of the Institute of Drug Safety and Risk Management has an objection against the results of deliberation by the Deliberative Committee, he or she may request the Minister of Food and Drug Safety to make a new decision. In such cases, the Minister of Food and Drug Safety shall consult with the Central Pharmaceutical Affairs Advisory Committee thereabout and inform the president of the Institute of Drug Safety and Risk Management of the results thereof; and the president of the Institute of Drug Safety and Risk Management shall pay benefits for relief of injury within 30 days from the date the Minister of Food and Drug Safety makes a new decision.
- (9) Matters necessary for mediation, procedures and methods therefor, etc. under paragraphs (2) through (8) shall be prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted by Act No. 12450, Mar. 18, 2014]

Article 86-5 (Determination to Cease Payment of Benefits for Relief of Injury, and Collection of Unjust Enrichment)

- (1) Where an applicant is deemed to have aggravated the disease by intention or gross negligence, or have refused or obstructed medical cure, the president of the Institute of Drug Safety and Risk Management may fully or partially cease to pay the benefits for relief of injury.
- (2) Where a person upon receipt of benefits for relief of injury falls under any of the following, the

president of the Institute of Drug Safety and Risk Management shall collect the benefits for relief of injury (referring to twice the amount of benefits for relief of injury in cases falling under subparagraph 1) and deposit them in the charges account as earnings:

1. Where he or she has received benefits for relief of injury by fraud or other improper means;
 2. Where adjustment or mediation is made or conducted for him or her as the case has been proved to be a medical accident after benefits for relief of injury are paid to him or her;
 3. Where benefits for relief of injury have been paid erroneously.
- (3) Matters necessary for the cessation of payment of benefits for relief of injury, collection thereof, etc. under paragraph (1) and (2) shall be prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted by Act No. 12450, Mar. 18, 2014]

Article 86-6 (Investigation of Injury from Side Effects)

- (1) Where the president of the Institute of Drug Safety and Risk Management conducts an investigation and appraisal prescribed in Article 86-4 (2), he or she may request applicants, drug manufacturers, persons who have obtained permission by item, importers, distributors, pharmacy founders, medical institution founders, persons who distribute or handle drugs pursuant to this Act or other statutes, interested parties, or expert witnesses to appear and make a statement or to submit data, articles, etc. necessary for investigation.
- (2) Where the president of the Institute of Drug Safety and Risk Management conducts an investigation and appraisal under Article 86-4 (2), he or she may request the medical personnel (including the relevant medical institution founder) who prescribed the drug causing side effects or the pharmacist who dispensed such drug to make a verbal or written statement on the condition of the patient, acts of prescription and dispensation, etc. as at the time of prescription and dispensation.
- (3) Where the president of the Institute of Drug Safety and Risk Management conducts an investigation and appraisal prescribed in Article 86-4 (2), he or she may have access to a drug manufacturer, person who has obtained permission by item, importer, or distributor of drugs causing side effects or a medical institution, pharmacy, etc. that prescribed or dispensed the relevant drug to investigate, peruse, or duplicate relevant documents or articles. In such cases, the investigator shall carry an identification indicating his or her authority and documents stating matters prescribed by Presidential Decree, such as the period and scope of an investigation, persons in charge of the investigation, and relevant statutes and regulations, and show it to relevant persons. *<Amended by Act No. 13655, Dec. 29, 2015>*
- (4) For the investigation necessary to identify the causal relationship of side effects for a person who has filed an application for benefits for relief of injury, the president of the Institute of Drug Safety and Risk Management may request a government agency or a public institution prescribed in the Act on the Management of Public Institutions to provide information in a form by which personal information can be identified for data matching. In such cases, a person upon receipt of such request shall comply therewith, unless there is good cause.
- (5) Except as provided in paragraphs (1) through (4), matters necessary for the investigation and appraisal of injury from side effects shall be prescribed by Ordinance of the Prime Minister.
- (6) Except as provided in this Act, the Framework Act on Administrative Investigations shall apply to the procedures, methods, etc. for investigating, perusing, or duplicating documents or articles under paragraph (3). *<Newly Inserted by Act No. 13655, Dec. 29, 2015>*

[This Article Newly Inserted by Act No. 12450, Mar. 18, 2014]

Article 86-7 (Protection of Rights to Benefits for Relief of Injury)

No right to benefits for relief of injury prescribed in this Act shall be transferred, seized, or provided as security.

[This Article Newly Inserted by Act No. 12450, Mar. 18, 2014]

Article 86-8 (Exemption from Public Dues)

The State or local governments shall not impose public dues on an amount paid as benefits for relief of injury.

[This Article Newly Inserted by Act No. 12450, Mar. 18, 2014]

Article 87 (Prohibition of Divulgence of Confidential Information)

- (1) Neither pharmacist nor oriental medicine pharmacist shall divulge other person's confidential information which he or she has become aware of while dispensing and distributing drugs, except as provided in this Act or other statutes and regulations. *<Amended by Act No. 8643, Oct. 17, 2007>*
- (2) No person who has become aware of trade secrets of a person who has obtained permission by item of a drug, a drug importer, a drug wholesaler, etc. in the course of performing business under Article 47-3 (2) shall divulge the trade secrets to third parties or use them for other purposes than the business purposes. *<Newly Inserted by Act No. 8643, Oct. 17, 2007; Act No. 14328, Dec. 2, 2016>*

Article 87-2 (Prohibition against Use of Similar Names)

No person other than a manufacturer of drugs, etc., a person who has filed a notification of contract manufacturing and distribution business, a person who has obtained permission by item, an importer, or a distributor under this Act shall use similar names prescribed by Ordinance of the Prime Minister, such as pharmaceuticals and medicine, in his or her trade name.

[This Article Newly Inserted by Act No. 14328, Dec. 2, 2016]

Article 88 (Protection of Data Submitted)

- (1) With respect to data submitted pursuant to Articles 31, 31-2, 32 through 34, 35-2, or 42, where a person who has submitted such data files a written request for protection of them, the Minister of Food and Drug Safety shall not disclose such data: *Provided*, That where the Minister of Food and Drug Safety deems it necessary to disclose such data for public interest, he or she may disclose it. *<Amended by Act No. 10788, Jun. 7, 2011; Act No. 11690, Mar. 23, 2013>*
- (2) No person who has perused or examined the submitted data, the protection of which is requested under paragraph (1), shall disclose the details of such data that he or she has become aware of.

Article 89 (Succession to Status of Manufacturers)

- (1) Where a manufacturer of drugs, etc., a person who has obtained permission by item of a drug, a person who has filed a notification of contract manufacturing and distribution business, a drug distributor (excluding herb druggists), a person who has obtained approval of a clinical trial protocol, or a person who has been designated as an inspection institution, etc. (hereafter in this Article and Article 89-2, referred to as "manufacturer, etc.") deceases or transfers the business or where a merger of corporate manufacturers, etc. occurs, a successor, transferee, corporation surviving such merger, or corporation incorporated by such merger shall succeed to the status of the manufacturer, etc.: *Provided*, That the same shall not apply where the transferee, the corporation surviving the merger, or the corporation incorporated by the merger falls under any of the following cases: *<Amended by Act No. 8643, Oct. 17, 2007; Act No. 10512, Mar. 30, 2011; Act No. 10788, Jun. 7, 2011; Act No. 14926, Oct. 24, 2017>*
 1. A manufacturer of drugs, etc., a person who has obtained permission by item of a drug, a person who has filed a notification of contract manufacturing and distribution business, and a person who has obtained approval of a clinical trial protocol: Where he or she falls under any of the subparagraphs of Article 31 (8);
 2. A drug distributor: Where he or she falls under any of the subparagraphs of Article 46.
- (2) Where a manufacturer of drugs, etc., a person who has obtained permission by item of a drug, a person who has filed a notification of contract manufacturing and distribution business, or an

importer has transferred the business of drugs, etc. for which permission has been obtained or a notification has been filed regarding manufactured items or imported items pursuant to Article 31 (2) through (4) or 42 (1), another manufacturer, person who has obtained permission by item of a drug, person who has filed a notification of contract manufacturing and distribution business, or importer who takes over such business shall succeed to the status of the previous manufacturer, person who obtained permission by item of a drug, person who filed a notification of contract manufacturing and distribution business, or importer with respect to permission for and a notification of the relevant items. <Amended by Act No. 10788, Jun. 7, 2011>

(3) A person who has succeeded to the status of a manufacturer, etc. pursuant to paragraphs (1) and (2) shall file a notification with the Minister of Food and Drug Safety (referring to the head of a *Si/Gun/Gu* in cases of a drug distributor) within one month from the date of succession, as classified in the following subparagraphs: *Provided*, That where a successor who succeeded to the status of a manufacturer, etc. pursuant to paragraph (1) falls under any subparagraph of paragraph (1), he or she shall transfer such status to another person within six months from the date when succession commenced: <Amended by Act No. 11690, Mar. 23, 2013>

1. A person who has succeeded to the status of a manufacturer of drugs, etc., a person who obtained permission by item of a drug, or a person who filed a notification of contract manufacturing and distributions business: As prescribed by Ordinance of the Prime Minister;
2. A person who has succeeded to the status of a drug distributor: As prescribed by Ordinance of the Ministry of Health and Welfare.

Article 89-2 (Succession to Effects of Dispositions of Administrative Sanctions)

Where the status has been succeeded pursuant to Article 89, a transferee, a corporation surviving a merger, or a corporation incorporated by a merger shall succeed to the effects of administrative dispositions on the previous manufacturer, etc. and importer for one year from the date such disposition took place, and where the procedures for administrative dispositions are underway, the procedures for disposition of administrative sanctions may proceed for the transferee, the corporation surviving a merger, the corporation incorporated by a merger: *Provided*, That the same shall not apply where a new manufacturer, etc. (excluding the succession to the status by inheritance) or an importer succeeds to business and is not aware of such disposition or violation.

[This Article Newly Inserted by Act No. 10788, Jun. 7, 2011]

Article 90 (Monetary Awards)

A monetary award may be paid to any person who has reported on or accused other persons of the fact of violating Article 23, 24 (1) and (2), 26 (1), 27 (1) and (3), or 50 (1) (including cases applied *mutatis mutandis* under Article 44-5 (1)) and (2) to any supervisory agency or any investigative agency, as prescribed by Presidential Decree. <Amended by Act No. 11421, May 14, 2012>

Article 91 (Establishment of the Korea Orphan and Essential Drug Center)

(1) The Korea Orphan and Essential Drug Center (hereinafter referred to as the "Center") shall be established to perform the affairs of providing various information on the following drugs and supplying (including the affairs of dispensation and administration of drugs; hereinafter the same shall apply) such drugs: <Amended by Act No. 14328, Dec. 2, 2016; Act No. 15891, Dec. 11, 2018>

1. Orphan drugs;
2. National essential drugs;
3. Other drugs that need to be urgently introduced for public health or require support for the stable supply, among the drugs deemed necessary by the Minister of Food and Drug Safety.

(2) The Center shall be a corporation.

(3) The articles of association of the Center shall contain each of the following matters: <Newly Inserted

by Act No. 15891, Dec. 11, 2018>

1. Objectives;
 2. The name;
 3. The location of the principal office;
 4. Matters concerning assets;
 5. Matters concerning the executive officers and employees;
 6. The operation of the board of directors;
 7. The scope, details, and execution of the business;
 8. Accounting;
 9. The methods of public announcement;
 10. Amendment of the articles of association;
 11. Other important matters concerning the operation of the Center.
- (4) Where the Center intends to modify any matter stated in the articles of association, it shall obtain authorization from the Minister of Food and Drug Safety. <Newly Inserted by Act No. 15891, Dec. 11, 2018>
- (5) The provisions governing an incorporated foundation in the Civil Act shall apply *mutatis mutandis* to the Center, except as provided in this Act. <Amended by Act No. 15891, Dec. 11, 2018>
- (6) Matters necessary for the operation, etc. of the Center established under paragraph (1) shall be prescribed by Presidential Decree. <Amended by Act No. 15891, Dec. 11, 2018>

Article 92 (Projects of the Center)

- (1) The Center shall conduct the following projects: <Amended by Act No. 11690, Mar. 23, 2013; Act No. 14328, Dec. 2, 2016; Act No. 15891, Dec. 11, 2018>
1. Projects for collecting various information regarding drugs prescribed in each subparagraph of Article 91 (1), and constructing a computer network;
 2. Projects for supplying and stockpiling drugs prescribed in each subparagraph of Article 91 (1). In such cases, the president of the Center shall install a dispensary in the Center, designate a pharmacist from among the employees of the Center, and have such pharmacist be responsible for such project;
 - 2-2. Projects for contract manufacturing and distribution of drugs prescribed in each subparagraph of Article 91 (1), pursuant to Article 31 (3) 4;
 3. Projects related to the establishment of a stable supply base of, support for research and development of, and support for safe use of national essential drugs;
 4. Other projects related to drugs prescribed in each subparagraph of Article 91 (1), which are deemed by the Minister of Food and Drug Safety.
- (2) Where the Center implements projects specified in paragraph (1), the Minister of Food and Drug Safety may provide the Center with financial assistance, etc. <Amended by Act No. 11690, Mar. 23, 2013>

Article 92-2 (Legal Fiction as Public Officials for Purposes of Penalty Provisions)

Any of the following persons shall be deemed a public official for the purposes of Articles 127 and 129 through 132 of the Criminal Act: <Amended by Act No. 15709, Jun. 12, 2018; Act No. 15891, Dec. 11, 2018>

1. Drug epidemiological inspectors (in cases of an employee of the Institute of Drug Safety and Risk Management, the application of the penalty provisions of Article 127 of the Criminal Act shall be excluded);
2. The executive officers and employees of the Center;
3. The executive officers and employees of a corporation engaged in the affairs entrusted under Article 68-2 (2).

[This Article Newly Inserted by Act No. 12450, Mar. 18, 2014]

Article 92-3 (Re-Examination of Regulation)

The Minister of Food and Drug Safety shall examine the appropriateness of permission for preferential distribution of items and the amount of administrative fines referred to in Article 97-2 every three years, counting from January 1, 2015 (referring to the period that ends on the day before January 1 of every third year) and shall take measures, such as making improvements.

[This Article Newly Inserted by Act No. 13219, Mar. 13, 2015]

CHAPTER IX Penalty Provisions

Article 93 (Penalty Provisions)

(1) Any of the following persons shall be punished by imprisonment with labor for not more than five years or by a fine not exceeding 50 million won: <Amended by Act No. 8643, Oct. 17, 2007; Act No. 13114, Jan. 28, 2015; Act No. 13655, Dec. 29, 2015; Act No. 14926, Oct. 24, 2017; Act No. 15891, Dec. 11, 2018>

1. A person who lends his or her license to other persons, in violation of Article 6 (3);
2. A person who establishes a pharmacy, in violation of Article 20 (1);
3. A person who violates Article 23 (1);
4. A person who fails to obtain permission, to file a notification, to obtain permission for modification, or to file a notification of modification, in violation of Article 31 (1) through (4) or (9);
5. A person who fails to obtain permission, to file a notification, to obtain permission for modification, or to file a notification of modification, in violation of Article 42 (1);
6. A person who violates Article 43;
7. A person who violates Article 44 (1);
8. A person who distributes drugs without obtaining permission under Article 44 (2) 2;
9. A person who violates Article 53 (1);
10. A person who violates Article 61 (including cases applied *mutatis mutandis* under Article 66):
Provided, That the same shall not apply to those who violate Article 56 (2) (including cases applied *mutatis mutandis* under Article 44-5 (1)) or Article 65 (2);
11. A person who falsely prepares and issues a clinical trial report, an analysis report of clinical trial samples, or a non-clinical study report referred to in Article 34-2 (3) 5 or 34-3 (3).

(2) In cases falling under paragraph (1), imprisonment with labor and a fine may be imposed concurrently.

Article 94 (Penalty Provisions)

(1) Any of the following persons shall be punished by imprisonment with labor for not more than three years or by a fine not exceeding 30 million won: *Provided*, That any person who violates Article 87 (1) may be prosecuted only when a criminal complaint is filed against him or her: <Amended by Act No. 8643, Oct. 17, 2007; Act No. 10788, Jun. 7, 2011; Act No. 11251, Feb. 1, 2012; Act No. 11421, May 14, 2012; Act No. 13114, Jan. 28, 2015; Act No. 14328, Dec. 2, 2016; Act No. 14926, Oct. 24, 2017; Act No. 15891, Dec. 11, 2018>

1. A person who violates Article 3 (3) or 4 (3);
2. A person who engages in collusion, in violation of Article 24 (2);
3. A person who violates the main clause of Article 34 (1), Article 34 (3) 1 or 2, or paragraph (4) of that Article, or a person who violates an order prescribed in paragraph (6) of that Article;
- 3-2. A person who conducts clinical trials without obtaining designation, in violation of Article 34-2 (1);
- 3-3. A person who conducts clinical trials without obtaining designation of modification, in

- violation of the main clause of Article 34-2 (2);
- 3-4. A person who violates Article 34-2 (3) 1 or 2;
 4. A person who violates Article 37 (3) (including cases applied *mutatis mutandis* under Article 42 (5));
 - 4-2. A person who fails to recall drugs or to take necessary measures for recall, in violation of the former part of Article 39 (1) (including cases applied *mutatis mutandis* under Article 44-5 (1));
 5. A person who violates Article 45 (5);
 - 5-2. A person who provides economic benefits, etc. in violation of Article 47 (2) or acquires economic benefits, etc. in violation of paragraph (3) of that Article. In such cases, any economic benefit, etc. acquired shall be confiscated; and where it is impossible to confiscate such economy benefit, etc., a value equivalent thereto shall be collected;
 6. Deleted; <by Act No. 13655, Dec. 29, 2015>
 7. A person who distributes, stores, or displays drugs, in violation of Article 49;
 8. A person who violates Article 50 (1) (including cases applied *mutatis mutandis* under Article 44-5 (1));
 9. A person who distributes, manufactures, imports, stores, or displays drugs, in violation of Article 62 (including case applied *mutatis mutandis* under Article 66);
 - 9-2. A person who divulges confidential information, in violation of Article 68-9;
 10. A person who refuses an order to manufacture a drug or an order to commence business without good cause, in violation of Article 70 (2);
 11. A person who violates an order under Articles 71 (1) and (2) (including cases applied *mutatis mutandis* under Article 44-5 (1)) and 72 (1) and (2) (including cases applied *mutatis mutandis* under Article 44-5 (1)), or refuses, obstructs, or evades the recall and destruction of articles, which are conducted by relevant public officials pursuant to Article 71 (3) (including cases applied *mutatis mutandis* under Article 44-5 (1)), and other necessary dispositions;
 12. A person who violates Article 87 or 88 (2).
- (2) In cases falling under paragraph (1), imprisonment with labor and a fine may be imposed concurrently.

Article 94-2 Deleted. <by Act No. 14328, Dec. 2, 2016>

Article 95 (Penalty Provisions)

- (1) Any of the following persons shall be punished by imprisonment with labor for not more than one year or by a fine not exceeding 10 million won: <Amended by Act No. 8558, Jul. 27, 2007; Act No. 8643, Oct. 17, 2007; Act No. 10324, May 27, 2010; Act No. 10788, Jun. 7, 2011; Act No. 11251, Feb. 1, 2012; Act No. 11421, May 14, 2012; Act No. 11985, Jul. 30, 2013; Act No. 12450, Mar. 18, 2014; Act No. 13114, Jan. 28, 2015; Act No. 13219, Mar. 13, 2015; Act No. 13655, Dec. 29, 2015; Act No. 14926, Oct. 24, 2017; Act No. 15709, Jun. 12, 2018; Act No. 15891, Dec. 11, 2018; Act No. 16250, Jan. 15, 2019>
1. A person who fails to file for registration of establishment in violation of the former part of Article 20 (2);
 2. A person who violates Article 21 (1) and (2);
 3. A person who violates Article 23 (2), (3), (4), (6), and (7);
 4. A person who refuses to dispense drugs without good cause, in violation of Article 24 (1);
 5. A person who dispenses drugs in violation of Article 26 (1);
 6. A person who violates Article 27 (1), (3), and (4);
 - 6-2. A person who fails to obtain insurance or to compensate test subjects in compliance with the procedures, etc. for compensation explained to them in advance, in violation of Article 34 (3) 5;
 - 6-3. A person who fails to evaluate, record, retain, or report the safety information of drugs, etc. for clinical trials or who evaluates, records, retains, or reports such data falsely, in violation of Article 34 (3) 6;
 - 6-4. A person who fails to prepare, retain, or report records on clinical trials or who prepares, retains,

- or reports such records falsely, in violation of Article 34-2 (3) 5 (excluding any violation prescribed in Article 93 (1) 11);
7. A person who fails to perform the affairs of safety management, in violation of Article 36 (including cases applied *mutatis mutandis* under Article 42 (5)), 37 (2) (including cases applied *mutatis mutandis* under Article 42 (5)) or 37-3 (1) (including cases applied *mutatis mutandis* under Article 42 (5));
 - 7-2. A person who fails to comply with the duty to manage the manufacturing or production of drugs, etc., in violation of Article 37 (1) or 38 (1);
 - 7-3. A person who fails to report a plan for recall or files a false report, in violation of the latter part of Article 39 (1);
 8. A person who violates Article 47 (1) (excluding Article 47 (1) 3 (b) and including cases applied *mutatis mutandis* under Article 44-5 (1)) or (4), or 85 (9);
 - 8-2. A person who removes the seal on a container or package of drugs affixed and distributes them, in violation of the main clause of Article 48;
 9. A person who distributes prescription drugs, in violation of Article 50 (2);
 - 9-2. A person who is registered under Article 50-2 (4), by fraud or other improper means;
 - 9-3. A person who files an application for prohibition of distribution or permission for preferential distribution of items under Article 50-5, by fraud or other improper means;
 10. A person who violates Article 60 (including cases applicable *mutatis mutandis* pursuant to Article 66), 64 (1), or 68;
 - 10-2. A person who arranges or advertises the distribution of drugs, in violation of Article 61-2 (1);
 - 10-3. A person who reports the details of agreement prescribed in Article 69-3, by fraud or other improper means;
 11. A person who distributes animal drugs without a prescription, in violation of Article 85 (6) and (7);
 12. A person who receives benefits for relief of injury by fraud or other improper means prescribed in Article 86-5 (2) 1.
- (2) Imprisonment with labor and a fine under paragraph (1) may be imposed concurrently.
- (3) Where a person is sentenced to punishment for committing a crime prescribed in paragraph (1) 7-2 and commits a crime prescribed in that subparagraph again within three years from the date his or her sentence becomes final and conclusive, the punishment shall be aggravated by up to 1/2 of the corresponding punishment. <Newly Inserted by Act No. 15891, Dec. 11, 2018>

Article 95-2 (Penalty Provisions)

A person who violates Article 26 (2) shall be punished by a fine not exceeding three million won.

[This Article Newly Inserted by Act No. 8558, Jul. 27, 2007]

Article 96 (Penalty Provisions)

Any of the following persons shall be punished by a fine not exceeding two million won: *Provided*, That a person who violates Article 30 (2) may be prosecuted only where a criminal complaint is filed against him or her: <Amended by Act No. 8643, Oct. 17, 2007; Act No. 10788, Jun. 7, 2011; Act No. 11251, Feb. 1, 2012; Act No. 11421, May 14, 2012; Act No. 12450, Mar. 18, 2014; Act No. 13114, Jan. 28, 2015; Act No. 13655, Dec. 29, 2015; Act No. 14328, Dec. 2, 2016; Act No. 14926, Oct. 24, 2017; Act No. 15891, Dec. 11, 2018>

1. A person who violates Article 24 (3);
2. A person who violates Articles 28, 29, or 30 (1), (2) and (3);
3. A person who violates Article 37-3 (2) or 47 (1) 3 (b);
- 3-2. A person who releases any drug into the market without placing an identification mark thereon or without registering an identification mark, in violation of Article 38-2 (1) (including cases applied

mutatis mutandis under Article 42 (5));

- 3-3. A person who releases any drug into the market without registering a modification, in violation of Article 38-2 (2) (including cases applied *mutatis mutandis* under Article 42 (5));
- 3-4. A person who fails to prepare an expense report or to retain the relevant expense report, books related thereto, and evidentiary data, in violation of Article 47-2 (1);
- 3-5. A person who prepares a false expense report under Article 47-2 (1);
- 3-6. A person who fails to comply with the request to submit an expense report under Article 47-2 (2), books related thereto, and evidentiary data;
4. A person who violates Article 56 (1), 57, 58, 63 (including cases applied *mutatis mutandis* under Article 66), 65 (1), or 65-2, or subparagraphs 1 through 3 of Article 65-3;
5. A person who refuses, obstructs, or evades any investigation, inspection, inquiry, collection, etc. by drug epidemiological inspectors or relevant public officials prescribed in Article 68-12 (3) or 69 (1) (including cases applied *mutatis mutandis* in Article 44-5 (1));
6. A person who violates an order for report, announcement, inspection, improvement, replacement, etc. prescribed in Articles 69 (1) (including cases applied *mutatis mutandis* under Article 44-5 (1)), 72 (3) and (4), 73, 74, and 75;
7. A person who refuses, obstructs, or evades investigation, perusal, or duplication prescribed in Article 86-6 (3) without good cause.

Article 97 (Joint Penalty Provisions)

Where the representative of a corporation or an agent or employee of, or any other person employed by, the corporation or an individual commits any violations described in Article 93, 94, 94-2, 95, 95-2, or 96 in connection with the business affairs of the corporation or individual, the corporation or individual shall, in addition to punishing the violators accordingly, be punished by a fine prescribed in the relevant Article: *Provided*, That this shall not apply where such corporation or individual has not been negligent in giving due attention and supervision concerning the relevant business affairs to prevent such violation.

[This Article Wholly Amended by Act No. 10788, Jun. 7, 2011]

Article 97-2 (Administrative Fines)

- (1) A person who fails to report the details of agreement under Article 69-3 without good cause shall be subject to an administrative fine of not more than 50 million won.
- (2) The administrative fine referred to in paragraph (1) shall be imposed and collected by the Minister of Food and Drug Safety, as prescribed by Presidential Decree.

[This Article Newly Inserted by Act No. 13219, Mar. 13, 2015]

Article 98 (Administrative Fines)

- (1) Any of the following persons shall be subject to an administrative fine of not more than one million won: <Amended by Act No. 8643, Oct. 17, 2007; Act No. 10788, Jun. 7, 2011; Act No. 11421, May 14, 2012; Act No. 11985, Jul. 30, 2013; Act No. 12450, Mar. 18, 2014; Act No. 13114, Jan. 28, 2015; Act No. 14328, Dec. 2, 2016; Act No. 14926, Oct. 24, 2017; Act No. 15891, Dec. 11, 2018; Act No. 16250, Jan. 15, 2019>
 1. A person who fails to file a notification of a pharmacist or oriental medicine pharmacist, in violation of Article 7;
 2. A person who fails to receive training and education prescribed in Article 15;
 - 2-2. A person who fails to file for registration of modification, in violation of the latter part of Article 20 (2);
 - 2-3. A person who uses the word "pharmacy" or similar names, in violation of Article 20 (6);
 3. A person who fails to observe matters necessary for the management of a pharmacy even after

- receiving a corrective order referred to in Article 69-4, in violation of Article 21 (3);
- 3-2. A person who fails to provide medical counselling, in violation of Article 24 (4);
- 4. A person who fails to file a notification of business closure, in violation of Article 22 or Article 40 (1) (including cases applied *mutatis mutandis* in Article 42 (5));
- 4-2. A person who fails to receive education, in violation of Article 37-2 (including cases applied *mutatis mutandis* in Article 42 (5));
- 4-3. A person who fails to receive education, in violation of Article 37-4 (including cases applied *mutatis mutandis* in Article 42 (5));
- 4-4. A person who fails to file a report on modification in violation of the proviso of Article 34 (1) or the proviso of Article 34-2 (2) or who publicly announces the recruitment of subjects of a clinical trial in violation of Article 34 (3) 3;
- 4-5. A person who fails to have persons engaged in clinical trials receive education, in violation of Article 34-4 (1) and (2);
- 5. A person who fails to file a report on production performance, import performance, etc. of drugs, etc., in violation of Article 38 (2) (including cases applied *mutatis mutandis* in Article 42 (5));
- 5-2. A person who fails to implement measures necessary for drugs, etc. in violation of Article 40 (2) (including cases applied *mutatis mutandis* in Article 42 (5));
- 6. Deleted; <by Act No. 11251, Feb. 1, 2012>
- 6-2. A person who fails to file a notification of the manufacturing, etc. of pharmacy medication or dispensary medication, in violation of Article 41 (1);
- 6-3. A person who fails to file a notification of business closure, suspension, or resumption, in violation of the main clause of Article 44-2 (4);
- 6-4. A person who fails to receive education, in violation of an order issued under Article 44-3 (2);
- 7. A person who fails to abide by the matters to be observed by distributors of safe and readily available drugs, in violation of Article 44-4;
- 7-2. A person who fails to submit the details of supply of drugs, in violation of Article 47-3 (2) (including cases applied *mutatis mutandis* under Article 44-5 (2));
- 7-3. A person who fails to indicate the price of a drug on the container or package of a drug even after receiving a corrective order referred to in Article 69-4, in violation of Article 56 (2) (including cases applied *mutatis mutandis* under Article 44-5 (1)) or 65 (2);
- 7-4. A person who fails to comply with a request for submission of data without good cause, in violation of Article 61-2 (2);
- 7-5. A person who fails to file a report on an adverse event, in violation of Article 68-8;
- 7-6. A person who uses the name "Institute of Drug Safety and Risk Management" or similar names, in violation of Article 68-10;
- 7-7. A person who fails to appear without good cause after receiving a request to appear under Article 86-6 (1) (excluding expert witnesses);
- 7-8. A person who fails to submit data, articles, etc. prescribed in Article 86-6 (1) without good cause after receiving a request to submit such data, articles, etc. (excluding expert witnesses);
- 7-9. A person who fails to comply with a request to make a statement prescribed in Article 86-6 (2) without good cause after receiving such request;
- 8. Deleted; <by Act No. 11251, Feb. 1, 2012>
- 9. A person who fails to renew a license, a permit, or a certificate of registration, in violation of Article 80;
- 10. A person who fails to observe the standards for use of drugs, etc. for animals, in violation of Article 85 (3);
- 10-2. A person who fails to prepare and retain records on the transactions of drugs, etc. for animals or who falsely prepares or retains such records, in violation of Article 85 (10);
- 11. A person who uses similar names prescribed by Ordinance of the Prime Minister, such as

pharmaceuticals and medicine, in violation of Article 87-2.

- (2) Administrative fines prescribed in paragraph (1) shall be imposed and collected by the Minister of Health and Welfare, the Minister of Food and Drug Safety, the Mayor/Do Governor, or the heads of Sis/Guns/Gus, as prescribed by Presidential Decree. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10788, Jun. 7, 2011; Act No. 11690, Mar. 23, 2013>
- (3) through (5) Deleted. <by Act No. 10788, Jun. 7, 2011>

Addenda <Act No. 16250, Jan. 15, 2019>

Article 1 (Enforcement Date)

This Act shall enter into force six months after the date of its promulgation: *Provided*, That the amended provisions of Articles 31, 36 (4), 40 (4), 41 (2), 42, and 45 (6) shall enter into force on the date of its promulgation; the amended provisions of Article 3 (2) 2 shall enter into force one year after the date of its promulgation; and the amended provisions of Articles 42 (6) through (9), and 76 (1) 5-3 and 5-4 of the Pharmaceutical Affairs Act (Act No. 15891) and Article 6 of the Addenda shall enter into force on December 12, 2019.

Article 2 (Transitional Measures concerning Qualification for Taking National Examinations for Pharmacist License)

Any person qualified to take a national examination for a pharmacist license under the previous Article 3 (2) 2 as at the time this Act enters into force shall be deemed qualified for the same under this Act.

Article 3 (Transitional Measures concerning Composition of the Central Pharmaceutical Affairs Advisory Committee)

- (1) Where the amended provisions of the latter part of Article 18 (2) are not complied with as at the time of appointing or commissioning a member after this Act enters into force, a member who is not a public official shall be commissioned until the requirements prescribed in the relevant amended provisions are satisfied.
- (2) The previous provisions shall apply to the composition of the members of the Central Pharmaceutical Affairs Advisory Committee until the amended provisions of the latter part of Article 18 (2) are complied with pursuant to paragraph (1).

Article 4 (Transitional Measures concerning Penalty Surcharges)

Notwithstanding the amended provisions of Article 81 (1), the previous provisions shall apply to the imposition of penalty surcharges for violations committed before this Act enters into force.

Article 5 Omitted.

2.13 Enforcement Decree of The Pharmaceutical Affairs Act

Presidential Decree No. 30170, Oct. 29, 2019

Article 1 (Purpose)

The purpose of this Decree is to prescribe the matters mandated by the Pharmaceutical Affairs Act and those necessary for enforcing said Act.

Article 2 (Administration of National Examinations for Pharmacist License or Oriental Medicine Pharmacist License)

- (1) Pursuant to Article 8 (2) of the Pharmaceutical Affairs Act (hereinafter referred to as the "Act"), the Minister of Health and Welfare shall require the Korea Health Personnel Licensing Examination Institute established under the Korea Health Personnel Licensing Examination Institute Act (hereinafter referred to as "national examination administrative agency") to manage a national examination for a pharmacist license or oriental medicine pharmacist license (hereinafter referred to as "national examination"). *<Amended by Presidential Decree No. 26742, Dec. 22, 2015>*
- (2) Where the head of the national examination administrative agency intends to administer a national examination, he or she shall, with prior approval from the Minister of Health and Welfare, publicly announce the date and time, places, and subjects of the examination, the deadline for submission of an application for the examination, and other matters necessary for the examination, no later than 90 days before the date of the examination: *Provided*, That he or she may publicly announce the places of the examination no later than 30 days before the examination date after the number of applicants for the examination for each region is determined. *<Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 23759, May 1, 2012>*

Article 3 (Application for National Examination)

- (1) Any person who intends to apply for a national examination shall submit to the head of the national examination administrative agency a written application prescribed by the head of the national examination administrative agency.
- (2) "Foreign college of pharmacy accredited by the Minister of Health and Welfare" in Article 3 (2) 2 of the Act means a college equivalent to or higher than those prescribed by Article 3 (2) 1 of the Act with respect to its curriculum or educational system. *<Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010>*
- (3) Any person who submits a written application pursuant to paragraph (1) shall pay in cash a fee determined by the head of the national examination administrative agency with approval from the Minister of Health and Welfare. In such cases, the amount and payment method of the fee and other necessary matters shall be publicly announced by the head of the national examination administrative agency pursuant to Article 2. *<Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 23459, Dec. 30, 2011>*
- (4) The head of the national examination administrative agency may have a fee referred to in paragraph (3) paid by means of electronic currencies, electronic settlement, etc. through the information and communications network. *<Amended by Presidential Decree No. 23459, Dec. 30, 2011>*

Article 4 (Subjects of Examinations)

- (1) A national pharmacist examination shall be administered in writing, covering the following subjects,

and the details of subjects shall be prescribed by Ordinance of the Ministry of Health and Welfare:

1. Life science in pharmacy;
 2. Industrial pharmacy;
 3. Clinical pharmacy and pharmacy practice;
 4. Regulations concerning health and pharmacy.
- (2) A national oriental pharmacist examination shall be administered in writing, covering the following subjects and the details of subjects shall be prescribed by Ordinance of the Ministry of Health and Welfare:
1. Basics of oriental pharmacy;
 2. Applied oriental pharmacy;
 3. Regulations concerning health and pharmacy.

[This Article Wholly Amended by Presidential Decree No. 24775, Sep. 26, 2013]

Article 5 (Decision on Successful Candidate)

A person who scores at least 40% in each subject and scores at least 60% on aggregate in all subjects shall be considered a successful candidate.

Article 6 (Announcement of Successful Candidates)

Where the head of the national examination administrative agency decides on the successful candidates of the national examinations held under Articles 2 and 5, he or she shall announce the list of the successful candidates without delay.

Article 7 (Examiners)

In order to give questions for the national examinations and mark papers thereof, the head of the national examination management agency shall commission examiners from among persons with much knowledge and experience in pharmacology or related statutes and regulations.

Article 8 (Request for Cooperation to Relevant Agencies)

The head of the national examination management agency may request the State and local governments, or relevant agencies or organizations for the cooperation in examination places, examination proctors, etc., if necessary for the smooth administration of national examinations.

Article 8-2 (Composition of Ethics Committee)

- (1) The Ethics Committee to be established within the Korean Pharmaceutical Association (hereinafter referred to as the "Pharmaceutical Association") and the Association of Korea Oriental Pharmacy (hereinafter referred to as the "Oriental Pharmacy Association") in accordance with Articles 11 (5) and 12 (5) of the Act shall be comprised of 11 members, including one chairperson.
- (2) The chairperson shall be commissioned by the head of the Pharmaceutical Association or the Oriental Pharmacy Association (hereafter in this Article through Article 8-4, referred to as "each Association") from among the members of each Association.
- (3) Members shall be commissioned by the head of each Association from among the following persons and shall include at least four persons who fall under subparagraph 2:
 1. A member of each Association who has at least 10 years of experience as a pharmacist or five years of experience as an oriental medicine pharmacist;
 2. A person who is not a pharmacist or oriental medicine pharmacist but has much knowledge and experience in law, health care, press, rights and interests of consumers, etc.
- (4) The term of office of a member shall be three years and may be renewed only once.

[This Article Newly Inserted by Presidential Decree No. 23843, Jun. 7, 2012]

Article 8-3 (Operation of Ethics Committee)

- (1) The Ethics Committee shall deliberate and decide on the following matters: *<Amended by Presidential Decree No. 28820, Apr. 24, 2018>*
1. Matters concerning the request for disposition of license revocation or qualification suspension under the subparagraphs of Article 79-2 (1) of the Act;
 2. Matters concerning the review of qualifications of, and the disciplinary actions against, members of each Association;
 3. Other matters necessary for the establishment of a code of ethics of members, which are prescribed by the articles of association of each Association.
- (2) A meeting of the Ethics Committee shall be convened by the chairperson where deemed necessary by the chairperson or where requested by the head of each Association or not less than 1/3 of its incumbent members.
- (3) In convening a meeting, the chairperson shall notify each member of the date and time, venue, and agenda items of the meeting no later than seven days before the opening of the meeting: *Provided*, That where an urgent meeting is required or where any unavoidable reason exists, the chairperson may notify such matters by the day before the meeting.
- (4) At least 2/3 of the members of the Ethics Committee shall constitute a quorum, and any decision thereof shall require the concurrent vote of at least 2/3 of those present: *Provided*, That the quorum for the matters referred to in paragraph (1) 2 and 3 shall be separately prescribed by the articles of association of each Association.
- (5) Where the chairperson of the Ethics Committee intends to deliberate and decide on the matters referred to in paragraph (1) 1 or 2, he or she shall give a party to the relevant agenda item an opportunity to state his or her opinion orally or in writing (including electronic documents).
- (6) Except as provided in paragraphs (1) through (5), matters necessary for the operation of each Ethics Committee shall be prescribed by the articles of association of each Association.

[This Article Newly Inserted by Presidential Decree No. 23843, Jun. 7, 2012]

Article 8-4 (Disqualification of Members of Ethics Committee)

- (1) A member of the Ethic Committee who falls under any of the following subparagraphs shall be disqualified from deliberations and decisions of the relevant Ethics Committee:
1. Where he or she becomes a party to the agenda item to be deliberated and decided by the Ethics Committee (hereafter in this Article, referred to as "relevant agenda item");
 2. Where he or she is or was a relative of a party to the relevant agenda item;
 3. Where he or she engages in or has engaged in an institution to which a party to the relevant agenda item belongs in the recent three years.
- (2) If there exists any ground for disqualification referred to in paragraph (1) or the circumstances indicate that it would be impracticable to expect fair deliberations and decisions by the Ethics Committee, a party to the relevant agenda item may file a written request for a challenge to the relevant member with the Ethics Committee by stating the reasons therefor.
- (3) Upon receipt of the request for the challenge under paragraph (2), the Ethics Committee shall determine whether or not to accept the challenge with the attendance of a majority of all the incumbent members and the concurring vote of a majority of those present. In such cases, the member against whom the request for challenge is filed shall not participate in such decision.
- (4) If any member of the Ethics Committee falls under any ground referred to in paragraph (1) or (2), he or he may voluntarily refrain from deliberations and decisions.

[This Article Newly Inserted by Presidential Decree No. 23843, Jun. 7, 2012]

Article 9 (Authorization for Establishment of the Pharmaceutical Association and the Oriental Pharmacy Association)

If the Pharmaceutical Association or the Oriental Pharmacy Association intends to obtain authorization for establishment under Article 13 (1) of the Act, it shall submit the following documents to the Minister of Health and Welfare: *<Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 23843, Jun. 7, 2012>*

1. The articles of association;
2. The detailed statement of assets;
3. A business plan and a budget of revenues and expenditures;
4. A resolution of establishment;
5. Documents regarding the election process for establishment representatives;
6. A letter of acceptance of appointment and a resume of an executive officer.

Article 10 (Matters to Be Included in Articles of Association)

Matters to be included in the articles of association of the Pharmaceutical Association or the Oriental Pharmacy Association shall be as follows: *<Amended by Presidential Decree No. 23843, Jun. 7, 2012>*

1. The objectives;
2. The title;
3. The principal office;
4. Matters concerning assets and accounting;
5. Matters concerning appointment of executive officers;
6. Matters concerning qualification and discipline of members;
7. Matters concerning amendments to the articles of association;
8. Matters concerning method of public announcement;
9. Matters concerning operation, etc. of the Ethics Committee.

Article 11 (Application for Authorization for Modification of Articles of Association)

If the Pharmaceutical Association or the Oriental Pharmacy Association intends to obtain authorization for the modification of its articles of association under Article 13 (3) of the Act, it shall submit the following documents:

1. Details of and reasons for modification of its articles of association;
2. Minutes concerning modification of its articles of association;
3. Comparison table of its new and old articles of association, and other reference documents.

Article 12 (Establishment of Chapters)

The Pharmaceutical Association or the Oriental Pharmacy Association shall establish its chapters in the Special Metropolitan City, Metropolitan Cities, Dos, and the Special Self-Governing Province under Article 14 of the Act within three weeks from the date of registration for establishment.

Article 13 (Functions of the Central Pharmaceutical Affairs Advisory Committee)

The Central Pharmaceutical Affairs Advisory Committee (hereafter in Articles 14-2, 14-3, 15 through 20, 20-2, 21 and 22, referred to as the "Advisory Committee") referred to in Article 18 (1) of the Act shall deliberate on the following matters: *<Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 23459, Dec. 30, 2011; Presidential Decree No. 24479, Mar. 23, 2013; Presidential Decree No. 25605, Sep. 11, 2014; Presidential Decree No. 29811, Jun. 4, 2019; Presidential Decree No. 29983, Jul. 16, 2019>*

1. Matters concerning the enactment and amendment of the Korean Pharmacopoeia prescribed in Article 51 of the Act;
2. Matters concerning the standards for drugs and quasi-drugs (hereinafter referred to as "drugs, etc.")

prescribed in Article 52 of the Act;

3. Matters concerning the investigation, research, and evaluation of safety and effectiveness of drugs, etc.;
4. Matters concerning the relief of injury from side effects of drugs;
5. Matters concerning the classification of over-the-counter drugs and prescription drugs;
6. Other matters to be brought to deliberation by the Minister of Health and Welfare or the Minister of Food and Drug Safety.

Article 14 Deleted. *<by Presidential Decree No. 29811, Jun. 4, 2019>*

Article 14-2 (Dismissal of Members of the Advisory Committee)

Where a member of the Advisory Committee commissioned pursuant to Article 18 (4) of the Act falls under any of the following subparagraphs, the Minister of Food and Drug Safety may dismiss the member: *<Amended by Presidential Decree No. 28081, May 29, 2017; Presidential Decree No. 29811, Jun. 4, 2019>*

1. Where the member is unable to perform the duties due to mental or physical disability;
2. Where the member commits a misdeed in connection with his or her duties;
3. Where the member is deemed unsuitable as a member due to neglect of duties, injury to dignity, or other causes;
4. Where the member admits that it is impracticable to voluntarily perform the duties;
5. Where the member fails to refrain from himself or herself, though he or she falls under any of the subparagraphs of Article 14-3 (1).

[This Article Newly Inserted by Presidential Decree No. 26844, Dec. 31, 2015]

Article 14-3 (Disqualification of, Challenge to, and Refrainment by, Members of the Advisory Committee)

- (1) Any member of the Advisory Committee who falls under any of the following subparagraphs shall be disqualified from deliberations and decisions of the Advisory Committee:
 1. Where the member or his or her spouse or ex-spouse is a party (including where he or she is related to a party as a co-obligee or co-obligor; hereinafter the same shall apply) to the relevant agenda item;
 2. Where the member is or was a relative of a party to the relevant agenda item;
 3. Where the member has offered any testimony, statement, advice, research, services, or appraisal for the relevant agenda item;
 4. Where the member or the corporation to which the member belongs is or was an agent of a party to the relevant agenda item;
 5. Cases corresponding to subparagraphs 1 through 4, where the Chairperson or the Vice Chairperson deems that the member has a direct interest in the relevant agenda item.
- (2) If the circumstances indicate that it would be impracticable to expect fair deliberations and decisions of a member, a party may file a request for a challenge to the member with the Advisory Committee by explaining the relevant fact in writing.
- (3) Upon receipt of a request for challenge under paragraph (2), the Advisory Committee shall determine whether or not to accept the request by decision. In such cases, the member against whom the request for challenge is filed shall not participate in the decision.
- (4) If a member falls under any of the grounds prescribed in the subparagraphs of paragraph (1) or finds himself or herself to be in the circumstances under which it would be impracticable to expect fair deliberations and decisions, he or she shall voluntarily refrain from deliberations and decisions on the relevant agenda item.

[This Article Newly Inserted by Presidential Decree No. 28081, May 29, 2017]

Article 15 (Duties of Chairperson)

- (1) The Chairperson shall exercise general supervision over the affairs of the Advisory Committee and represent the Advisory Committee. *<Amended by Presidential Decree No. 23459, Dec. 30, 2011>*
- (2) Vice Chairpersons shall assist the Chairperson, and the Vice Chairperson appointed by the Chairperson shall act on behalf of the Chairperson where the Chairperson is unable to perform the duties due to unavoidable reasons.

Article 16 (Convocation of Meetings)

- (1) The Chairperson shall convene and preside over meetings of the Advisory Committee.
- (2) The Chairperson shall convene a meeting of the Advisory Committee without delay when requested by the Minister of Health and Welfare, the Minister of Food and Drug Safety, or a majority of the incumbent members. *<Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 24479, Mar. 23, 2013>*

Article 17 (Subcommittees)

- (1) Subcommittees and sectional committees may be established within the Advisory Committee, if necessary.
- (2) Matters relating to organization and operation of the subcommittees and sectional committees under paragraph (1) shall be determined by the Minister of Food and Drug Safety following consultation with the Minister of Health and Welfare. *<Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 24479, Mar. 23, 2013>*

Article 18 (Proceedings)

- (1) A majority of the members of the Advisory Committee shall constitute a quorum, and any decision thereof shall require the concurring vote of at least 2/3 of those present.
- (2) Matters deliberated by the subcommittees or sectional committees shall be deemed decided by the Advisory Committee, except where the Chairperson of the Advisory Committee determines that it is necessary for another committee to re-deliberate the matters.

Article 19 (Reporting)

The Chairperson shall without delay report matters deliberated by the Advisory Committee to the Minister of Food and Drug Safety and shall without delay inform the Minister of Health and Welfare of the matters to be brought to deliberation by the Minister of Health and Welfare under subparagraph 6 of Article 13. *<Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 24479, Mar. 23, 2013>*

Article 20 (Research Committee Members)

- (1) Not more than 10 research committee members shall, in advance, be assigned to the Advisory Committee.
- (2) The research committee members shall investigate and research in advance matters to be deliberated by the Advisory Committee, following an order from the Chairperson.
- (3) The research committee members may attend and speak at meetings of the Advisory Committee.
- (4) The Advisory Committee shall assign not more than 10 researchers to assist the research committee members.
- (5) The research committee members and researchers referred to in paragraphs (1) and (4) shall be appointed by the Minister of Food and Drug Safety from among persons who have much knowledge and experience in pharmaceutical affairs. *<Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 24479, Mar. 23, 2013>*

Article 20-2 (Hearing of Opinions)

If necessary in connection with deliberation by the Advisory Committee, the Chairperson may require a relevant expert who has expertise and experience in pharmaceutical affairs to attend the relevant meetings to hear his or her opinion. *<Amended by Presidential Decree No. 29983, Jul. 16, 2019>*
[This Article Newly Inserted by Presidential Decree No. 29811, Jun. 4, 2019]

Article 21 (Executive Secretary and Clerks)

- (1) One executive secretary and several clerks shall be assigned to the Advisory Committee.
- (2) The executive secretary and clerks shall be appointed by the Minister of Food and Drug Safety from among public officials of the Ministry of the Food and Drug Safety. *<Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 24479, Mar. 23, 2013>*
- (3) The executive secretary shall perform administrative affairs of the Advisory Committee following an order from the Chairperson, and clerks shall assist the executive secretary.

Article 22 (Allowances and Traveling Expenses)

The Minister of Food and Drug Safety may pay allowances and traveling expenses to the members of the Advisory Committee, subcommittees, and sectional committees, and research expenses and traveling expenses to the research committee members and researchers, respectively, within budgetary limits. *<Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 24479, Mar. 23, 2013>*

Article 22-2 (Standards for Facilities of Pharmacies)

- (1) A pharmacy shall be equipped with the following facilities under Article 20 (3) of the Act:
 1. A dispensary;
 2. A facility for low-temperature storage and sun screen;
 3. A facility for providing tap water or underground water, etc. that satisfies the quality standards for drinking water under Article 5 of the Drinking Water Management Act;
 4. Devices necessary for dispensing drugs.
- (2) Detailed standards for facilities under paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare following consultation between the Minister of Health and Welfare and the Minister of Food and Drug Safety.

[This Article Newly Inserted by Presidential Decree No. 24479, Mar. 23, 2013]

Article 23 (Scope of Direct Dispensing by Physicians or Dentists)

"Cases prescribed by Presidential Decree" in Article 23 (4) 14 of the Act means any of the following cases: *<Amended by Presidential Decree No. 20875, Jun. 25, 2008; Presidential Decree No. 21084, Oct. 14, 2008; Presidential Decree No. 23459, Dec. 30, 2011; Presidential Decree No. 23734, Apr. 17, 2012; Presidential Decree No. 23886, Jun. 27, 2012; Presidential Decree No. 24247, Dec. 21, 2012; Presidential Decree No. 27673, Dec. 13, 2016>*

1. Where physicians or dentists, who serve in military medical facilities under Article 15 of the Act on the Organization of National Armed Forces, dispense drugs for patients who are soldiers under Article 4 of that Act in the course of performing their duties;
2. Where physicians or dentists, who serve in the National Police Hospital under Article 31 of the Regulations on the Organization of Office of the National Police Agency and Its Affiliated Agencies or in the Central Fire Fighter Treatment Center under Article 7 of the Enforcement Decree of the Framework Act on Health, Safety and Welfare of Fire Officials, dispense drugs for patients who are police officers or fire officials in the course of performing their duties;
3. Where physicians or dentists, who serve in medial institutions established and operated by the Korea

Workers' Compensation and Welfare Service pursuant to Article 11 (2) of the Industrial Accident Compensation Insurance Act, dispense, in the course of performing their duties, drugs for patients suffering from pneumoconiosis from among persons who had occupational accidents under subparagraph 1 of Article 5 of that Act;

4. Where physicians or dentists, who serve in the Korea Veterans Hospital established under Article 7 of the Korea Veterans Welfare and Healthcare Corporation Act, dispense drugs for patients for whom the total amount of medical expenses is borne by the State pursuant to the Act on the Honorable Treatment and Support of Persons, etc. of Distinguished Services to the State, the Act on Support for Persons Eligible for Veteran's Compensation, the Act on Assistance to Patients Suffering from Actual or Potential Aftereffects of Defoliants, etc. and Establishment of Related Organizations, and the Act on the Honorable Treatment of Persons of Distinguished Services to the May 18 Democratization Movement in the course of performing their duties;
5. Where physicians or dentists, who serve in a health room under Article 3 of the School Health Act (excluding those who serve in a medical institution established in the relevant school under the Medical Service Act), dispense drugs for patients who are students or teaching staff of the relevant school in the course of performing their duties;
6. Where physicians or dentists, who are health managers under Article 16 of the Industrial Safety and Health Act (excluding those who serve in a medical institution established in the relevant workplace under the Medical Service Act), dispense drugs for patients who are workers of the relevant workplace in the course of performing their duties;
7. Where physicians or dentists dispense drugs for foreign patients pursuant to Article 27 (3) 2 of the Medical Service Act.

Article 24 (Similar Collusive Acts)

- (1) "Other acts prescribed by Presidential Decree, which have the potential for collusion as being similar to any of those referred to in subparagraphs 1 through 4" in Article 24 (2) 5 of the Act means the following acts: *<Amended by Presidential Decree No. 29950, Jul. 2, 2019>*
 1. An act of making dispensing available only at a specific pharmacy by stating the names, etc. of drugs on a prescription with a symbol or code pursuant to a prearrangement between a pharmacy founder and a medical institution founder;
 2. An act, performed by a medical institution founder, of making dispensing available only at a specific pharmacy by prescribing the drugs not in the list of prescription drugs under Article 25 of the Act;
 3. An act, performed together by a pharmacy founder and a medical institution founder, of supporting or managing the affairs of purchasing drugs, dispensing drugs, filing applications for the review of the costs of health care benefits, etc. under the National Health Insurance Act;
 4. An act, performed by a medical institution founder, of transmitting the prescription by utilizing a facsimile or computer communications, etc. so as to make dispensing available at a specific pharmacy without any request from the holder of such prescription;
 5. The act, performed by a medical institution founder, of ordering a pharmacist under his or her *de facto* control and supervision to establish a pharmacy, or of operating a pharmacy actually by controlling or supervising a pharmacist who has established the pharmacy.
- (2) The Minister of Health and Welfare, the Special Metropolitan City Mayor, a Metropolitan City Mayor, a *Do* Governor, or a Special Self-Governing Province Governor (hereinafter referred to as the "Mayor/*Do* Governor"), or the head of a *Si/Gun/Gu* (the head of a *Gu* refers to the head of an autonomous *Gu*; hereinafter the same shall apply) shall require relevant public officials to conduct an inspection under Article 69 of the Act on a medical institution founder or a pharmacy founder in accordance with the standards determined by the Minister of Health and Welfare in order to prevent any collusive act under Article 24 (2) of the Act, in any of the following cases: *<Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010;*

Presidential Decree No. 24479, Mar. 23, 2013>

1. Where it is considered that a medical institution founder (if a medical institution founder is a corporation, including the executive officers of such corporation) and a pharmacy founder have the relationship of spouse, parent, sibling, child, or child’s spouse and that the relevant pharmacy exclusively induces prescriptions issued by the relevant medical institution;
2. Where a medical institution and a pharmacy are installed in the same building with the same entrance and it is considered that the relevant pharmacy exclusively induces the prescriptions issued by the relevant medical institution.

Article 24-2 (Entrustment of Affairs of Registrating Drug Identification Mark)

- (1) “Relevant specialized institution prescribed by Presidential Decree” in Article 38-2 (3) of the Act means a corporation designated and publicly notified by the Minister of Food and Drug Safety, among drug-related corporations established with permission from the Minister of Food and Drug Safety, pursuant to Article 32 of the Civil Act.
- (2) Where the Minister of Food and Drug Safety entrusts the affairs pursuant to Article 38-2 (3) of the Act, he or she shall publicly notify an entity entrusted and the details of affairs.

[This Article Newly Inserted by Presidential Decree No. 26544, Sep. 22, 2015]

Article 25 (Examination for Herb Druggists)

The examination for herb druggists provided for in Article 45 (3) of the Act shall be administered by the Mayor/Do Governor with regard to the knowledge necessary for the handling of herbal drugs and their working-level functions.

Article 26 (Eligibility Requirements for Examination)

A person with at least five years of career in handling of herbal drugs at an oriental medical clinic or an herb drugstore, who has graduated from a high school or higher educational institution or who is recognized by the Minister of Education as one with educational attainment equal to or higher than such school shall be entitled to apply for the examination for herb druggists.

[This Article Wholly Amended by Presidential Decree No. 29983, Jul. 16, 2019]

Article 27 (Subjects of Examination and Allotting Percentage)

The examination for herb druggists shall be classified into a written examination and a practical examination, and the subjects of the examination and allocated examination percentage shall be as follows:

Section	Subjects	Percentage
1. Written examination	(a) Names, properties, use, and storing methods of herbal drugs which are entered in BON-CHO-KANG-MOK (a botanical list), BANG-YAK HAP-PYON (a comprehensive herb pharmacopoeia), and YAK-SUNG-KA (a chant to the nature of a drug), and distinctions between poisonous and powerful drugs;	45%
	(b) Prescription and mixing method entered in accepted herbal drug books;	20%
	(c) Statutes and regulations on pharmaceutical affairs and narcotics.	15%
2. Practical examination	Discrimination ability for at least 50 herbal drug materials.	20%

[This Article Wholly Amended by Presidential Decree No. 29950, Jul. 2, 2019]

Article 28 (Public Announcement of Examination)

Where the Mayor/*Do* Governor administers the examination for herb druggists, he or she shall publicly announce the date and time, place of the examination, subjects of the examination, deadline for submission of applications, an area where business permission is expected to be granted, the expected number of persons who obtain such permission, and other matters necessary for the examination, no later than 30 days before the examination date.

Article 29 (Application Form)

- (1) A person who intends to apply for the examination for herb druggists shall submit an application form to the Mayor/*Do* Governor, along with the following documents: *<Amended by Presidential Decree No. 21084, Oct. 14, 2008>*
1. A resume;
 2. Documents evidencing educational attainment and career experience under Article 26;
 3. A medical certificate issued by a physician evidencing that an applicant does not fall under the main clause of subparagraph 1 of Article 5 of the Act or a medical certificate issued by a medical specialist evidencing that an applicant falls under the proviso of subparagraph 1 of Article 5 of the Act;
 4. A medical certificate issued by a physician evidencing that an applicant does not fall under subparagraph 3 of Article 5 of the Act;
 5. The expected place of business and a rough map thereof.
- (2) A person who submits an application form under paragraph (1) shall pay a fee, as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010>*

Article 30 (Determination of Successful Applicants)

- (1) After administering the examination for herb druggists, the Mayor/*Do* Governor shall determine applicants who score at least 60 percent on aggregate in all subjects, as successful applicants within the limit of expected number of those to be granted permission for each area where business permission is expected to be granted as publicly announced under Article 28: *Provided*, That where there are not less than two persons with a tie score, exceeding the expected number of those to be granted permission for each area where business permission is expected to be granted, the person with a higher score on the written examination shall be chosen, and even where there is a tie score on the written examination, all the persons with a tie score shall be chosen as successful applicants.
- (2) The Mayor/*Do* Governor shall inform the successful applicants under paragraph (1) of their passing of the examination.

Article 31 (Examination Committee Members)

- (1) The Mayor/*Do* Governor shall appoint examination committee members from among persons who have much knowledge and experience in herbal drugs and who have substantial knowledge of statutes and regulations on pharmaceutical affairs and narcotics.
- (2) The examination committee under paragraph (1) shall consist of two to five persons per subject.

Article 31-2 (Standards for Facilities of Herb Druggists and Drug Wholesalers)

- (1) Detailed standards for a business place that an herb druggist is required to be equipped with under Article 45 (2) 1 of the Act shall be prescribed by Ordinance of the Ministry of Health and Welfare following consultation between the Minister of Health and Welfare and the Minister of Food and Drug Safety.
- (2) In accordance with Article 45 (2) 2 of the Act, a drug wholesaler shall be equipped with a business place and a warehouse prescribed by Ordinance of the Ministry of Health and Welfare following

consultation between the Minister of Health and Welfare and the Minister of Food and Drug Safety and shall own assets prescribed by Ordinance of the Ministry of Health and Welfare for the operation, etc. of the relevant facilities: *Provided*, That a medical high-pressure gas wholesaler shall comply with the standards for facilities for the sales of high-pressure gas under Article 4 (4) of the High-Pressure Gas Safety Control Act, and a radiopharmaceuticals wholesaler shall comply with the standards for facilities for radioisotope sales business under Article 55 (1) of the Nuclear Safety Act.

- (3) Notwithstanding the main clause of paragraph (2), a drug wholesaler need not be equipped with a warehouse, if he or she entrusts the management of distribution, such as storage and delivery, of drugs to another drug wholesaler who meets the requirements prescribed by Ordinance of the Ministry of Health and Welfare.
- (4) If a druggist or drug seller referred to in Article 5 of the Addenda to the Pharmaceutical Affairs Act (Act No. 8365) intends to operate his or her business, he or she shall be equipped with a business place prescribed by Ordinance of the Ministry of Health and Welfare following consultation between the Minister of Health and Welfare and the Minister of Food and Drug Safety.

[This Article Newly Inserted by Presidential Decree No. 24479, Mar. 23, 2013]

Article 32 (Grounds for Retail or Distribution of Drugs by Persons Who Obtained Permission by Item of Drugs)

“Ground prescribed by Presidential Decree, such as cases for public interests” in Article 47 (1) 2 of the Act means grounds falling under attached Table 1-2.

[This Article Wholly Amended by Presidential Decree No. 27048, Mar. 22, 2016]

Article 32-2 (Designation of the Korea Pharmaceutical Information Service)

The Minister of Health and Welfare shall designate the Health Insurance Review and Assessment Service under Article 62 of the National Health Insurance Act as an agency managing information on the distribution of drugs (hereinafter referred to as the "Korea Pharmaceutical Information Service") pursuant to Article 47-3 (1) of the Act. *<Amended by Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 24077, Aug. 31, 2012; Presidential Decree No. 28081, May 29, 2017>*

[This Article Newly Inserted by Presidential Decree No. 21084, Oct. 14, 2008]

Article 32-3 (Operation of the Korea Pharmaceutical Information Service)

- (1) The Korea Pharmaceutical Information Service shall perform the following affairs: *<Amended by Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 27048, Mar. 22, 2016; Presidential Decree No. 28081, May 29, 2017>*

1. Collection, investigation, processing, utilization, and provision of drug distribution information;
2. Formulation and implementation of a basic plan for informatization on the distribution of drugs;
3. Construction and operation of database of drug distribution information;
4. Management of bar codes or RFID tags of drugs determined by the Minister of Health and Welfare, such as a public announcement of drug standard codes [referring to serial numbers imposed on each drug for identification thereof, which are numbers in 13 figures, including country identification code; identification code of a person who has obtained permission by item of drugs (referring to the person who has obtained permission for manufacturing and distribution of items or filed a notification of manufacturing and distribution of items in accordance with Article 31 (2) or (3) of the Act; hereinafter the same shall apply) or of a person who has filed a notification of import business pursuant to the former part of Article 42 (1) of the Act (hereinafter referred to as “importer”); item code; and verification code];
5. Research, education, and public relations on standardization of drug distribution information;
6. Support of informatization on the distribution of drugs, such as the development and dissemination of programs necessary for the submission of supply details, etc. of drugs under Article 47-3 (2) of

the Act;

7. Other matters recognized necessary by the Minister of Health and Welfare in connection with drug distribution information.
- (2) The president of the Korea Pharmaceutical Information Service shall report, to the Minister of Health and Welfare, a business plan for the affairs under paragraph (1), business performance, budget, and settlement of accounts of the relevant fiscal year by the deadline classified as follows: *<Amended by Presidential Decree No. 22075, Mar. 15, 2010>*
1. A business plan and budget of the relevant fiscal year: Not later than the commencement of the relevant fiscal year;
 2. Business performance and settlement of accounts of the relevant fiscal year: Not later than the end of February of the following fiscal year.
- (3) If necessary for the management of bar codes or RFID tags of drugs under paragraph (1) 4, the president of the Korea Pharmaceutical Information Service may require persons who have obtained permission by item of drugs or importers to submit a report on the product information of drugs which they intend to manufacture and distribute or import as determined and publicly notified by the Minister of Health and Welfare. *<Amended by Presidential Decree No. 22075, Mar. 15, 2010>*
[This Article Newly Inserted by Presidential Decree No. 21084, Oct. 14, 2008]

Article 32-4 (Fees for Providing Drug Distribution Information)

- (1) Where the Korea Pharmaceutical Information Service provides the processed information on distribution of drugs at the request of persons who have obtained permission by item of drugs, importers, drug wholesalers, etc. (excluding cases of disclosure to the public under subparagraph 2 of Article 2 of the Official Information Disclosure Act), it may receive fees from the relevant requester: *Provided*, That in any of the following cases, fees may be reduced or exempted: *<Amended by Presidential Decree No. 22075, Mar. 15, 2010>*
1. Where a State agency or a local government requests to provide drug distribution information in connection with the performance of affairs pursuant to statutes and regulations;
 2. Where a non-profit corporation or a non-profit academic and public organization requests to provide drug distribution information for the purpose of academic research or administrative surveillance;
 3. Where a requester makes a request for providing the information on distribution of the same drugs as that processed according to the same standards in the same year;
 4. Other cases where the Minister of Health and Welfare recognizes that reduction or exemption of fees is necessary for public welfare, etc.
- (2) Fees referred to in paragraph (1) shall be determined within the extent of actual expenses in consideration of expenses incurred in processing and providing drug distribution information, expenses incurred in developing programs necessary for the management of drug distribution information, etc.
- (3) Fees referred to in paragraph (1) shall be paid in cash (including payment by methods of electronic currencies, electronic settlement, etc. through the information and communications network) to a financial institution or postal service agency designated by the Korea Pharmaceutical Information Service.
- (4) Matters necessary for the methods for requesting drug distribution information, and eligibility for and percentage of reduction or exemption of fees under paragraph (1), the specific methods for calculating fees under paragraph (2), etc. shall be determined and publicly notified by the Minister of Health and Welfare. *<Amended by Presidential Decree No. 22075, Mar. 15, 2010>*

[This Article Newly Inserted by Presidential Decree No. 21084, Oct. 14, 2008]

Article 32-5 (Grounds for Exceptions to Informing of Application for Permission by Item)

“Cases prescribed by Presidential Decree” in Article 50-4 (1) 4 of the Act (including cases applied

mutatis mutandis under Article 42 (5) of the Act) means cases where the registered patent information regarding medical usage referred to in Article 50-2 (4) 1 (d) of the Act is not relevant to the efficacy nor effectiveness of the drug for which an application for permission for manufacturing and distribution or import of items or permission for modification is filed pursuant to Article 31 (2), (3) or (9) or 42 (1) of the Act. <Amended by Presidential Decree No. 26544, Sep. 22, 2015>

[This Article Newly Inserted by Presidential Decree No. 26143, Mar. 13, 2015]

Article 32-6 (Entrustment of Affairs of Deliberation on Advertisement)

The Minister of Food and Drug Safety shall entrust an incorporated association designated and publicly notified by him or her among incorporated associations established pursuant to Article 67 of the Act with deliberation on advertisement of drugs pursuant to Article 68-2 (2) of the Act. <Amended by Presidential Decree No. 24479, Mar. 23, 2013>

[This Article Newly Inserted by Presidential Decree No. 20767, Apr. 10, 2008]

Article 32-7 (Organization and Operation of the Korea Institute of Drug Safety and Risk Management)

(1) Directors and auditors, including the president, shall be appointed as executive officers for the Korea Institute of Drug Safety and Risk Management established under Article 68-3 of the Act (hereinafter referred to as the "Institute of Drug Safety and Risk Management").

(2) The president of the Institute of Drug Safety and Risk Management shall be appointed by the Minister of Food and Drug Safety, as prescribed by the articles of association. <Amended by Presidential Decree No. 24479, Mar. 23, 2013>

(3) A board of directors shall be established within the Institute of Drug Safety and Risk Management in order to deliberate and decide on important matters concerning the affairs of the Institute of Drug Safety and Risk Management.

(4) Except as provided in paragraphs (1) through (3), matters necessary for the organization and operation of the Institute of Drug Safety and Risk Management shall be prescribed by the articles of association.

[This Article Newly Inserted by Presidential Decree No. 23459, Dec. 30, 2011]

Article 32-8 (For-Profit Projects)

"For-profit projects prescribed by Presidential Decree" in Article 68-4, with the exception of its subparagraphs, of the Act means any of the following projects: <Amended by Presidential Decree No. 24479, Mar. 23, 2013>

1. Education and training of a person in charge of the affairs concerning drug safety information;
2. Production and distribution of publications, etc. related to drug safety information;
3. Other projects approved by the Minister of Food and Drug Safety to attain the establishment purposes of the Institute of Drug Safety and Risk Management.

[This Article Newly Inserted by Presidential Decree No. 23459, Dec. 30, 2011]

Article 32-9 (Approval of Business Plans and Budget Bills)

(1) Where the Institute of Drug Safety and Risk Management intends to obtain approval of its business plan and budget bill pursuant to the former part of Article 68-6 (2) of the Act, it shall submit the budget bill accompanied by a business plan for the following year and the following documents to the Minister of Food and Drug Safety after decision by the board of directors, before each fiscal year begins: <Amended by Presidential Decree No. 24479, Mar. 23, 2013>

1. An estimated balance sheet;
2. An estimated profit and loss statement;
3. A plan for revenue and expenditure.

(2) Where the Institute of Drug Safety and Risk Management intends to obtain approval of modification

of a business plan and a budget bill pursuant to the latter part of Article 68-6 (2) of the Act, it shall submit a document stating the details of and grounds for modification to the Minister of Food and Drug Safety after decision by the board of directors. <Amended by Presidential Decree No. 24479, Mar. 23, 2013>

[This Article Newly Inserted by Presidential Decree No. 23459, Dec. 30, 2011]

Article 32-10 (Documents for Access or Inspection by Drug Epidemiological Investigators)

"Matters prescribed by Presidential Decree, such as the period and scope of an investigation, persons in charge of the investigation, and relevant statutes and regulations" in the latter part of Article 68-12 (3) of the Act means the following matters:

1. The purpose, period, scope, and details of the investigation;
2. Names and positions of persons in charge of the investigation;
3. A list of data that shall be submitted;
4. Basis statutes and regulations concerning the investigation;
5. Details and basis statutes and regulations concerning administrative dispositions or penalties against a refusal, obstruction, evasion, etc. of the investigation;
6. Matters corresponding to those falling under subparagraphs 1 through 5, which are deemed necessary by the Minister of Food and Drug Safety for the relevant investigation.

[This Article Newly Inserted by Presidential Decree No. 27673, Dec. 13, 2016]

Article 32-11 (Documents for Access or Investigation by Relevant Public Officials)

"Matters prescribed by Presidential Decree, such as the period and scope of investigation, persons in charge of the investigation, and relevant statutes and regulations" in Article 69 (2) of the Act means the following matters:

1. Matters under subparagraphs 1 through 5 of Article 32-10;
2. Matters corresponding to those falling under subparagraph 1, which are deemed necessary by the Minister of Health and Welfare or the Minister of Food and Drug Safety for the relevant investigation.

[This Article Newly Inserted by Presidential Decree No. 27673, Dec. 13, 2016]

Article 32-12 (Informing Relevant Agencies)

"Head of the relevant central administrative agency prescribed by Presidential Decree" in Article 69-2 of the Act means the following persons:

1. The Minister of Health and Welfare;
2. The Chairperson of the Fair Trade Commission;
3. The Commissioner of the Korean Intellectual Property Office.

[This Article Newly Inserted by Presidential Decree No. 26143, Mar. 13, 2015]

Article 33 (Standards for Calculation of Penalty Surcharges Imposed in Lieu of Disposition of Business Suspension)

The amount of penalty surcharges under Article 81 (2) of the Act shall be calculated based on the standards prescribed in attached Table 2 according to the standards for the disposition of business suspension classified as follows, taking into consideration the types, degree, etc. of violations: <Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 24479, Mar. 23, 2013>

1. In cases of imposition of a penalty surcharge on a manufacturer of drugs, etc., a person who has obtained permission by item, or an importer: The standards prescribed by Ordinance of the Prime Minister;
2. In cases of imposition of a penalty surcharge on a pharmacy founder or a drug distributor: The standards prescribed by Ordinance of the Ministry of Health and Welfare.

Article 34 (Procedures for Imposition and Collection of Penalty Surcharges Imposed in Lieu of Disposition of Business Suspension)

- (1) If the Minister of Food and Drug Safety, the Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* intends to impose a penalty surcharge under Article 81 of the Act, he or she shall give written information of the payment thereof, stating the type of violation and the amount of penalty surcharge. *<Amended by Presidential Decree No. 24479, Mar. 23, 2013>*
- (2) Procedures for collecting penalty surcharges shall be subject to the following classification: *<Amended by Presidential Decree No. 24479, Mar. 23, 2013>*
 1. In cases of imposition of a penalty surcharge on a manufacturer of drugs, etc., a person who has obtained permission by item, or an importer: The procedures for collection prescribed by Ordinance of the Prime Minister;
 2. In cases of imposition of a penalty surcharge on a pharmacy founder or a drug distributor: The procedures for collection prescribed by Ordinance of the Ministry of Health and Welfare.

Article 34-2 (Disposition to Defaulters of Penalty Surcharges Imposed in Lieu of Disposition of Business Suspension)

- (1) When a person fails to pay a penalty surcharge by the deadline for payment, the Minister of Food and Drug Safety, the Mayor/*Do* Governor, the head of a *Si/Gun/Gu* shall issue a demand for payment within 15 days after the elapse of the deadline for payment pursuant to the main clause of Article 81 (4) of the Act. In such cases, a new deadline for payment shall be within 10 days after the demand for payment is issued. *<Amended by Presidential Decree No. 24479, Mar. 23, 2013>*
- (2) If a person who fails to pay a penalty surcharge pursuant to paragraph (1) fails to pay it by the relevant payment deadline even after receipt of a demand for payment, a disposition to impose penalty surcharges shall be revoked and a disposition to suspend business shall be imposed: *Provided*, That where he or she falls under the proviso of Article 81 (4) of the Act, the penalty surcharge shall be collected in the same manner as delinquent national taxes are collected or pursuant to the Act on the Collection, etc. of Local Non-Tax Revenue. *<Amended by Presidential Decree No. 25605, Sep. 11, 2014>*
- (3) Where a disposition to suspend business is imposed after the revocation of the disposition to impose a penalty surcharge pursuant to the main clause of paragraph (2), a person subject to the disposition shall be given written information, stating matters necessary for the disposition of business suspension, including grounds for the change of the disposition and a period for the suspension of business. *<Amended by Presidential Decree No. 25605, Sep. 11, 2014>*

[This Article Newly Inserted by Presidential Decree No. 20156, Jul. 3, 2007]

Article 34-3 (Standards for Imposing Penalty Surcharges for Manufacturing of Hazardous Drugs)

The standards for imposing penalty surcharges pursuant to Article 81-2 (1) of the Act shall be as specified in attached Table 2-2.

[This Article Newly Inserted by Presidential Decree No. 29811, Jun. 4, 2019]

Article 34-4 (Imposition and Payment of Penalty Surcharges for Manufacturing of Hazardous Drugs)

- (1) Where the Minister of Food and Drug Safety intends to impose a penalty surcharge under Article 81-2 (1) of the Act, he or she shall give written information of the payment thereof, specifying the type of offense and the amount of penalty surcharge.
- (2) A person informed pursuant to paragraph (1) (hereinafter referred to as “person liable to pay a penalty surcharge”) shall pay the penalty surcharge to the receiving agency designated by the Minister of Food and Drug Safety within 60 days from the date of receiving the information.
- (3) The receiving agency upon receipt of the penalty surcharge under paragraph (2) shall issue a receipt

to the payer and inform without delay the Minister of Food and Drug Safety of the fact of receiving the penalty surcharge.

- (4) Except as provided in paragraphs (1) through (3), matters necessary for imposing and paying penalty surcharges shall be prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted by Presidential Decree No. 29811, Jun. 4, 2019]

Article 34-5 (Extension of Deadline for Payment of Penalty Surcharges for Manufacturing of Hazardous Drugs, and Installment Payment)

- (1) Where a person liable to pay a penalty surcharge is deemed unable to pay the full amount of the penalty surcharge in a lump sum due to any of the following grounds, the Minister of Food and Drug Safety may extend the deadline for payment or permit the penalty surcharge to be paid in installments, upon the application of the person liable to pay the penalty surcharge. In such cases, the Minister of Food and Drug Safety may require such person to offer an asset as security, if deemed necessary:
1. Where the person suffers a serious loss in property due to a natural disaster, calamity, etc.;
 2. Where the business of the person faces a critical crisis due to a deterioration of business conditions;
 3. Where a lump-sum payment of the penalty surcharge is likely to cause severe financial difficulties to the person;
 4. Where the person has sustained a net loss consecutively for the three immediately preceding business years as at the time of filing an application for an extension of the payment deadline or for installment payment;
 5. Where the person has a debt exceeding twice the total capital as at the time of filing an application for an extension of the payment deadline or for installment payment;
 6. Where the Minister of Food and Drug Safety deems that there exists any ground corresponding to subparagraphs 1 through 5.
- (2) Where a person liable to pay a penalty surcharge intends to extend the deadline for payment of the penalty surcharge or to pay the penalty surcharge in installments under paragraph (1), he or she shall file an application therefor with the Minister of Food and Drug Safety, along with documents evidencing the grounds for the extension of the payment deadline or for the installment payment, within 30 days from the date he or she is informed of the payment of the penalty surcharge.
- (3) With respect to the extension of the deadline for payment of a penalty surcharge or the installment payment thereof under paragraph (1), the period extended shall not exceed one year from the date immediately after the payment deadline; and the interval between individual deadlines for installment payment shall not be longer than three months, and the number of installments shall not exceed three.
- (4) Where a person liable to pay a penalty surcharge granted an extension of the payment deadline or permitted to pay such penalty surcharge in installments under paragraph (1) falls under any of the following cases, the Minister of Food and Drug Safety may revoke the decision to extend the deadline for payment or to permit the payment in installments and collect the penalty surcharge in a lump sum:
1. Where the person fails to pay an installment of the penalty surcharge by the deadline for payment;
 2. Where the person fails to comply with the order from the Minister of Food and Drug Safety necessary to change security or to preserve security;
 3. Where it is deemed impossible to collect the full or remaining amount of the penalty surcharge on the grounds of compulsory execution, commencement of an auction, declaration of bankruptcy, dissolution of a corporation, disposition on delinquent national or local taxes, etc.;
 4. Where it is deemed that the person is able to pay the penalty surcharge in a lump sum because any of the grounds provided in the subparagraphs of paragraph (1) has ceased to exist.

- (5) Except as provided in paragraphs (1) through (4), matters necessary for the extension of the deadlines for payment of penalty surcharges, installment payment thereof, etc. shall be prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted by Presidential Decree No. 29811, Jun. 4, 2019]

Article 34-6 (Demand for Payment of Penalty Surcharges for Manufacturing of Hazardous Drugs)

- (1) If a person liable to pay a penalty surcharge fails to pay it by the deadline for payment, the Minister of Food and Drug Safety shall issue a demand for payment within 10 days after the elapse of the deadline for payment (referring to the deadline for payment in a lump sum, where a decision to permit the installment payment of the penalty surcharge is revoked under Article 34-5 (4) after such decision is made under paragraph (1) of that Article) pursuant to Article 81-2 (5) of the Act.
- (2) In cases of issuing a demand for payment under paragraph (1), the deadline for payment of the penalty surcharge in arrears shall be within 10 days from the date of issuing the demand for payment.

[This Article Newly Inserted by Presidential Decree No. 29811, Jun. 4, 2019]

Article 34-7 (Designation of Professional Training Institution)

- (1) The Minister of Health and Welfare and the Minister of Food and Drug Safety may designate any of the following institutions or organizations as a professional training institution pursuant to Article 83-2 (2) of the Act (hereinafter referred to as “professional training institution”):
1. The Institute of Drug Safety and Risk Management;
 2. Corporations established pursuant to Article 67 of the Act;
 3. Universities and colleges where drug-related departments or majors are established, among universities and colleges defined in subparagraph 1 of Article 2 of the Higher Education Act;
 4. Other institutions or organizations established to perform duties relevant to drugs or health.
- (2) A person who intends to be designated as a professional training institution pursuant to paragraph (1) shall submit to the Minister of Health and Welfare or the Minister of Food and Drug Safety, an application for designation prescribed by Ordinance of the Ministry of Health and Welfare or by Ordinance of the Prime Minister, along with the documents prescribed by Ordinance of the Ministry of Health and Welfare or by Ordinance of the Prime Minister.
- (3) The standards for designating a professional training institution shall be as follows:
1. The courses and curricula of education and training shall be appropriate;
 2. Appropriate personnel, facilities and equipment for conducting education and training shall be secured;
 3. The plan for raising operational funds shall be reasonable.
- (4) Where the Minister of Health and Welfare or the Minister of Food and Drug Safety designates a professional training institution, he or she shall issue a certificate of designation prescribed by Ordinance of the Ministry of Health and Welfare or Ordinance of the Prime Minister and publicly announce such fact on the website of the Ministry of Health and Welfare or the Ministry of Food and Drug Safety.
- (5) Expenses to be subsidized to a professional training institution pursuant to Article 83-2 (3) of the Act shall be as follows: *<Amended by Presidential Decree No. 28081, May 29, 2017>*
1. Lecture fees and allowances;
 2. Expenses for producing teaching materials and expenses for purchasing tools for practice;
 3. Expenses for field practice;
 4. Other expenses deemed necessary to train professional personnel.

[This Article Newly Inserted by Presidential Decree No. 26544, Sep. 22, 2015]

Article 34-8 (Functions of the Council for Stable Supply of National Essential Drugs)

The Council for Stable Supply of National Essential Drugs (hereinafter referred to as the “Council”)

under Article 83-3 (3) of the Act shall consult about the following:

1. Designation of national essential drugs;
2. Affairs under the subparagraphs of Article 83-3 (1) of the Act.

[This Article Newly Inserted by Presidential Decree No. 28081, May 29, 2017]

Article 34-9 (Organization of the Council)

- (1) The Council shall be comprised of not more than 20 members, including one chairperson.
- (2) The Vice Minister of Food and Drug Safety shall serve as the chairperson of the Council.
- (3) Members shall be appointed by the head of a relevant agency from among the public officials in general service of the Senior Executive Service of the Ministry of Education, the Ministry of National Defense, the Ministry of the Interior and Safety, the Ministry of Health and Welfare, the Ministry of Employment and Labor, the Ministry of Patriots and Veterans Affairs, the Ministry of Food and Drug Safety, the Office for Government Policy Coordination, and the Nuclear Safety and Security Commission. *<Amended by Presidential Decree No. 28211, Jul. 26, 2017; Presidential Decree No. 28456, Nov. 28, 2017>*

[This Article Newly Inserted by Presidential Decree No. 28081, May 29, 2017]

Article 34-10 (Operation of the Council)

- (1) The chairperson shall represent the Council and exercise general supervision over its affairs.
- (2) If the chairperson is unable to perform the duties due to any unavoidable reasons, the member pre-designated by the chairperson shall act on behalf of the chairperson.
- (3) A regular meeting of the Council shall be held once a year; and a special meeting shall be convened when the chairperson deems it necessary or at the request of at least 1/3 of the members.
- (4) Where the chairperson intends to hold a meeting, the chairperson shall inform each member of the date and time, place, and agenda item of the meeting not later than seven days prior to the date of holding the meeting: *Provided*, That where it is required to urgently hold a meeting or there exists any other unavoidable reason, he or she may give such information not later than the day before the meeting.
- (5) A majority of the members of the Council shall constitute a quorum, and any decision thereof shall require the concurrent vote of a majority of those present.
- (6) If necessary for efficient consultation, the chairperson may have a person related to the agenda item or an expert in the relevant field attend and speak at a meeting.

[This Article Newly Inserted by Presidential Decree No. 28081, May 29, 2017]

Article 34-11 (Working Committee and Subcommittees)

- (1) A working committee and subcommittees may be established in the Council if necessary to efficiently perform the Council's affairs.
- (2) Matters necessary for the organization and operation of the working committee and subcommittees shall be determined by the Minister of Food and Drug Safety.

[This Article Newly Inserted by Presidential Decree No. 28081, May 29, 2017]

Article 34-12 (Executive Secretary)

- (1) The Council and the working committee, respectively shall have one executive secretary to deal with the administrative affairs thereof.
- (2) An executive secretary shall be designated by the Minister of Food and Drug Safety from among the public officials of the Ministry of Food and Drug Safety.

[This Article Newly Inserted by Presidential Decree No. 28081, May 29, 2017]

Article 34-13 (Allowances)

Allowances, travel expenses, and other necessary expenses may be paid to relevant experts attending

meetings of the Council, the working committee, and subcommittees, within budgetary limits.

[This Article Newly Inserted by Presidential Decree No. 28081, May 29, 2017]

Article 35 (Delegation and Entrustment of Affairs)

(1) Pursuant to Article 84 (2) of the Act, the Minister of Food and Drug Safety shall delegate the following authority to the head of a regional office of food and drug safety: *<Amended by Presidential Decree No. 24479, Mar. 23, 2013; Presidential Decree No. 26544, Sep. 22, 2015; Presidential Decree No. 28820, Apr. 24, 2018; Presidential Decree No. 29811, Jun. 4, 2019>*

1. Permission for manufacturing and distribution of items, permission for modification, and permission for renewal; permission for import of each item, permission for modification, and permission for renewal; and acceptance of a notification of import business or a notification of modification, with regard to drugs (limited to the items that need the verification of equivalence of drugs), under Article 31 (2) and (9), 31-5 (3) (including cases applied *mutatis mutandis* under Article 42 (5) of the Act), or 42 (1) of the Act;
2. Acceptance of a notification of manufacturing and distribution, notification of modification, or notification of renewal, and acceptance of a notification of import of each item, notification of modification, or notification of renewal, with regard to drugs (excluding drug substances determined and publicly notified by the Minister of Food and Drug Safety), under Article 31 (2) and (9), 31-5 (3) (including cases applied *mutatis mutandis* under Article 42 (5) of the Act), or 42 (1) of the Act;
3. Acceptance of a notification of an import manager or a notification of business closure, etc. by an importer under Article 36 (3) or 40 of the Act applied *mutatis mutandis* pursuant to Article 42 (5) of the Act;
- 3-2. Imposition or collection of a penalty surcharge on or from a drug manufacturer, a person who has obtained permission by item, or an importer, and disposition on delinquency under Article 81-2 of the Act;
4. Imposition or collection of administrative fines under Article 98 (1) 4-3 of the Act.

(2) Deleted. *<by Presidential Decree No. 24479, Mar. 23, 2013>*

(3) The Minister of Health and Welfare shall entrust the following affairs to the Pharmaceutical Association or the Oriental Pharmacy Association pursuant to Article 16 (2) of the Act: *<Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 23459, Dec. 30, 2011>*

1. Receipt of notifications of pharmacists or oriental medicine pharmacists under Article 7 of the Act;
2. Training and education of pharmacists or oriental medicine pharmacists under Article 15 of the Act;
3. Review of pharmacists' or oriental medicine pharmacists' ethics under Article 16 (2) of the Act;
4. Investigation and verification of a distribution price indication at pharmacies under subparagraph 10 of Article 56 of the Act.

Article 36 (Special Cases concerning Animal Drugs)

In applying Articles 33, 34, 38-2 and 39 to animal drugs, etc. referred to in Article 85 of the Act, the "Minister of Health and Welfare" or the "Minister of Food and Drug Safety" in those Articles shall be construed as "the Minister of Agriculture, Food and Rural Affairs or the Minister of Oceans and Fisheries", and "Ordinance of the Prime Minister" or "Ordinance of the Ministry of Health and Welfare" as "Ordinance of the Ministry of Agriculture, Food and Rural Affairs or Ordinance of the Ministry of Oceans and Fisheries". *<Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 24479, Mar. 23, 2013; Presidential Decree No. 28456, Nov. 28, 2017>*

Article 36-2 (Field Survey Documents for Investigation and Evaluation of Injury from Side Effects of Drugs)

“Matters prescribed by Presidential Decree, such as the period and scope of an investigation, persons in charge of investigation, and relevant statutes and regulations” in the latter part of Article 86-6 (3) of the Act means matters under the subparagraphs of Article 32-10.

[This Article Newly Inserted by Presidential Decree No. 27673, Dec. 13, 2016]

Article 37 (Procedures for Paying Monetary Awards)

- (1) Any supervisory agency or investigative agency upon receipt of a report or accusation of the fact of violating related statutes and regulations under Article 90 of the Act shall inform the head of the competent *Si/Gun/Gu* of the outline of such violation.
- (2) The head of a *Si/Gun/Gu* informed under paragraph (1) may pay the monetary award within budgetary limits, where an adjudication of the court concerning the relevant case is final and conclusive.
- (3) The monetary award under paragraph (2) shall not exceed 10/100 of the amount of a fine sentenced for the said case (where sentenced to imprisonment with labor, the maximum amount of fines under the relevant applied penalty provisions).

Article 38 (Operation of the Korea Orphan and Essential Drug Center)

- (1) The chairperson of the Korea Orphan and Essential Drug Center under Article 91 of the Act (hereinafter referred to as the "Center") shall submit a business plan and a budget of revenues and expenses for the following year to the Minister of Food and Drug Safety not later than April 30 of each business year. *<Amended by Presidential Decree No. 24479, Mar. 23, 2013; Presidential Decree No. 28081, May 29, 2017>*
- (2) Where the important matters of the business plan and the budget of revenues and expenses under paragraph (1) are modified, the documents stating the details of and reasons for such modification shall be submitted to the Minister of Food and Drug Safety. *<Amended by Presidential Decree No. 24479, Mar. 23, 2013>*
- (3) Upon receipt of the business plan and the budget of revenues and expenses for the following year under paragraph (1), the Minister of Food and Drug Safety may, if deemed necessary, request the chairperson of the Center to submit data concerning the following matters: *<Amended by Presidential Decree No. 24479, Mar. 23, 2013>*
 1. Matters concerning the projects under the subparagraphs of Article 92 (1) of the Act;
 2. Matters concerning the details of financial assistance under Article 92 (2) of the Act.

Article 38-2 (Handling of Sensitive Information and Personally Identifiable Information)

The Minister of Health and Welfare (including a person to whom the Minister of Health and Welfare has entrusted his or her affairs pursuant to Article 35), the Minister of Food and Drug Safety, the Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* (where the relevant authority is delegated or entrusted, including a person to whom such authority has been delegated or entrusted), or the national examination administrative agency may handle information on health under Article 23 of the Personal Information Protection Act, information corresponding to criminal history records under subparagraph 2 of Article 18 of the Enforcement Decree of that Act, and data containing resident registration numbers and alien registration numbers prescribed in subparagraph 1 or 4 of Article 19 of that Decree, if inevitable to perform any of the following administrative affairs: *<Amended by Presidential Decree No. 24144, Oct. 22, 2012; Presidential Decree No. 24479, Mar. 23, 2013; Presidential Decree No. 26544, Sep. 22, 2015; Presidential Decree No. 28081, May 29, 2017; Presidential Decree No. 28456, Nov. 28, 2017>*

1. Administrative affairs concerning registration of a pharmacist or oriental medicine pharmacist

- license, and issuance and re-issuance thereof under Article 6 of the Act;
2. Administrative affairs concerning notifications by pharmacists or oriental medicine pharmacists under Article 7 of the Act;
 3. Administrative affairs concerning national examinations for a pharmacist license or an oriental medicine pharmacist license under Article 8 of the Act;
 4. Administrative affairs concerning verification of eligibility requirements for national examinations for a pharmacist license or an oriental medicine pharmacist license under Article 9 of the Act;
 5. Administrative affairs concerning registration of establishment of pharmacies or registration of modification thereof under Article 20 of the Act;
 6. Administrative affairs concerning notifications of business closure, suspension, or resumption of pharmacies under Article 22 of the Act;
 7. Administrative affairs concerning permission for drug manufacturing business, notifications of contract manufacturing and distribution business of drugs, notifications of quasi-drug manufacturing business, and permission for and notifications of modification thereof under Article 31 of the Act;
 8. Administrative affairs concerning conditional permission for drug manufacturing business under Article 35 of the Act;
 - 8-2. Administrative affairs concerning notifications of manufacturing managers of drugs, etc. under Article 36 of the Act (including import managers applied *mutatis mutandis* under Article 42 (5) of the Act);
 9. Administrative affairs concerning recall of drugs, etc. under Article 39 of the Act;
 10. Administrative affairs concerning notifications of business closure, suspension, and resumption or notifications of replacement of manufacturing managers under Article 40 of the Act;
 11. Administrative affairs concerning notifications of manufacturing of pharmacy medications and dispensary medications under Article 41 of the Act;
 - 11-2. Administrative affairs concerning notifications of import business of drugs, etc. or notifications of modification thereof under Article 42 (1) of the Act;
 - 11-3. Administrative affairs concerning registration of a distributor of safe and readily available drugs and registration of modification thereof under Article 44-2 of the Act;
 12. Administrative affairs concerning permission, etc. for herb druggists or drug wholesalers under Article 45 of the Act;
 13. Administrative affairs concerning directions given under Article 69 of the Act;
 14. Administrative affairs concerning administrative dispositions under Articles 70 through 76 and 76-3 of the Act;
 15. Administrative affairs concerning hearings under Article 77 of the Act;
 16. Administrative affairs concerning appointment of pharmaceutical inspectors under Article 78 of the Act;
 17. Administrative affairs concerning revocation of a pharmacist or oriental medicine pharmacist license and suspension of qualifications as a pharmacist or oriental medicine pharmacist under Article 79 of the Act;
 18. Administrative affairs concerning renewal of a license, permit, certificate of registration, etc. under Article 80 of the Act;
 19. Administrative affairs concerning imposition and collection of penalty surcharges under Article 81 of the Act;
 20. Administrative affairs concerning succession to the status of a manufacturer, etc. under Article 89 of the Act;
 21. Administrative affairs concerning payment of a monetary award under Article 90 of the Act;
 22. Administrative affairs concerning issuance of a druggist license under Article 5 of the Addenda to the Pharmaceutical Affairs Act (wholly amended by Act No. 8365).

[This Article Newly Inserted by Presidential Decree No. 23488, Jan. 6, 2012]

Article 38-3 (Re-Examination of Regulation)

The Minister of Health and Welfare shall examine the appropriateness of the following matters every three years, counting from each base date specified in the following (referring to the period that ends on the day before the base date of every third year) and shall take measures, such as making improvements:

1. Standards for facilities of pharmacies prescribed in Article 22-2: January 1, 2014;
2. Standards for facilities of herb druggists, drug wholesalers, etc., prescribed in Article 31-2: January 1, 2014;
3. Standards for imposition of administrative fines prescribed in Article 39 (1) and attached Table 3: January 1, 2014.

[This Article Newly Inserted by Presidential Decree No. 25050, Dec. 30, 2013]

Article 39 (Imposition and Collection of Administrative Fines)

- (1) The standards for imposing administrative fines referred to in Article 97-2 (1) of the Act shall be as listed in attached Table 2-3. *<Newly Inserted by Presidential Decree No. 26143, Mar. 13, 2015; Presidential Decree No. 29811, Jun. 4, 2019>*
- (2) The standards for imposing administrative fines referred to in Article 98 (1) of the Act shall be as listed in attached Table 3. *<Amended by Presidential Decree No. 26143, Mar. 13, 2015>*
- (3) Deleted. *<by Presidential Decree No. 27673, Dec. 13, 2016>*

[This Article Wholly Amended by Presidential Decree No. 21084, Oct. 14, 2008]

Addenda *<Presidential Decree No. 30170, Oct. 29, 2019>*

Article 1 (Enforcement Date)

This Decree shall enter into force on November 1, 2019.

Articles 2 and 3 Omitted.

2.14 Child Care Act

Act No. 16404, Apr. 30, 2019

CHAPTER I General Provisions

Article 1 (Purpose)

The purpose of this Act is to contribute to promoting the welfare of infants and young children and their families by fostering them to become healthy members of the society by nurturing their minds and bodies, and their sound education, and by facilitating their guardians' economic and social activities.

<Amended by Act No. 11003, Aug. 4, 2011>

[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 2 (Definitions)

The terms used in this Act shall be defined as follows: *<Amended by Act No. 9165, Dec. 19, 2008; Act No. 10789, Jun. 7, 2011>*

1. The term "infants and young children" means pre-schoolers under the age of six;
2. The term "child care" means social welfare services supporting child care centers and home nurseries that protect and foster infants and young children in a healthy and safe manner and providing infants and young children with education tailored to their growth patterns;
3. The term "child care center" means institutions caring for infants and young children entrusted by guardians;
4. The term "guardian" means a person in parental authority, a tutor and any other person actually caring for an infant or a young child;
5. The term "child care teachers and staff" means principals, child care teachers, and other employees of child care centers, in charge of the nursery and health care of infants and young children in the child care centers, consultations with guardians, and other affairs concerning the management and operation of the child care centers.

[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 3 (Concept of Child Care)

- (1) Child care services shall be rendered with priority consideration given to the interests of infants and young children.
- (2) Child care services shall be rendered so that infants and young children can grow up healthily in a safe and comfortable environment.
- (3) Infants and young children shall be cared for without discrimination due to their or their guardians' gender, age, religion, social standing, property status, disabilities, race, place of birth, etc. *<Amended by Act No. 11003, Aug. 4, 2011>*

[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 4 (Responsibility)

- (1) All people shall have responsibility to care for infants and young children in a healthy manner.
- (2) The State and local governments shall have responsibility to care for infants and young children in a healthy manner together with the guardians thereof and endeavor to secure financial resources therefor in a stable manner. *<Amended by Act No. 11627, Jan. 23, 2013>*
- (3) The Special Self-Governing Province Governor and the heads of Sis/Guns/Gus (referring to the heads of autonomous Gus; hereinafter the same shall apply) shall ensure there are appropriate child

care centers in their jurisdictional areas to care for infants and young children. <Amended by Act No. 10789, Jun. 7, 2011; Act No. 11003, Aug. 4, 2011>

- (4) The State and local governments shall endeavor to train child care teachers and staff, and to improve their working conditions. <Newly Inserted by Act No. 13321, May 18, 2015>

[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 5 (Child Care Policy Coordination Committee)

- (1) The Child Care Policy Coordination Committee (hereinafter referred to as the "Child Care Policy Coordination Committee") shall be established under the Prime Minister to coordinate opinions of the relevant Ministries on child care policies.
- (2) The Child Care Policy Coordination Committee shall deliberate on and coordinate the following:
1. Matters concerning the basic direction-setting for child care policies;
 2. Matters concerning the improvement of relevant systems of child care and budgetary support;
 3. Matters concerning cooperation among the relevant Ministries for child care;
 4. Other matters placed on the agenda by the chairperson.
- (3) The Child Care Policy Coordination Committee shall be comprised of up to 12 members, including a chairperson. The Minister of the Office for Government Policy Coordination shall be the chairperson and the following persons shall be members of the Child Care Policy Coordination Committee: <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10339, Jun. 4, 2010; Act No. 10789, Jun. 7, 2011; Act No. 11690, Mar. 23, 2013>
1. Vice-Ministers of Strategy and Finance, Vice-Ministers of Education, Vice-Ministers of Health and Welfare, Vice-Ministers of Employment and Labor, and Vice-Ministers of Gender Equality and Family;
 2. Each person representing the child care sector, the early childhood education sector, the women's sector, the social and welfare sector, civic groups, and guardians, who are commissioned by the chairperson on the recommendation of the members referred to in subparagraph 1.
- (4) Necessary matters concerning the organization, operation, etc. of the Child Care Policy Coordination Committee shall be prescribed by Presidential Decree.

[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 6 (Child Care Policy Committees)

- (1) The Central Child Care Policy Committee shall be established under the Ministry of Health and Welfare, and local child care policy committees shall be established under a Special Metropolitan City, a Metropolitan City, a *Do* and a Special Self-Governing Province (hereinafter referred to as "City/*Do*") and a *Si/Gun/Gu* (referring to an autonomous *Gu*; hereinafter the same shall apply) to deliberate matters, etc. concerning policies, projects, guidance on child care, and evaluation of child care centers: *Provided*, That where another suitable committee exists to function as a local child care policy committee and members of the other committee meet the qualifications referred to in paragraph (2), the other committee may assume the functions of the local child care policy committee, as prescribed by municipal ordinance of a City/*Do* or *Si/Gun/Gu*. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10789, Jun. 7, 2011; Act No. 15892, Dec. 11, 2018>
- (2) Members of the Central Child Care Policy Committee and local child care policy committees referred to in paragraph (1) (hereinafter referred to as "Child Care Policy committees") shall be comprised of child care experts, principals of child care centers, representatives of child care teachers, representatives of guardians, persons representing the public interest, relevant public officials, etc. <Amended by Act No. 10789, Jun. 7, 2011>
- (3) Matters necessary for the composition, functions, operation, etc. of the Child Care Policy committees shall be prescribed by Presidential Decree.

[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 7 (Child Care Support Centers)

- (1) The Minister of Health and Welfare shall establish and operate the Central Child Care Support Center; and each Special Metropolitan City Mayor, Metropolitan City Mayor, Special Self-Governing City Mayor, *Do* Governor, or Special Self-Governing Province Governor (hereinafter referred to as "Mayor/*Do* Governor"), or the head of each *Si/Gun/Gu* shall establish and operate local child care support centers to provide part-time care services for infants and young children referred to in Article 26-2, to collect and provide information on child care, and to provide counseling services on child care. In such cases, where deemed necessary, child care support centers for infants, children with disabilities, etc., may be established and operated, separately. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11858, Jun. 4, 2013; Act No. 16078, Dec. 24, 2018>*
- (2) The Central Child Care Support Center or each local child care support center referred to in paragraph (1) (hereinafter referred to as "child care support center") shall consist of a head, child care experts engaging in providing information on child care services, counseling experts engaging in emotional and psychological counseling services for child care teachers and staff, and others. *<Amended by Act No. 11858, Jun. 4, 2013; Act No. 13321, May 18, 2015>*
- (3) Deleted. *<by Act No. 11003, Aug. 4, 2011>*
- (4) Matters necessary for the establishment, operation, and functions of child care support centers, qualifications for and duties of the heads of child care support centers, child care experts, and counseling experts, shall be prescribed by Presidential Decree. *<Amended by Act No. 11003, Aug. 4, 2011; Act No. 11858, Jun. 4, 2013; Act No. 13321, May 18, 2015>*
- [This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]*

Article 8 (Establishment and Operation of Korea Childcare Promotion Institute)

- (1) To promote the improvement of quality of child care services and assist child care policies systematically, the Korea Childcare Promotion Institute (hereinafter referred to as "KCPI") shall be established.
- (2) KCPI shall conduct the following affairs:
1. Developing measures of evaluating child care centers;
 2. Providing education, training, and public relations on child care projects;
 3. Developing child care programs, teaching materials, and teaching aids for infants and young children;
 4. Developing training programs and teaching materials for child care teachers and staff;
 5. Affairs entrusted by the Minister of Health and Welfare pursuant to this Act;
 6. Other affairs related to child care policies, which the Minister of Health and Welfare deems necessary.
- (3) KCPI shall be a juristic person, and shall be established by filing an establishment registration in the location of its principal office.
- (4) KCPI shall be operated with subsidies, donations, and other income.
- (5) The Minister of Health and Welfare may subsidize expenses incurred in operating KCPI within budgetary limits.
- (6) KCPI may entrust affairs referred to in paragraph (2) 3 and 4 to relevant specialized institutions, etc.
- (7) Except as provided in this Act and the Act on the Management of Public Institutions, the provisions of the Civil Act governing incorporated foundations shall apply *mutatis mutandis* to KCPI.
- [This Article Wholly Amended by Act No. 15892, Dec. 11, 2018]*

Article 9 (Fact-Finding Surveys of Child Care)

- (1) The Minister of Health and Welfare shall conduct a fact-finding survey of child care every three years to properly enforce this Act. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10789, Jun. 7, 2011>*

- (2) Matters necessary for methods and details, etc. of fact-finding surveys of child care under paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 9-2 (Education of Guardians)

- (1) The State and local governments may provide guardians of infants and young children with education on the growth and methods of bringing up infants and young children, roles of guardians, human rights of infants and young children, etc.
- (2) The Minister of Health and Welfare or the head of each local government may provide subsidies for expenses for education prescribed in paragraph (1) within budgetary limits.
- (3) Matters necessary for the contents, methods of implementation, etc. of education prescribed in paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 14597, Mar. 14, 2017]

CHAPTER II Establishment of Child Care Centers

Article 10 (Types of Child Care Centers)

The types of child care centers shall be as follows: <Amended by Act No. 10789, Jun. 7, 2011; Act No. 11003, Aug. 4, 2011; Act No. 14001, Feb. 3, 2016; Act No. 14597, Mar. 14, 2017>

1. National or public child care centers: Child care centers established and operated by the State or local governments;
2. Child care centers of social welfare corporations: Child care centers established and operated by social welfare corporations established under the Social Welfare Services Act (hereinafter referred to as "social welfare corporations");
3. Child care centers of corporations, organizations, etc.: Child care centers established and operated by various kinds of corporations (non-profit corporations, excluding social welfare corporations), organizations, etc., prescribed by Presidential Decree;
4. Workplace child care centers: Child care centers established and operated by business owners for their employees (including child care centers established and operated by the State or the heads of local governments for relevant public officials and non-public officials who have concluded a labor contract with the State or with the heads of local governments);
5. Home-based child care centers: Child care centers established and operated by individuals at their homes and in places corresponding thereto;
6. Cooperative child care centers: Child care centers established and operated by associations founded by guardians, or by guardians and child care teachers and staff (limited to non-profit associations);
7. Private child care centers: Child care centers not falling under any of subparagraphs 1 through 6.

[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 11 (Formulation and Implementation of Child Care Plans)

- (1) To facilitate the provision of child care services, the Minister of Health and Welfare shall formulate and implement child care plans, including supply and demand plans for child care centers following deliberation by the Central Child Care Policy Committee, and a Mayor/Do Governor and the head of a *Si/Gun/Gu* shall formulate and implement the same following deliberation by the relevant local child care policy committee. In such cases, child care plans shall include plans and objectives for the supply of national or public child care centers. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10789, Jun. 7, 2011; Act No. 12068, Aug. 13, 2013>

- (2) If deemed necessary to formulate and/or implement child care plans referred to in paragraph (1), the Minister of Health and Welfare, Mayor/*Do* Governor, and head of a *Si/Gun/Gu* may request child care centers, child care-related corporations, organizations, etc. to submit materials, etc. The child care centers, child care-related corporations, organizations, etc. in receipt of such request shall comply therewith, without good cause. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10789, Jun. 7, 2011>*
- (3) Matters necessary for details of child care plans referred to in paragraph (1), timing and procedures for formulation thereof, etc. shall be prescribed by Presidential Decree.
[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 11-2 (Securing Child Care Centers or Sites for Child Care Centers)

Each Mayor/*Do* Governor or the head of each *Si/Gun/Gu* shall endeavor to secure child care centers or sites for child care centers in the development, maintenance, improvement, and preparation projects to be implemented under the Urban Development Act, the Act on the Maintenance and Improvement of Urban Areas and Dwelling Conditions for Residents, the Housing Site Development Promotion Act, the Industrial Sites and Development Act, the Special Act on Public Housing, etc. *<Amended by Act No. 9511, Mar. 20, 2009; Act No. 10789, Jun. 7, 2011; Act No. 11003, Aug. 4, 2011; Act No. 12251, Jan. 14, 2014; Act No. 13498, Aug. 28, 2015>*
[This Article Newly Inserted by Act No. 8851, Jan. 17, 2008]

Article 12 (Establishment of National or Public Child Care Centers)

- (1) The State and local governments shall establish and operate national or public child care centers. In such cases, national or public child care centers shall be preferentially established in the following areas according to child care plans under Article 11: *<Amended by Act No. 10789, Jun. 7, 2011; Act No. 12068, Aug. 13, 2013; Act No. 14597, Mar. 14, 2017; Act No. 16078, Dec. 24, 2018>*
1. Vulnerable areas, such as urban residential areas densely populated by low income people and agricultural and fishing communities;
 2. Deleted; *<by Act No. 16078, Dec. 24, 2018>*
 3. Industrial complex areas defined in subparagraph 8 of Article 2 of the Industrial Sites and Development Act.
- (2) The State and local governments shall, when establishing a national or public child care center pursuant to paragraph (1), undergo deliberation by the local child care policy committee prescribed in Article 6 (1). *<Newly Inserted by Act No. 16078, Dec. 24, 2018>*
- (3) The State and local governments shall operate child care centers to be established in multi-family housing defined in subparagraph 3 of Article 2 of the Housing Act pursuant to Article 35 of the same Act as national or public child care centers: *Provided*, That the same shall not apply to cases prescribed by Presidential Decree, such as where a majority of occupants, etc. defined in subparagraph 7 of Article 2 of the Multi-Family Housing Management Act disapproves the operation of such child care centers as national or public child care centers. *<Newly Inserted by Act No. 16078, Dec. 24, 2018>*
- (4) The size of multi-family housing to establish and operate national or public child care centers pursuant to paragraph (3) and matters necessary for establishing and operating national or public child care centers shall be prescribed by Presidential Decree. *<Newly Inserted by Act No. 16078, Dec. 24, 2018>*

[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 13 (Establishment of Child Care Centers Other Than National or Public Child Care Centers)

- (1) A person who intends to establish and operate child care centers other than national or public child care centers shall obtain authorization from the Special Self-Governing Province Governor or the head of a *Si/Gun/Gu*. The same shall also apply where the person intends to modify an important

authorized matter. <Amended by Act No. 10789, Jun. 7, 2011; Act No. 11003, Aug. 4, 2011>

- (2) The Special Self-Governing Province Governor or the head of a *Si/Gun/Gu* shall, when granting authorization prescribed in paragraph (1), consider the child care demand of the relevant regions. <Newly Inserted by Act No. 16251, Jan. 15, 2019>
- (3) A person who has obtained authorization to establish a child care center pursuant to paragraph (1) shall place the certificate of authorization of the child care center where it can be readily seen by visitors, etc. <Newly Inserted by Act No. 11003, Aug. 4, 2011>
- (4) Matters necessary for authorization under paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11003, Aug. 4, 2011>

[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 14 (Establishment of Workplace Child Care Centers)

- (1) Each business owner, who operates a workplace in a size larger than that prescribed by Presidential Decree, shall establish workplace child care centers: *Provided*, That where a business owner is unable to establish a workplace child care center alone, he/she shall establish and operate a joint workplace child care center with other business owners, or conclude an entrustment contract for child care services with a local child care center (hereinafter referred to as "entrusted child care services" in this Article) to support his/her employees. <Amended by Act No. 10789, Jun. 7, 2011; Act No. 12619, May 20, 2014>
- (2) Where a business owner provides entrusted child care services pursuant to the proviso of paragraph (1), the ratio of employees' children provided with child care services to those entitled for child care services in the workplace shall exceed a certain ratio prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10789, Jun. 7, 2011; Act No. 12619, May 20, 2014>
- (3) Matters necessary to establish child care centers, and to provide entrusted child care services under paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Newly Inserted by Act No. 12619, May 20, 2014>

[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 14-2 (Publication of List of Business Entities Failing to Perform Duty to Establish Workplace Child Care Centers)

- (1) The Minister of Health and Welfare and the head of the agency prescribed by Presidential Decree (hereafter referred to as "inspection agency"; the same shall apply in this Article) shall annually inspect whether a business entity performs his/her duty, etc. referred to in Article 14, such as establishment of workplace child care centers. In such cases, the head of the inspection agency shall notify the Minister of Health and Welfare of the findings of such inspection.
- (2) The Minister of Health and Welfare may publish a list of business entities who have failed to perform their duty to establish workplace child care centers, etc., and business entities who have refused to undergo the inspection (hereafter referred to as "business entities failing to perform duty"; the same shall apply in this Article) after completing the inspection referred to in paragraph (1): *Provided*, That the same shall not apply where any ground specified in Presidential Decree occurs. <Amended by Act No. 12619, May 20, 2014>
- (3) There shall be established a Deliberative Committee on Publication of the List of Workplace Child Care Centers (hereafter referred to as the "Committee" in this Article) in the Ministry of Health and Welfare to deliberate on the publication of the list of business entities failing to perform duty referred to in paragraph (2). In such cases, the Committee shall be comprised of at least five members, including a chairperson, each appointed or commissioned by the Minister of Health and Welfare, from among the following persons: <Amended by Act No. 12619, May 20, 2014>

1. Public officials of Grade III, or public officials in general service who shall be a member of the Senior Executive Service, in charge of child care policies in the Ministry of Health and Welfare;
 2. Legal experts, such as attorneys-at-law;
 3. Persons representing employees;
 4. Persons representing business owners;
 5. Persons representing public interest;
 6. Other persons prescribed by Presidential Decree, such as child care experts.
- (4) The Minister of Health and Welfare shall notify business owners of the list to be published following deliberation by the Committee, and give them with an opportunity to make explanatory statements, as prescribed by Presidential Decree.
- (5) A publication referred to in paragraph (2) shall be made by means of posting the list on the websites of the Ministry of Health and Welfare and the Ministry of Employment and Labor for one year, and publishing it in at least two daily newspapers. <Amended by Act No. 12619, May 20, 2014>
- (6) Details and methods of inspections on whether business entities perform duty to establish workplace child care centers or other duty, matters necessary to publish the list of business entities failing to perform duty, matters necessary to establish and operate the Committee, etc., referred to in paragraphs (1) through (3), shall be prescribed by Presidential Decree.

[This Article Newly Inserted by Act No. 11144, Dec. 31, 2011]

Article 15 (Standards for Establishment of Child Care Centers)

Each person, who intends to establish and operate child care centers, shall meet the establishment standards prescribed by Ordinance of the Ministry of Health and Welfare: *Provided*, That matters related to the installation of playgrounds, accident prevention facilities, and closed-circuit televisions shall be governed by Articles 15-2 through 15-4, respectively. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10789, Jun. 7, 2011; Act No. 11144, Dec. 31, 2011; Act No. 13321, May 18, 2015>

[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 15-2 (Installation of Playgrounds)

- (1) Each person, who has established or operates a child care center, shall install playgrounds, and the installation standards shall be prescribed by Ordinance of the Ministry of Health and Welfare: *Provided*, That the same shall not apply to any of the following child care centers:
1. Child care centers with a capacity of less than 50 children;
 2. Child care centers having playgrounds meeting standards prescribed by Ordinance of the Ministry of Health and Welfare within a distance of 100 meters.
- (2) Notwithstanding paragraph (1), when it is impracticable for a child care center authorized before January 29, 2005 to install playgrounds due to its locational circumstance, such as downtown areas, islands or remote areas, the Governor of a Special Self-Governing Province, or the head of a *Si/Gun/Gu* may exempt the installation of playgrounds, or grant revised authorization by mitigating the installation standards for playgrounds, through deliberation by the relevant local child care policy committee referred to in Article 6 (1) unless any obstacle to child care arises.

[This Article Newly Inserted by Act No. 10789, Jun. 7, 2011]

Article 15-3 (Accident Prevention Facilities)

- (1) Each person, who has established or operates a child care center, shall install accident prevention facilities specific for each floor level, and the installation standards shall be prescribed by Ordinance of the Ministry of Health and Welfare.
- (2) Notwithstanding paragraph (1), when the Governor of a Special Self-Governing Province, or the head of a *Si/Gun/Gu*, deems that child care centers already authorized before July 3, 2009 (hereafter

referred to as "authorized child care center"; the same shall apply in this Article) have no obstruction to accident prevention, he/she may apply the former standards effective as at the time of authorization. In such cases, the Governor of a Special Self-Governing Province, or the head of a *Si/Gun/Gu*, shall establish and operate a deliberative committee on standards for accident prevention facilities to determine whether authorized child care centers have any obstruction to accident prevention, and shall undergo deliberation by the relevant committee.

- (3) Each deliberative committee on standards for accident prevention facilities referred to in paragraph (2) shall be comprised of at least five members appointed or commissioned by the Governor of a Self-Governing Province or the head of a *Si/Gun/Gu*, from among the following persons. In such cases, at least 1/2 of members shall fall under subparagraphs 1 through 4, and the chairperson shall be elected from among the members by mutual vote:
1. Fire-fighting official;
 2. Professional fire-fighting engineers;
 3. Fire equipment managers;
 4. Persons with professional knowledge about fire fighting and disaster prevention referred to in Article 4-2 of the Installation, Maintenance, and Safety Control of Fire-Fighting Systems Act;
 5. Public officials in charge of child care-related affairs;
 6. Professors in the child care-related field, working for a school referred to in Article 2 of the Higher Education Act.
- (4) The provisions pertaining to local child care policy committees referred to in Article 6 shall apply *mutatis mutandis* to matters necessary for the term of office of members, operation, meetings, etc.

[This Article Newly Inserted by Act No. 11144, Dec. 31, 2011]

Article 15-4 (Installation of Closed-Circuit Televisions)

- (1) Each person, who has established or operates a child care center, shall install or manage closed-circuit televisions under the Personal Information Protection Act and relevant statutes or regulations (hereinafter referred to as "closed circuit television") to secure the safety of infants and young children, such as prevention of child abuse, and to provide security to the child care center: *Provided*, That the same shall not apply to either of the following cases:
1. Where a person, who has established or operates a child care center, files a report with the head of a *Si/Gun/Gu* after obtaining consent from all the guardians;
 2. Where a person, who has established or operates a child care center, has installed network cameras under the Personal Information Protection Act and relevant statutes or regulations after obtaining consent from all the guardians and child care teachers and staff.
- (2) Each person in charge of installing or managing closed-circuit televisions pursuant to paragraph (1) shall observe the following so as not to infringe on the rights of data subjects, such as infants, young children, and child care teachers and staff:
1. He/she shall collect video information to the minimum extent possible by lawful and reasonable means to secure the safety of infants and young children, such as preventing child abuse, and to provide security to a child care center, and shall ensure that such information is not used for any purpose other than the intended purpose;
 2. He/she shall manage video information safely, taking into account the possibility of infringing on the rights of data subjects, such as infants, young children, and child care teachers and staff, and the degree of harm involved;
 3. He/she shall handle video information in a manner that minimizes invasion of privacy of data subjects, such as infants, young children, and child care teachers and staff.
- (3) Each person, who has established or operates a child care center, shall keep video information recorded in a closed-circuit television for at least 60 days.
- (4) Matters necessary for the standards for installation and management of closed-circuit televisions, the

method, procedures and requirements for obtaining consent or filing a report under paragraph (1), and the standards, period, etc., for storage of video information under paragraph (3) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 13321, May 18, 2015]

Article 15-5 (Prohibition of Inspection of Video Information)

- (1) No person in charge of installing or managing closed-circuit televisions shall make the video information under Article 15-4 (1) available for inspection, except in any of the following cases:
1. Where a guardian requests inspection thereof in accordance with the timing, procedures, method, etc., for inspection prescribed by Ordinance of the Ministry of Health and Welfare, for the purpose of checking the safety of his/her child or a child under his/her guardianship;
 2. Where a public institution defined in subparagraph 6 (a) of Article 2 of the Personal Information Protection Act requests inspection thereof to conduct affairs related to the safety of infants and young children prescribed in relevant statutes or regulations, including Article 42 of this Act, and Article 66 of the Child Welfare Act;
 3. Where inspection thereof is necessary to investigate crimes, to institute or maintain public prosecution, or to conduct trial affairs of a court;
 4. Other cases where an institution, which conducts safety affairs related to child care and is prescribed by Ordinance of the Ministry of Health and Welfare, requests inspection thereof in accordance with the timing, procedures, method, etc., for inspection prescribed by Ordinance of the Ministry of Health and Welfare to perform its duties.
- (2) No person, who establishes or operates a child care center, shall commit any of the following:
1. Arbitrarily manipulating a closed-circuit television for any purpose other than its installation purpose specified in Article 15-4 (1), or making it focus on a place other than the originally intended place;
 2. Using its sound recording function, or storing video information in a device or apparatus other than the storage device prescribed by Ordinance of the Ministry of Health and Welfare.
- (3) Each person, who has established or operates a child care center, shall take technical, managerial, and physical measures necessary to secure safety, such as formulating internal management plans and keeping access records, to prevent the video information referred to in Article 15-4 (1) from being lost, stolen, leaked, modulated, or damaged, as prescribed by Presidential Decree.
- (4) To ensure that the rights of data subjects, such as infants, young children, and child care teachers and staff, are not infringed due to the installation or management of closed-circuit televisions at child care centers or the inspection of the relevant video information, the State and local governments shall examine and check the actual status of installation, management, and inspection at least once a year, as prescribed by Ordinance of the Ministry of Health and Welfare.
- (5) Except as provided in this Act, the Personal Information Protection Act (except for Article 25) shall apply to the installation and management of closed-circuit televisions, and to the inspection of the relevant video information.

[This Article Newly Inserted by Act No. 13321, May 18, 2015]

Article 16 (Grounds for Disqualification)

None of the following persons shall establish and operate any child care center: *<Amended by Act No. 10789, Jun. 7, 2011; Act No. 12068, Aug. 13, 2013; Act No. 12697, May 28, 2014; Act No. 13321, May 18, 2015; Act No. 15892, Dec. 11, 2018>*

1. A minor, a person under adult guardianship, or a person under limited guardianship;
2. A mentally ill person defined in subparagraph 1 of Article 3 of the Act on the Improvement of Mental Health and the Support for Welfare Services for Mental Patients;
3. A person addicted to narcotics, etc. defined in subparagraph 1 of Article 2 of the Narcotics

Control Act;

4. A person declared bankrupt, but not yet reinstated;
5. A person for whom five years (or 20 years if he/she has committed a child abuse-related crime defined in subparagraph 7-2 of Article 3 of the Child Welfare Act) have not elapsed since his/her imprisonment without labor or a heavier punishment declared by a court was completely executed (including where such execution is deemed completed) or exempted;
6. A person who is under suspension of the execution of his/her imprisonment without labor or a heavier punishment declared by a court: *Provided*, That a person to whom a suspended sentence of imprisonment without prison labor or a heavier punishment has been declared by a court for committing a child abuse-related crime defined in subparagraph 7-2 of Article 3 of the Child Welfare Act shall remain disqualified until 20 years elapse after such suspended sentence is final and conclusive;
7. A person for whom five years have not elapsed since he/she was ordered to close a child care center under Article 45;
8. A person for whom two years have not elapsed since his/her punishment by a fine of at least three million won was final and conclusive under Article 54, or a person for whom 10 years have not elapsed since his/her punishment by a fine was final and conclusive for committing a child abuse-related crime defined in subparagraph 7-2 of Article 3 of the Child Welfare Act;
9. A person who fails to perform an order to undergo education under Article 23-3.

[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

CHAPTER III Child Care Teachers and Staff

Article 17 (Placement of Child Care Teachers and Staff)

- (1) Child care teachers and staff shall be placed in child care centers. *<Amended by Act No. 10789, Jun. 7, 2011>*
- (2) A child care center operated by dividing child care hours pursuant to Article 24-2 (1) may place child care teachers by child care hour prescribed in the subparagraphs of the same paragraph. *<Newly Inserted by Act No. 16404, Apr. 30, 2019>*
- (3) Child care centers shall place assistant teachers, etc. to reduce the work burden of child care teachers. *<Newly Inserted by Act No. 13321, May 18, 2015>*
- (4) Where a child care teacher is unable to perform his/her duties due to vacation, continuing education, etc., a substitute teacher shall be placed to perform duties on his/her behalf. *<Newly Inserted by Act No. 13321, May 18, 2015>*
- (5) Matters necessary for the standards for placing child care teachers and staff, and other personnel shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10789, Jun. 7, 2011; Act No. 13321, May 18, 2015>*

[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 18 (Duties of Child Care Teachers and Staff)

- (1) Principals of child care centers shall have overall control of the child care centers, guide and supervise child care teachers and other staff members, and care for infants and young children. *<Amended by Act No. 10789, Jun. 7, 2011>*
- (2) Child care teachers shall care for infants and young children and shall perform the duties of the principals of the child care centers on behalf of the principals when they are unable to exercise their duties due to unavoidable reasons. *<Amended by Act No. 10789, Jun. 7, 2011>*

[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 18-2 (Responsibilities of Child Care Teachers and Staff)

- (1) In caring for infants and young children, no child care teachers and staff shall inflict physical or mental pain, including screaming, abusive language, etc., on infants and young children. *<Amended by Act No. 14597, Mar. 14, 2017>*
- (2) Child care teachers and staff member shall do best to pay attention to the protection of lives and safety of infants and young children and prevention of danger in the conduct of duties. *<Newly Inserted by Act No. 14597, Mar. 14, 2017>*

[This Article Newly Inserted by Act No. 13321, May 18, 2015]

Article 19 (Appointment and Dismissal of Child Care Teachers and Staff)

- (1) The Governor of a Special Self-Governing Province and the head of a *Si/Gun/Gu* shall manage the matters concerning appointment, dismissal and career, etc. of child care teachers and staff to ensure the rights and interests of child care teachers and staff, and to improve their working conditions. *<Amended by Act No. 10789, Jun. 7, 2011; Act No. 11003, Aug. 4, 2011>*
- (2) Principals of child care centers shall report matters concerning the appointment and dismissal of child care teachers and staff to the Governor of a Special Self-Governing Province and the head of a *Si/Gun/Gu*, as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10789, Jun. 7, 2011; Act No. 11003, Aug. 4, 2011>*

[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 20 (Grounds for Disqualification)

None of the following persons shall be employed by any child care center: *<Amended by Act No. 10789, Jun. 7, 2011; Act No. 12068, Aug. 13, 2013>*

1. A person falling under any subparagraph of Article 16;
2. A person whose qualification has been suspended pursuant to Article 46 or 47;
3. A person for whom the period for reissuing qualifications under Article 48 (2) has not elapsed since his/her qualifications were revoked pursuant to Article 48 (1).

[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 21 (Qualifications for Principals or Child Care Teachers of Child Care Centers)

- (1) Principals of child care centers shall be persons qualified as prescribed by Presidential Decree, who have acquired a certificate of qualification approved and issued by the Minister of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No.9932, Jan. 18, 2010; Act No. 10789, Jun. 7, 2011>*
- (2) Child care teachers shall be any of the following persons who have acquired a certificate of qualification approved and issued by the Minister of Health and Welfare: *<Amended by Act No. 8851, Jan. 17, 2008; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11003, Aug. 4, 2011>*
 1. A person who has acquired an academic degree higher than a two-year bachelor, and completed a course related to child care with credits prescribed by Ordinance of the Ministry of Health and Welfare from a school as defined in Article 2 of the Higher Education Act;
 - 1-2. A person recognized as having an academic background at least equivalent to a graduate from a school as defined in Article 2 of the Higher Education Act pursuant to statutes or regulations, and who has acquired an academic degree higher than a two-year bachelor and completed a course related to child care with credits prescribed by Ordinance of the Ministry of Health and Welfare;
 2. A graduate from a high school or any other school at least equivalent to high school and has

completed due curricula in educational and training facilities designated by the Mayor/Do Governor.

- (3) Child care teachers falling under paragraph (2) shall be graded I, II, or III, and the standards for qualification by grade shall be prescribed by Presidential Decree.
- (4) Matters necessary for the designation and cancellation of designation of educational and training facilities, curricula, etc. referred to in paragraph (2) shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Newly Inserted by Act No. 11003, Aug. 4, 2011>*
[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 22 (Issuance of Certificates of Qualification as Principals or Child Care Teachers of Child Care Centers)

- (1) The Minister of Health and Welfare shall examine the qualifications as principals and child care teachers of child care centers pursuant to Article 21 (1) and (2) and issue certificates of qualifications. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10789, Jun. 7, 2011>*
- (2) The Minister of Health and Welfare may collect fees, as prescribed by Ordinance of the Ministry of Health and Welfare, from persons who intend to have a certificate of qualification as a principal or child care teacher of a child care center issued or re-issued (hereinafter referred to as "issuance, etc. of certificates of qualification for child care") pursuant to paragraph (1). *<Newly Inserted by Act No. 10789, Jun. 7, 2011>*
- (3) and (4) Deleted. *<by Act No. 11003, Aug. 4, 2011>*
- (5) A public or civil institution or organization entrusted with affairs concerning the issuance, etc. of certificates of qualification for child care pursuant to Article 51-2 (1) 2 may appropriate fees it collects under paragraph (2) directly for costs incurred in the issuance, etc. of certificates of qualification for child care, after obtaining approval from the Minister of Health and Welfare. *<Newly Inserted by Act No. 10789, Jun. 7, 2011; Act No. 11003, Aug. 4, 2011>*
- (6) Matters necessary for the issuance, etc. of certificates of qualification for child care shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10789, Jun. 7, 2011>*
[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 22-2 (Prohibition on Lending Name)

No principal or child care teacher of any child care center shall permit any other person to perform any of the duties of such principal or child care teacher of the relevant child care center by using his/her name or under the title of such child care center, nor lend his/her certificate of qualification to any other person. *<Amended by Act No. 10789, Jun. 7, 2011>*
[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 23 (Continuing Education for Principals of Child Care Centers)

- (1) The Minister of Health and Welfare shall provide continuing education to improve the quality of principals of child care centers. In such cases, continuing education shall be conducted in the form of off-the-job training. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10789, Jun. 7, 2011; Act No. 11144, Dec. 31, 2011; Act No. 13321, May 18, 2015>*
- (2) Continuing education referred to in paragraph (1) shall be divided into preliminary on-the-job education and on-the-job education. *<Amended by Act No. 11144, Dec. 31, 2011>*
- (3) Deleted. *<by Act No. 11003, Aug. 4, 2011>*
- (4) Continuing education referred to in paragraph (1) shall include the following: *<Newly Inserted by Act No. 13321, May 18, 2015; Act No. 13656, Dec. 29, 2015>*
 1. Prevention of sexual violence and child abuse;

2. Precaution against, and prevention of, missing and kidnapping;
 3. Prevention of infectious diseases and drug misuse and abuse, and management of health and hygiene;
 4. Disaster preparedness and safety;
 5. Traffic safety;
 6. Improving human nature of principals of child care centers (including education on protecting human rights of infants and young children);
 7. Other matters prescribed by Ordinance of the Ministry of Health and Welfare.
- (5) Other matters necessary for the period, method, etc., of continuing education shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11003, Aug. 4, 2011; Act No. 13321, May 18, 2015>*
[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 23-2 (Continuing Education for Child Care Teachers)

- (1) The Minister of Health and Welfare shall provide continuing education to improve the quality of child care teachers. In such cases, continuing education shall be conducted in the form of off-the-job training. *<Amended by Act No. 13321, May 18, 2015>*
- (2) Continuing education referred to in paragraph (1) shall be divided into on-the-job education and promotion education.
- (3) Continuing education referred to in paragraph (1) shall include the following: *<Newly Inserted by Act No. 13321, May 18, 2015; Act No. 13656, Dec. 29, 2015>*
 1. Prevention of sexual violence and child abuse;
 2. Precaution against, and prevention of, missing and kidnapping;
 3. Prevention of infectious diseases and drug misuse and abuse, and management of health and hygiene;
 4. Disaster preparedness and safety;
 5. Traffic safety;
 6. Improving human nature of child care teachers (including education on protecting human rights of infants and young children);
 7. Other matters prescribed by Ordinance of the Ministry of Health and Welfare.
- (4) Other necessary matters concerning the period, method, etc., of continuing education shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Act Newly Inserted by Act No. 11144, Dec. 31, 2011]

Article 23-3 (Order to Undergo Education)

- (1) Where a person, who has committed a child abuse-related crime defined in subparagraph 7-2 of Article 3 of the Child Welfare Act, intends to establish and operate, or work for, a child care center because he/she is not disqualified under subparagraphs 5 through 8 of Article 16 or subparagraph 1 of Article 20 (limited to subparagraphs 5 through 8 of Article 16), the Minister of Health and Welfare shall order such person to first undergo education for the prevention of child abuse. In such cases, expenses incurred in conducting education shall be borne by the person who undergoes education. *<Amended by Act No. 13321, May 18, 2015>*
- (2) Matters necessary for issuing an order to undergo education referred to in paragraph (1), such as procedures, educational institutions, method and curricula of education, shall be determined by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 12068, Aug. 13, 2013]

CHAPTER IV Operation of Child Care Centers

Article 24 (Standards for Operation of Child Care Centers)

- (1) An establisher/operator of a child care center shall operate it pursuant to the standards for operation of child care centers prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10789, Jun. 7, 2011>*
- (2) The State or a local government may entrust the operation of a national or public child care center established under Article 12 to a corporation, organization, or individual. In such cases, the first entrustment shall be deliberated upon pursuant to the standards for selection and management of entities to which national or public child care centers are entrusted, which are prescribed by Ordinance of the Ministry of Health and Welfare, and shall follow the method of open tender, unless entrusted to the following persons: *<Amended by Act No. 8851, Jan. 17, 2008; Act No. 10789, Jun. 7, 2011; Act No. 11003, Aug. 4, 2011; Act No. 15892, Dec. 11, 2018>*
 1. When a private child care center is donated to the State or a local government to be converted into a national or public child care center, the establisher/operator of the child care center before the donation;
 2. When establishing a national or public child care center, the person who has donated the relevant site or building to the State or a local government or has allowed the State or a local government to use it without compensation;
 3. When a private child care center established under the Housing Act is converted into a national or public child care center, the establisher/operator of the child care center before the conversion.
- (3) A business owner who has established a workplace child care center pursuant to Article 14 may entrust the operation thereof to a corporation, organization, or individual. *<Amended by Act No. 10789, Jun. 7, 2011>*
- (4) Matters necessary for the entrustment of child care centers and cancellation thereof, etc. under paragraphs (2) and (3) shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10789, Jun. 7, 2011; Act No. 11003, Aug. 4, 2011>*

[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

#Article 24-2 (Division of Child Care Hours)

- (1) A child care center may be operated by dividing child care hours as follows:
 1. Basic child care: A course essentially provided to all infants and young children using the child care center, in which child care services are provided for hours equal to or below the hours prescribed by Ordinance of the Ministry of Health and Welfare;
 2. Extended child care: A child care service provided to meet the needs, etc. of guardians in excess of the basic child care.
- (2) Matters concerning the standards for and details of operating child care hours prescribed in paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 16404, Apr. 30, 2019]

[Enforcement Date: Mar. 1, 2020] Article 24-2

Article 25 (Child Care Center Operating Committees)

- (1) The principal of each child care center may establish and operate a child care center operating committee within the child care center, to enhance autonomy and transparency in the operation of the child care center, and to provide child care services suitable for local conditions and characteristics by strengthening ties with the local community: *Provided*, That a child care center which shall preferentially provide child care services to the vulnerable under Article 26, and a child care center

prescribed by Presidential Decree, shall establish and operate a child care center operating committee. <Amended by Act No. 10789, Jun. 7, 2011>

- (2) A child care center operating committee shall be comprised of the principal of the relevant child care center, representatives of child care teachers, representatives of parents, and prominent persons of the local community (in cases of a workplace child care center, referring to the person in charge of the affairs of the child care center in the relevant workplace). In such cases, the representatives of parents shall account for at least a half of the members of the committee. <Amended by Act No. 10789, Jun. 7, 2011; Act No. 13321, May 18, 2015>
- (3) The principal of each child care center may fix the number of members of a child care center operating committee consisting of at least five and not more than ten members, considering the scale, etc., of the relevant child care center. <Amended by Act No. 10789, Jun. 7, 2011>
- (4) Each child care center operating committee shall deliberate on the following: <Amended by Act No. 10789, Jun. 7, 2011; Act No. 11003, Aug. 4, 2011; Act No. 12068, Aug. 13, 2013; Act No. 13321, May 18, 2015>
 1. Matters concerning the establishment of, or amendment to, operating rules of the relevant child care center;
 2. Matters concerning budget reporting and the settlement of accounts of the relevant child care center;
 3. Matters concerning the health, nutrition, and safety of infants and young children;
 - 3-2. Matters concerning the prevention of child abuse;
 4. Matters concerning the operation of the child care center, such as hours of caring for infants and young children and the method of operating child care courses;
 5. Matters concerning the improvement of working conditions of child care teachers and staff;
 6. Matters concerning the improvement of nursing environment for infants and young children;
 7. Matters concerning cooperation between the child care center and local communities;
 8. Matters concerning determination on the amount of expenses to be received within the limit under Article 38, where the relevant child care center receives necessary expenses other than child care fees;
 9. Other matters concerning proposals and recommendations on the operation of the child care center.
- (5) Meetings of a child care center operating committee shall be held at least quarterly. <Newly Inserted by Act No. 13321, May 18, 2015>
- (6) Other matters necessary for the establishment and operation of child care center operating committees shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10789, Jun. 7, 2011; Act No. 13321, May 18, 2015>

[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 25-2 (Parental Monitoring Groups)

- (1) A Mayor/Do Governor or the head of a *Si/Gun/Gu* may establish and operate a monitoring group comprised of parents and child care and health care experts (hereafter in this Article, referred to as "parental monitoring group") to monitor the environment of child care centers and provide consultation for improving the environment thereof.
- (2) Each parental monitoring group shall perform the following duties:
 1. Monitoring the state of operation of child care centers, such as meals, hygiene, health, and safety management;
 2. Consultation to improve the environment of child care centers;
 3. Other matters related to child care determined by Ordinance of the Ministry of Health and Welfare.
- (3) Each parental monitoring group shall be comprised of up to ten persons and commissioned by the

relevant Mayor/*Do* Governor or the head of the relevant *Si/Gun/Gu*.

- (4) A Mayor/*Do* Governor or the head of a *Si/Gun/Gu* may provide persons commissioned as members of a parental monitoring group with education necessary for performing their duties.
- (5) The State and each local government may provide full or partial subsidies for expenses incurred in the organization, operation, education, etc. of parental monitoring groups, within budgetary limits.
- (6) Each parental monitoring group may visit child care centers to perform its duties listed under paragraph (2), and in such cases, after first obtaining approval from the relevant Mayor/*Do* Governor or the head of the relevant *Si/Gun/Gu*.
- (7) Where a parental monitoring group visits a child care center after obtaining approval required in paragraph (6), it shall produce a written approval and an identification certificate to the relevant persons, such as the principal of the child care center.
- (8) Where public officials visit a child care center to investigate its operating condition pursuant to Article 42, a parental monitoring group may visit the child care center together with such public officials. In such cases, it need not obtain approval from the relevant Mayor/*Do* Governor or the head of the relevant *Si/Gun/Gu*.
- (9) Details necessary for the composition, operation, education, subsidization, duties, etc. of parental monitoring groups referred to in paragraphs (1) through (8), shall be determined by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 11858, Jun. 4, 2013]

Article 25-3 (Child Care Center Observation by Guardians)

- (1) Guardians may request the principal of a child care center to allow their child care center observation to check its operation realities, such as the care environment for infants and young children and the details of child care. In such cases, the principal of a child care center shall comply with such request unless there is a compelling reason not to do so.
- (2) Matters necessary for the standards, method, etc., for observation referred to in paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 13321, May 18, 2015]

Article 26 (Preferential Provision of Child Care Services for the Vulnerable)

- (1) Principals of child care centers established by the State, local governments, social welfare corporations, and other nonprofit corporations, and child care centers prescribed by Presidential Decree shall preferentially provide child care services for infants, children with disabilities, children of multicultural families, etc. defined in subparagraph 1 of Article 2 of the Multicultural Families Support Act. (hereinafter referred to as "child care services for the vulnerable"). *<Amended by Act No. 9165, Dec. 19, 2008; Act No. 10789, Jun. 7, 2011>*
- (2) The Minister of Health and Welfare, a Mayor/*Do* Governor, and the head of a *Si/Gun/Gu* shall formulate and implement various policies necessary to vitalize child care services for the vulnerable. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*
- (3) Matters necessary for the type, provision, etc., of child care services for the vulnerable shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 26-2 (Part-Time Child Care Services)

- (1) If necessary, the State or a local government may support part-time child care services for infants and young children who do not benefit from child care without compensation under Article 34, or free-of-charge education under Article 24 of the Early Childhood Education Act. In such cases, types, eligibility, supporting methods of part-time child care services, and other matters necessary

for the provision of part-time child care services shall be determined by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 16078, Dec. 24, 2018>

- (2) The Special Self-Governing City Mayor, the Special Self-Governing Province Governor, and the head of a *Si/Gun/Gu* may designate any of the following facilities as an institution providing part-time child care services (hereafter in this Article, referred to as "part-time child care services provider"): <Amended by Act No. 16078, Dec. 24, 2018>
1. Child care support centers;
 2. Child care centers;
 3. Other facilities prescribed by Ordinance of the Ministry of Health and Welfare which can provide part-time child care services.
- (3) The Minister of Health and Welfare, a Mayor/Do Governor, or the head of a *Si/Gun/Gu* may subsidize expenses incurred in providing part-time child care services to part-time child care services providers, within budgetary limits. <Amended by Act No. 16078, Dec. 24, 2018>
- (4) Where a part-time child care service provider falls under any of the following cases, the head of a *Si/Gun/Gu* may cancel designation referred to in paragraph (2): <Amended by Act No. 16078, Dec. 24, 2018>
1. Where a part-time child care service provider uses a subsidy or expenses for other than the intended purpose;
 2. Where a part-time child care service provider receives a subsidy or expenses by fraud or other improper means;
 3. Where other grounds determined by Presidential Decree exist.
- (5) Article 31-2 shall apply *mutatis mutandis* to the prevention of accidents at a part-time child care service provider and compensation for harm to the lives, bodies, etc. of infants and young children caused by an accident. In such cases, "child care center" shall be construed as "part-time child care service provider" and "principal of a child care center" as "head of a part-time child care service provider." <Amended by Act No. 16078, Dec. 24, 2018>

[This Article Newly Inserted by Act No. 11858, Jun. 4, 2013]

Article 27 (Eligibility for Use of Child Care Centers)

Those eligible for using child care centers shall be infants and young children who need child care: *Provided*, That principals of child care centers may, if necessary, extend their child care by up to 12 years in full. <Amended by Act No. 10789, Jun. 7, 2011>

[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 28 (Preferential Provision of Child Care)

- (1) Principals of child care centers established by the State, local governments, social welfare corporations, and other nonprofit corporations, and of child care centers prescribed by Presidential Decree shall enable any of the following persons to preferentially use child care centers: *Provided*, That principals of child care centers established and operated by public organizations or nonprofit corporations entrusted with the establishment and operation of employment promotion facilities pursuant to Article 40 (2) of the Framework Act on Employment Policy may enable workers' children to preferentially use such child care centers: <Amended by Act No. 8655, Oct. 17, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9792, Oct. 9, 2009; Act No. 9932, Jan. 18, 2010; Act No. 10789, Jun. 7, 2011; Act No. 12068, Aug. 13, 2013; Act No. 14001, Feb. 3, 2016; Act No. 14597, Mar. 14, 2017; Act No. 15270, Dec. 19, 2017; Act No. 15892, Dec. 11, 2018>

1. Beneficiaries designated under the National Basic Living Security Act;
2. Children of persons eligible for protection under Article 5 of the Single-Parent Family Support Act;
3. Children of the near-poverty class under Article 24 of the National Basic Living Security Act;

4. Children of persons with the degree of disability prescribed by Ordinance of the Ministry of Health and Welfare among persons with disabilities defined in Article 2 of the Act on Welfare of Persons with Disabilities;
 - 4-2. Infants and young children whose sibling has the degree of disability prescribed by Ordinance of the Ministry of Health and Welfare among persons with disabilities defined in Article 2 of the Act on Welfare of Persons with Disabilities;
 5. Children of multicultural families defined in subparagraph 1 of Article 2 of the Multicultural Families Support Act;
 6. Children of soldiers or police officers killed in action in subparagraph 3, soldiers, police officers, or persons wounded in action in subparagraph 4, 6, 12, 15, or 17 prescribed by Ordinance of the Ministry of Health and Welfare, and soldiers, police officers, or persons killed in the line of duty in subparagraph 5, 14, or 16, among persons of distinguished service to the State prescribed in Article 4 (1) of the Act on the Honorable Treatment of and Support for Persons of Distinguished Service to the State;
 7. Children who have type 1 diabetes and have no problem in caring, as they are easily treated medically and able to live a daily life normally;
 8. Children of other persons prescribed by Ordinance of the Ministry of Health and Welfare, considering the level of income, demand for child care, etc.
- (2) Each business owner shall enable children of workers of his/her place of business to preferentially use its workplace child care center. *<Amended by Act No. 10789, Jun. 7, 2011>*
- (3) Matters concerning methods of application to, standards for, etc. of persons eligible for preferential use of child care centers prescribed in paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Newly Inserted by Act No. 14597, Mar. 14, 2017>*
- [This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]*

Article 29 (Child Care Courses)

- (1) Child care courses shall be comprised of curricula to promote the bodily, emotional, linguistic, social, and cognitive development of infants and young children.
 - (2) The Minister of Health and Welfare shall develop and proliferate standard child care courses and, if necessary, modify and supplement such standard child care courses through the review of their curricula. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*
 - (3) Principals of child care centers shall endeavor to care for infants and young children by means of the standard child care courses pursuant to paragraph (2). *<Amended by Act No. 10789, Jun. 7, 2011>*
 - (4) Principals of child care centers may conduct extracurricular activity programs, other than the child care courses, for infants and young children of at least a certain age provided inside and outside of the child care centers within a certain time zone determined by Ordinance of the Ministry of Health and Welfare (hereinafter referred to as "extracurricular activity") after obtaining consent from their guardians. In such cases, the principals of such child care centers shall prepare programs as an alternative to the extracurricular activity for infants and young children not participating in the extracurricular activity. *<Newly Inserted by Act No. 12068, Aug. 13, 2013>*
 - (5) Matters necessary for child care courses in paragraph (1), the age of infants and young children eligible for, and details of, the extracurricular activity under paragraph (4), and other matters, shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 12068, Aug. 13, 2013>*
- [This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]*

Article 29-2 (Records of Life in Child Care Centers)

Principals of child care centers shall prepare and manage records of the lives of infants and young children pursuant to the standards prescribed by the Minister of Health and Welfare by comprehensively

observing and evaluating the conditions of development, etc. of the infants and young children so that the records may be used for living guidance of the infants and young children and for guidance linked with elementary school education. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10789, Jun. 7, 2011>*

[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 30 (Evaluation of Child Care Centers)

- (1) For the safety of infants and young children and the improvement of quality of child care services, the Minister of Health and Welfare shall evaluate the environment of child care centers, operation of child care courses, expertise of child care workers, level of satisfaction of users, etc. on a regular basis.
- (2) The Minister of Health and Welfare may take necessary measures, such as the management of child care services of child care centers, and financial and administrative support for child care projects, based on the results of evaluation prescribed in paragraph (1).
- (3) The Minister of Health and Welfare shall publish the results of evaluation prescribed in paragraph (1), such as the evaluation grading of child care centers.
- (4) Where a child care center evaluated pursuant to paragraph (1) comes to have any of the following grounds, the Minister of Health and Welfare shall adjust the evaluation grade to the lowest grade:
 1. Where a child care center receives an evaluation by fraud or other improper means;
 2. Where an establisher/operator of a child care center is sentenced to imprisonment without labor or a heavier punishment by violating this Act and such sentence is made final and conclusive;
 3. Where a child care center is subject to an order to return a subsidy pursuant to subparagraph 2 or 3 of Article 40, or to an administrative disposition prescribed in Article 45, 45-2, or 46 through 48, which is prescribed by Ordinance of the Ministry of Health and Welfare;
 4. Where the representative, or child care teachers and staff of a child care center violates Article 17 of the Child Welfare Act, or commits a sexual crime against children or juveniles defined in subparagraph 2 of Article 2 of the Act on the Protection of Children and Youth against Sex Offenses.
- (5) If necessary to manage the quality of child care services of child care centers evaluated pursuant to paragraph (1), the Minister of Health and Welfare may adjust the evaluation grade in paragraph (1) by undergoing verification and check.
- (6) Necessary matters, such as the timing and methods of evaluation; objects and methods of verification and check and following determination and adjustment of evaluation grades; details and methods of publishing the results of evaluation, etc. under paragraphs (1), (3), and (5), shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Wholly Amended by Act No. 15892, Dec. 11, 2018]

CHAPTER V Health, Nutrition and Safety

Article 31 (Health Care and Emergency Measures)

- (1) Principals of child care centers shall take care of the health of infants and young children, and child care teachers and staff by giving regular medical checkups, etc., and by recording the medical checkups of infants and young children in records of lives prescribed in Article 29-2: *Provided*, That a medical checkup may be omitted for infants and young children whose guardians have had them receive a medical checkup separately and submitted the results of the medical checkup. *<Amended by Act No. 10789, Jun. 7, 2011; Act No. 14597, Mar. 14, 2017>*
- (2) Principals of child care centers shall, if any emergency situation affects an infant or young child due

to a disease, accident, or disaster, immediately transport him/her to an emergency medical institution. <Amended by Act No. 10789, Jun. 7, 2011>

- (3) Matters necessary for details of standards, matters, etc. of medical checkups, under paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 14597, Mar. 14, 2017>

[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 31-2 (Mutual Aid Business for Safety of Child Care Centers)

- (1) Mutual aid business for safety of child care centers (hereinafter referred to as "mutual aid business") may be conducted through a cooperative organization of child care centers with permission of the Minister of Health and Welfare in order to prevent accidents in child care centers and compensate infants, young children, and child care teachers and staff for loss of their lives, bodily harm, or property damage caused by accidents in child care centers. <Amended by Act No. 9932, Jan. 18, 2010; Act No. 10789, Jun. 7, 2011; Act No. 11003, Aug. 4, 2011>
- (2) A mutual aid association for safety of child care centers (hereinafter referred to as "mutual aid association") established for mutual aid business shall be a corporation and be duly formed by completing registration for corporation at the registry of its principal place of business. <Amended by Act No. 10789, Jun. 7, 2011>
- (3) Principals of child care centers shall become members of a mutual aid association. <Amended by Act No. 11003, Aug. 4, 2011>
- (4) The principal of a child care center who is a member of a mutual aid association shall pay money invested to conduct mutual aid business, the following mutual aid fees, etc. to the mutual aid association: *Provided*, That mutual aid fees referred to in subparagraphs 2 and 3 may be paid selectively by principals of child care centers: <Newly Inserted by Act No. 11003, Aug. 4, 2011>
1. Mutual aid fees to compensate for harm to the lives and bodies of infants and young children;
 2. Mutual aid fees to compensate for harm to the lives and bodies of child care teachers and staff, etc.;
 3. Mutual aid fees to compensate for loss to the property of child care centers.
- (5) An endowment of the mutual aid association shall be created with investments, etc. of members: *Provided*, That the Minister of Health and Welfare may partially subsidize expenses incurred in establishing and operating the head office of the mutual aid association. <Amended by Act No. 9932, Jan. 18, 2010>
- (6) Qualifications for membership, matters concerning executive officers, and matters concerning the standards for a share in investments of the mutual aid association shall be prescribed by the articles of association.
- (7) The standards and procedures for permission for establishment, particulars to be stated in the articles of association, matters necessary for operation and supervision, etc. of the mutual aid association shall be prescribed by Presidential Decree.
- (8) The mutual aid association shall determine the regulations on mutual aid, including matters necessary for operating the mutual aid business, such as the scope of the mutual aid business, fees for mutual aid, and a liability reserve for appropriation to the mutual aid business, and obtain permission therefor from the Minister of Health and Welfare. The same shall also apply when it intends to amend the regulations on mutual aid. <Amended by Act No. 9932, Jan. 18, 2010>
- (9) Except as provided in this Act, the provisions of the Civil Act governing incorporated foundations shall apply *mutatis mutandis* to the mutual aid associations.
- (10) The Insurance Business Act shall not apply to the mutual aid business of the mutual aid association under this Act.
- (11) Principals of child care centers who pay the mutual aid fee referred to in paragraph (4) 3 shall be deemed to have performed the duty to subscribe to insurance pursuant to Article 34-3 of the Social

Welfare Services Act. <Newly Inserted by Act No. 11003, Aug. 4, 2011; Act No. 16078, Dec. 24, 2018>

[This Article Newly Inserted by Act No. 9165, Dec. 19, 2008]

Article 31-3 (Confirmation of Protective Inoculation)

- (1) The principal of a child care center shall confirm facts about the protective inoculation of infants and young children by utilizing the integrated vaccination management system prescribed in Article 33-2 of the Infectious Disease Control and Prevention Act each year on a regular basis: *Provided*, That in cases of providing child care services to an infant or young child for the first time, he/she shall confirm such facts within 30 days from the date he/she provides the child care services. <Amended by Act No. 16078, Dec. 24, 2018>
- (2) The principal of a child care center may guide the guardians of infants and young children found to have failed to be vaccinated as a result of confirmation under paragraph (1) for vaccination, and when necessary, request the head of the competent public health center to render cooperation in terms of protective inoculation, etc.
- (3) For the confirmation and management of vaccination of infants and young children, principals of child care centers shall record and manage matters concerning protective inoculation and details thereof in the records of life in the child care center under Article 29-2.

[This Article Newly Inserted by Act No. 11003, Aug. 4, 2011]

Article 32 (Medical Treatment and Preventive Measures)

- (1) If an infant or young child is infected or is feared to be infected by a disease as a result of a medical checkup under Article 31, the principal of a child care center shall take necessary measures to treat and prevent the disease in consultation with his/her guardian. <Amended by Act No. 10789, Jun. 7, 2011>
- (2) The principal of a child care center may segregate infants, young children, dwellers, child care teachers and staff of the child care center who are found to be infected, or suspected or feared to be infected by an infectious disease as a result of medical checkup under Article 31, or as a result of other doctor's diagnoses, from the child care center, or take other necessary measures, as prescribed by Ordinance of the Ministry of Health and Welfare. <Newly Inserted by Act No. 11003, Aug. 4, 2011>
- (3) If necessary to take the measures under paragraph (1), the principal of a child care center may request a public health center or its branch under Articles 10 and 13 of the Regional Public Health Act or a medical institution under Article 3 of the Medical Service Act to provide cooperation. <Amended by Act No. 10789, Jun. 7, 2011; Act No. 13323, May 18, 2015>
- (4) The head of a public health center or its branch, or a medical institution in receipt of a request for cooperation pursuant to paragraph (2), shall take appropriate measures.
- (5) The principal of each child care center may have nurses (including assistant nurses) render assistance when administering medicine to infants and young children by following doctor's prescriptions and directions. In such cases, the principal shall obtain consent from the guardians thereof. <Newly Inserted by Act No. 14001, Feb. 3, 2016>

[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 33 (Management of Meal Program)

The principal of each child care center shall hygienically provide infants and young children with nutritionally balanced and safe meals, as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10789, Jun. 7, 2011>

[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 33-2 (Safety Management of Child Care Center Vehicles)

Where the principal of a child care center operates a vehicle to transport infants and young children to and from the child care center, he/she shall first report such vehicle to the head of the competent police station as a school bus for children pursuant to Article 52 of the Road Traffic Act.

[This Article Newly Inserted by Act No. 12068, Aug. 13, 2013]

CHAPTER VI Expenses**Article 34 (Child Care without Compensation)**

- (1) The State and local governments shall provide child care without compensation, on condition that the details and scope thereof be prescribed by Presidential Decree.
- (2) The State and local governments may provide child care without compensation for children with disabilities and children of multicultural families defined in subparagraph 1 of Article 2 of the Multicultural Families Support Act, considering the situations in which they are and characteristics they have, as prescribed by Presidential Decree.
- (3) Expenses incurred in providing child care without compensation under paragraph (1) shall be borne or covered by the State or local governments, as prescribed by Presidential Decree.
- (4) The Minister of Health and Welfare may survey standard child care costs, etc. of child care centers, and, based on the results thereof, determine expenses to be borne by the State and local governments under paragraph (3) in consultation with the heads of relevant administrative agencies, within budgetary limits.
- (5) The State and local governments may provide families with at least two children with additional subsidies.
- (6) Notwithstanding the latter part of Article 12 (1), the State and local governments shall establish and operate child care centers for infants, young children, children with disabilities, and children of multicultural families who intend to receive child care without compensation under paragraphs (1) and (2). *<Amended by Act No. 16078, Dec. 24, 2018>*
- (7) The Minister of Health and Welfare shall conduct a survey necessary to determine standard child care costs prescribed in paragraph (4) every three years, and determine standard child care costs by undergoing deliberation by the Central Child Care Policy Committee prescribed in Article 6, based on the results of the survey. *<Newly Inserted by Act No. 16251, Jan. 15, 2019>*
- (8) Matters necessary for the methods, details, etc. of survey prescribed in paragraph (7) shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Newly Inserted by Act No. 16251, Jan. 15, 2019>*

[This Article Wholly Amended by Act No. 11627, Jan. 23, 2013]

Article 34-2 (Child Home-Care Allowances)

- (1) The State and a local government may provide child home-care allowances for infants and young children who do not use child care centers or kindergartens defined in Article 2 of the Early Childhood Education Act, taking into consideration the age of the relevant infants and young children. *<Amended by Act No. 10789, Jun. 7, 2011; Act No. 16078, Dec. 24, 2018>*
- (2) Even if part-time child care services referred to in Article 26-2 are provided for infants and young children eligible under paragraph (1), child home-care allowances referred to in paragraph (1) may be paid for them. *<Newly Inserted by Act No. 11858, Jun. 4, 2013; Act No. 16078, Dec. 24, 2018>*
- (3) Where an infant or young child, for whom a child home-care allowance is provided pursuant to paragraph (1), stays overseas continuously for at least 90 days, the State and the relevant local government shall suspend the provision of such allowance during the relevant period. *<Newly*

Inserted by Act No. 13321, May 18, 2015>

- (4) Where the Minister of Health and Welfare or the head of a local government suspends the provision of a child home-care allowance pursuant to paragraph (3), he/she shall notify the relevant infant's or young child's guardian of such fact, expressly specifying the reason therefor. <Newly Inserted by Act No. 13321, May 18, 2015>
- (5) Matters necessary for eligibility, criteria, etc. for child home-care allowances under paragraph (1), shall be prescribed by Presidential Decree. <Amended by Act No. 11858, Jun. 4, 2013; Act No. 13321, May 18, 2015>

[This Article Newly Inserted by Act No. 9165, Dec. 19, 2008]

Article 34-3 (Voucher for Care Services)

- (1) The State and a local government may supply guardians of infants and young children with voucher for care services (hereinafter referred to as "voucher") to cover expenses under Articles 34 and 34-2. <Amended by Act No. 10789, Jun. 7, 2011; Act No. 11003, Aug. 4, 2011; Act No. 11627, Jan. 23, 2013>
- (2) Deleted. <by Act No. 11003, Aug. 4, 2011>
- (3) Matters necessary for the provision, procedure for use, etc. of voucher shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 9932, Jan. 18, 2010; Act No. 11003, Aug. 4, 2011>

[This Article Newly Inserted by Act No. 9165, Dec. 19, 2008]

Article 34-4 (Applications for Subsidies and Allowances)

- (1) A guardian of an infant or young child may file an application for subsidies and allowances under Articles 34 and 34-2. <Amended by Act No. 10789, Jun. 7, 2011; Act No. 11627, Jan. 23, 2013>
- (2) Deleted. <by Act No. 16078, Dec. 24, 2018>
- (3) Methods of, and procedures for, filing applications for subsidies and allowances under paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 11003, Aug. 4, 2011>

[This Article Newly Inserted by Act No. 9165, Dec. 19, 2008]

Article 34-5 (Examinations and Inquiries)

- (1) The Minister of Health and Welfare or the head of a local government may request an applicant under Article 34-4 (1) and a person for whom subsidization has been determined to provide documents necessary for verifying his/her entitlement to subsidization of expenses, or other data concerning activities to earn income, family relationships, etc., and assign public officials under his/her control to visit the residence or other necessary places of the applicant for subsidies and allowances and the person for whom subsidization has been determined to examine documents, etc. or inquire of relevant persons. <Amended by Act No. 9932, Jan. 18, 2010; Act No. 14001, Feb. 3, 2016; Act No. 16078, Dec. 24, 2018>
- (2) The Minister of Health and Welfare or the head of a local government may request the head of a related agency to provide data concerning national tax, local tax, health insurance, national pension, employment insurance, industrial accident compensation insurance, etc. necessary to conduct an examination under paragraph (1) to provide subsidies and allowances. In such cases, the head of a related agency in receipt of a request to provide data shall comply with such request unless there is a compelling reason not to do so. <Amended by Act No. 9932, Jan. 18, 2010; Act No. 16078, Dec. 24, 2018>
- (3) A person who makes a visit, examines, and inquires pursuant to paragraph (1) shall carry an identification indicating his/her authority and documents indicating the period, scope, and person in charge of examination, relevant statutes or regulations, etc. and produce them to relevant persons.

<Amended by Act No. 14001, Feb. 3, 2016>

- (4) Where an applicant for subsidies and allowances or a person for whom subsidization has been determined refuses to provide documents or data, or refuses, obstructs, or evades an examination and inquiry under paragraph (1), the Minister of Health and Welfare or the head of a local government may dismiss the relevant application or cancel, discontinue, or change a decision to subsidize. *<Amended by Act No. 9932, Jan. 18, 2010>*
- (5) Matters necessary for scope, timing, and details of examinations and inquiries under paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 9932, Jan. 18, 2010>*
- (6) Administrative data matching may be used under Article 36 (1) of the Electronic Government Act to ascertain the places of domicile of resident registration, etc. of persons eligible for subsidization of child care expenses. *<Amended by Act No. 10012, Feb. 4, 2010>*
- (7) Except as provided in this Act, matters concerning the details, procedures, methods, etc. of examination or inquiry prescribed in paragraph (1) shall be governed by the Framework Act on Administrative Investigations. *<Newly Inserted by Act No. 14001, Feb. 3, 2016>*
- [This Article Newly Inserted by Act No. 9165, Dec. 19, 2008]*

Article 34-6 Deleted. *<by Act No. 16078, Dec. 24, 2018>*

Article 34-7 (Notice of Information on Applications for Subsidies and Allowances)

- (1) The Minister of Health and Welfare or the head of a local government shall notify, in writing, the guardians of infants and young children of the information on applications for subsidies and allowances referred to in Article 34-4.
- (2) Matters necessary for the method, timing, procedures for, and the details of, notice under paragraph (1) and other matters shall be prescribed by Ordinance of the Ministry of Health and Welfare.
- [This Article Newly Inserted by Act No. 13321, May 18, 2015]*

Article 35 Deleted. *<by Act No. 11627, Jan. 23, 2013>*

Article 36 (Subsidization)

The State and local governments shall, fully or partially, provide subsidies for expenses incurred in establishing child care centers specified in Article 10; operating expenses, such as personnel expenses for child care teachers (including substitute teachers), and expenses for extra child care; expenses incurred in implementing child care programs, such as establishment and operation of local child care support centers, welfare promotion of child care teachers and staff, provision of child care for the vulnerable; and expenses incurred in installing closed-circuit televisions referred to in Article 15-4. *<Amended by Act No. 10789, Jun. 7, 2011; Act No. 11003, Aug. 4, 2011; Act No. 11858, Jun. 4, 2013; Act No. 13321, May 18, 2015>*

[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 37 (Obligation for Expenses by Business Owners)

Any business owner who has established a child care center under Article 14 shall fully or partially bear expenses incurred in operating the child care center and child care, as prescribed by Presidential Decree. *<Amended by Act No. 10789, Jun. 7, 2011>*

[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 38 (Collection of Child Care Fees)

No establisher/operator of a child care center pursuant to Articles 12 through 14 shall collect child care fees and other necessary expenses, etc. from the persons who use the child care center within the limit

prescribed by the Mayor/Do Governor having jurisdiction over the place of the child care center: *Provided*, That the Mayor/Do Governor may prescribe different standard, considering the type of the child care center and local conditions, when necessary. <Amended by Act No. 10789, Jun. 7, 2011> [This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 39 (Taxation Support)

- (1) Expenses borne by a business entity to establish and operate a workplace child care center referred to in Articles 14 and 37, child care fees paid by guardians for caring for infants and young children, and other expenses necessary for child care, are entitled to tax reduction or exemption, as prescribed by the Restriction of Special Taxation Act. <Amended by Act No. 10789, Jun. 7, 2011; Act No. 12619, May 20, 2014>
- (2) Expenses incurred in operating child care centers, other than workplace child care centers referred to in subparagraph 4 of Article 10, are entitled to tax reduction or exemption, as prescribed by the Restriction of Special Taxation Act. <Amended by Act No. 10789, Jun. 7, 2011; Act No. 11003, Aug. 4, 2011>

[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 39-2 (Lending of State and Public Property)

If necessary to establish and operate the following child care centers, the State or local governments may lend state property or have state property used without compensation, in accordance with the Act on Regulation of Special Cases of State Property and lend public property or have public property used without compensation, notwithstanding the Public Property and Commodity Management Act:

1. A national or public child care center prescribed in Article 12;
2. A workplace child care center prescribed in Article 14, which is established and operated jointly by small and medium enterprises prescribed in Article 2 (1) of the Framework Act on Small and Medium Enterprises.

[This Article Newly Inserted by Act No. 16078, Dec. 24, 2018]

Article 40 (Orders to Refund Expenses and Subsidies)

Where an establisher/operator of a child care center, the head of a child care support center, a person entrusted with continuing education, etc. falls under any of the following cases, the State or a local government may issue orders to fully or partially refund the expenses and subsidy already paid: <Amended by Act No. 10789, Jun. 7, 2011; Act No. 11003, Aug. 4, 2011; Act No. 11144, Dec. 31, 2011; Act No. 11858, Jun. 4, 2013; Act No. 16251, Jan. 15, 2019>

1. Where the operation of the child care center is suspended, the child care center is closed or the license to operate the child care center is revoked;
2. Where he/she uses a subsidy for other than business purposes;
3. Where he/she obtains a subsidy by fraud or other improper means;
- 3-2. Where he/she is subsidized for costs prescribed in Article 34 by fraud or other improper means;
4. Deleted; <by Act No. 11003, Aug. 4, 2011>
5. Where he/she obtains a subsidy by mistake or slight negligence, which falls under a cause prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 40-2 (Recovery of Child Care Subsidies)

- (1) When a guardian is subsidized for expenses under Articles 34 and 34-2 by fraud or other improper means, the State or the local government may fully or partially recover such subsidies. <Amended by Act No. 11627, Jan. 23, 2013>
- (2) In recovering subsidies pursuant to paragraph (1), when the person to repay the subsidies fails to do

so by the deadline, such subsidies may be collected in the same manner as delinquent national or local taxes are collected.

[This Article Newly Inserted by Act No. 10789, Jun. 7, 2011]

CHAPTER VII Guidance and Supervision

Article 41 (Guidance and Orders)

The Minister of Health and Welfare, the Mayor/Do Governor and the head of a *Si/Gun/Gu* may guide and order the establisher/operator of child care centers, and child care teachers and staff to smoothly providing child care services. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10789, Jun. 7, 2011>

[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 42 (Reporting and Examinations)

(1) The Minister of Health and Welfare, the Mayor/Do Governor and the head of a *Si/Gun/Gu* may require the establisher/operator of child care centers to file necessary reports on their child care centers, and relevant public officials to investigate the operating conditions of child care centers and examine books and other documents. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10789, Jun. 7, 2011>

(2) Relevant public officials who perform their duties under paragraph (1) shall carry certificates indicating their authority and produce them to related persons.

[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 42-2 (Reporting of Violations and Protection of Reporting Persons)

(1) Any person may file a report on, or complaint against, any of the following persons with the relevant administrative or investigative agency:

1. A person who obtains a subsidy by fraud or other improper means, or misappropriates a subsidy;
2. A person who fails to comply with the standards for operation of child care centers referred to in Article 24 (1);
3. A person who fails to comply with the standards for management of meals referred to in Article 33;
4. A person who fails to comply with the standards for safety management of child care center vehicles referred to in Article 33-2;
5. A person who commits child abuse referred to in subparagraph 7 of Article 3 of the Child Welfare Act;
6. Other persons prescribed by Ordinance of the Ministry of Health and Welfare.

(2) No establisher/operator of a child care center shall take disadvantageous measures defined in subparagraph 6 of Article 2 of the Protection of Public Interest Reporters Act against child care teachers and staff for filing a report or complaint referred to in paragraph (1).

(3) The Minister of Health and Welfare, Mayors/Do Governors, and the heads of *Sis/Guns/Gus* may pay prize money to persons who file a report or complaint of matters referred to in paragraph (1) 1, and 3 through 5 within budgetary limits. <Amended by Act No. 15892, Dec. 11, 2018>

(4) Matters necessary for the procedures, methods, etc., of reporting prescribed in paragraph (1) and standards, methods, procedures, etc. of paying prize money prescribed in paragraph (3) shall be prescribed by Presidential Decree. <Newly Inserted by Act No. 15892, Dec. 11, 2018>

[This Article Newly Inserted by Act No. 13321, May 18, 2015]

Article 43 (Reporting on Closure, Suspension, and Resumption of Operation of Child Care Centers)

(1) A person who intends to close a child care center authorized pursuant to Article 13 (1) or suspend its

operation for a certain period, or resume the operation thereof shall report in advance to the Governor of a Special Self-Governing Province or the head of a *Si/Gun/Gu*, as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10789, Jun. 7, 2011; Act No. 11003, Aug. 4, 2011>

- (2) Where a child care center is closed or the operation thereof is suspended for a certain period, the principal of the child care center shall take measures to protect the rights and interests of infants and young children provided with child care services in such child care center by transferring them to other child care centers, as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10789, Jun. 7, 2011>

[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 43-2 (Order for Suspension of Operation of Child Care Centers)

- (1) Where the Minister of Health and Welfare, a City Mayor/Do Governor or the head of a *Si/Gun/Gu* deems that normal child care is impractical due to grounds of great urgency, such as a natural disaster or infectious disease, he/she may issue an order for suspension of operation to the principals of child care centers.
- (2) The principal of each child care center in receipt of an order prescribed in paragraph (1) shall suspend the operation of the child care center without delay, and in preparation for urgent demand of child care where an infant or young child cannot be taken care of by his/her guardian at home if the child care center suspends its operation, the principal shall take necessary measures for the operation of the child care center by informing the guardians of contingency plan for child care through parents letters in advance.
- (3) Matters necessary for standards for orders for suspension of operation in paragraph (1), and measures, etc. in paragraph (2) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 13656, Dec. 29, 2015]

#Article 44 (Orders for Rectification and Modification)

Where a child care center falls under any of the following cases, the Minister of Health and Welfare, the relevant Mayor/Do Governor, or the head of the relevant *Si/Gun/Gu* may order the principal of the child care center or the establisher/operator thereof to take measures for rectification or modification within a fixed period: <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10789, Jun. 7, 2011; Act No. 11003, Aug. 4, 2011; Act No. 11858, Jun. 4, 2013; Act No. 12068, Aug. 13, 2013; Act No. 13321, May 18, 2015; Act No. 13656, Dec. 29, 2015; Act No. 15892, Dec. 11, 2018; Act No. 16078, Dec. 24, 2018; Act No. 16404, Apr. 30, 2019>

1. Where it is operated without authorization for modification pursuant to Article 13 (1);
2. Where it fails to comply with any standard for establishment of child care centers referred to in Article 15, 15-2, or 15-3;
- 2-2. Where it fails to comply with any standard for installation or management of a closed-circuit television, and for storage of video information referred to in Article 15-4;
3. Where it fails to comply with any standard for placement of child care teachers and staff referred to in Article 17 (5);
- 3-2. Where it fails to report the appointment or dismissal of a child care teachers and staff referred to in Article 19 (2), or files a false report thereon;
4. Where it fails to comply with any standard for operation of child care centers referred to in Article 24 (1);
- 4-2. Where it fails to establish or operate a child care center operating committee, in violation of the proviso of Article 25 (1);
- 4-3. Where it provides extracurricular activity programs to infants and young children, in violation of the former part of Article 29 (4);

- 4-4. Where it fails to provide an alternative program to infants and young children not participating in the extracurricular activity programs, in violation of the latter part of Article 29 (4);
- 4-5. Where it fails to prepare or manage records of daily life referred to in Article 29-2;
- 4-6. Where it refuses, obstructs, or evades an evaluation referred to in Article 30 (1) or verification and checking referred to in paragraph (5) of the same Article without good cause, or receives an evaluation or verification and checking by fraud or other improper means;
- 4-7. Where it fails to take measures to treat and prevent diseases pursuant to Article 32 (1);
- 4-8. Where it fails to hygienically provide nutritionally-balanced and safe meals pursuant to Article 33;
- 5. Where it collects child care fees, etc. referred to in Article 38 in excess;
- 6. Where it fails to file a report under Article 42 or files a false report, or where it refuses or evades any investigation or examination;
- 7. Where it is closed or operation thereof is suspended for a certain period, or resumed without reporting pursuant to Article 43 (1);
- 7-2. Where it fails to suspend its operation or take measures in preparation for urgent demand of child care, in violation of Article 43-2 (2);
- 8. Where it violates any matter concerning the official announcement of information referred to in Article 49-2.

[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 44-2 (Execution Order against Business Entity Failing to Perform Duty to Establish Workplace Child Care Centers)

Where the business owner of a workplace referred to in Article 14 fails to perform his/her duty to establish a workplace child care center or other duty, the relevant Mayor/Do Governor or the head of the relevant *Si/Gun/Gu* may order him/her to execute such duty within a reasonable time.

[This Article Newly Inserted by Act No. 12619, May 20, 2014]

Article 44-3 (Charges for Compelling Compliance)

- (1) A Mayor/Do Governor or the head of a *Si/Gun/Gu* may reissue against a person who has failed to comply with an order under Article 44-2 an order to execute such order within a reasonable period required for the compliance thereof, and may impose and collect a charge for compelling compliance not exceeding 100 million won each time, up to twice a year from the date on which the order under the same Article was issued, if such person still fails to comply with the order.
- (2) A Mayor/Do Governor or the head of a *Si/Gun/Gu* may raise the amount prescribed in paragraph (1) within the scope of 50/100 in consideration of the period, grounds, etc. of failure in establishing workplace child care centers. *<Newly Inserted by Act No. 16404, Apr. 30, 2019>*
- (3) Before a charge for compelling compliance referred to in paragraphs (1) and (2) is imposed, a Mayor/Do Governor or the head of a relevant *Si/Gun/Gu* shall give an advance written warning stating that the charge for compelling compliance is to be imposed and collected if a person fails to comply with the order within a reasonable period determined. *<Amended by Act No. 16404, Apr. 30, 2019>*
- (4) Where a Mayor/Do Governor or the head of a *Si/Gun/Gu* imposes a charge for compelling compliance pursuant to paragraphs (1) and (2), he/she shall give a written notice to the relevant person, specifying an amount of the charge for compelling compliance, the grounds for imposition, the deadline for payment, the receiving agency, the method of filing objections, etc. *<Amended by Act No. 16404, Apr. 30, 2019>*
- (5) Where a person in receipt of the order referred to in Article 44-2 complies with such order, the relevant Mayor/Do Governor or the head of the relevant *Si/Gun/Gu* shall suspend imposition of a subsequent charge for compelling the execution, but shall collect the charge for compelling compliance already imposed.

- (6) Where a person for whom a charge for compelling compliance has been imposed pursuant to paragraphs (1) and (2) fails to pay the charge for compelling compliance by the deadline for payment, the relevant Mayor/*Do* Governor or the head of the relevant *Si/Gun/Gu* shall collect the charge in accordance with the Act on the Collection of Local Non-Tax Revenue. *<Amended by Act No. 16404, Apr. 30, 2019>*
- (7) Matters necessary for standards for imposing charges for compelling compliance under paragraphs (1) and (2), and procedures, etc., for refunding charges for compelling compliance already imposed and collected, shall be prescribed by Presidential Decree. *<Amended by Act No. 16404, Apr. 30, 2019>*

[This Article Newly Inserted by Act No. 12619, May 20, 2014]

Article 45 (Closure of Child Care Centers)

- (1) Where a person who has established or operates a child care center (hereafter in this Article, referred to as "establisher/operator"), falls under any of the following cases, the Minister of Health and Welfare, the relevant Mayor/*Do* Governor, and the head of the relevant *Si/Gun/Gu* may order such person to suspend the operation of the child care center within one year or to close the child care center. In such cases, where persons under the control and supervision of an establisher/operator, such as child care teachers and staff, commit offences falling under subparagraph 4, such offences shall be deemed committed by the establisher/operator (the same shall not apply where the establisher/operator has not been negligent in giving due attention and supervision to preventing such offences): *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10789, Jun. 7, 2011; Act No. 12068, Aug. 13, 2013; Act No. 12697, May 28, 2014; Act No. 13321, May 18, 2015>*
1. Where he/she obtains a subsidy by fraud or other improper means, or misappropriates a subsidy;
 2. Where he/she is ordered to, but fails to, repay expenses or subsidies referred to in Article 40;
 3. Where he/she violates an order for rectification or modification referred to in Article 44;
 4. Where he/she commits child abuse defined in subparagraph 7 of Article 3 of the Child Welfare Act;
 5. Where an infant or young child dies or suffers a serious injury to his/her body prescribed by Ordinance of the Ministry of Health and Welfare due to a traffic accident that occurs while a school bus for children (including one failing to report thereon under Article 33-2 and Article 52 of the Road Traffic Act) is being operated without child care teachers and staff aboard, in violation of Article 53 (3) of the Road Traffic Act.
- (2) Deleted. *<by Act No. 10789, Jun. 7, 2011>*
- (3) Where any establisher/operator, or child care teachers and staff is suspected of committing child abuse referred to in paragraph (1) 4, the relevant Special Self-Governing City Mayor, the relevant Special Self-Governing Province Governor, or the head of the relevant *Si/Gun/Gu* shall immediately receive a report thereon referred to in Article 42 or conduct investigation or examination. *<Newly Inserted by Act No. 13321, May 18, 2015>*
- (4) After receiving a report or conducting investigation or examination pursuant to paragraph (3), the relevant Special Self-Governing City Mayor, the relevant Special Self-Governing Province Governor, or the head of the relevant *Si/Gun/Gu* shall determine, without delay, whether he/she takes an administrative disposition referred to in paragraph (1), after consulting with the National Center for the Rights of the Child established under Article 10-2 of the Child Welfare Act, specialized child protection agencies established under Article 45 of the same Act, or other relevant institutions. *<Newly Inserted by Act No. 13321, May 18, 2015; Act No. 16248, Jan. 15, 2019>*
- (5) Where the operation of a child care center is suspended or a child care center is closed under paragraph (1), the relevant Special Self-Governing Province Governor or the head of the relevant *Si/Gun/Gu* shall take necessary measures to protect the rights and interests of infants and young

children of the child care center, such as transferring infants and young children to another child care center. <Newly Inserted by Act No. 11003, Aug. 4, 2011; Act No. 13321, May 18, 2015>

- (6) Detailed standards for administrative dispositions provided for in paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10789, Jun. 7, 2011; Act No. 11003, Aug. 4, 2011; Act No. 13321, May 18, 2015>

[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 45-2 (Imposition of Surcharges)

- (1) When the Minister of Health and Welfare, a Mayor/Do Governor, or the head of a *Si/Gun/Gu* shall issue an order to suspend the operation of a child care center by the reason that the establisher/operator of the child care center falls under any subparagraph of Article 45 (1), he/she may impose a surcharge not exceeding 30 million won, in lieu of suspension of operation of the child care center, if such suspension of operation is feared to cause severe inconvenience to infants, young children, and their guardians, or threaten public interests.
- (2) Matters necessary for types of offences to which surcharges are imposed under paragraph (1), the amount of surcharges depending on the severity of the relevant violation, etc. shall be prescribed by Presidential Decree.
- (3) When a person liable to pay a surcharge under paragraph (1) fails to do so by the deadline, the Minister of Health and Welfare, the relevant Mayor/Do Governor, or the head of the relevant *Si/Gun/Gu* shall collect it in the same manner as national taxes in arrears or in accordance with the Act on the Collection, etc. of Local Non-Tax Revenue. <Amended by Act No. 11998, Aug. 6, 2013>

[This Article Newly Inserted by Act No. 10789, Jun. 7, 2011]

Article 45-3 (Succession to Effect of Administrative Dispositions)

- (1) When a person, who has established or operates a child care center, transfers the child care center or dies, or when a corporation is merged, the effect of an administrative disposition imposed on him/her or it due to the grounds specified in any subparagraph of Article 45 (1) shall succeed to a transferee, heir, or corporation newly established or surviving the merger for one year after the date of such disposition; and where proceedings for an administrative disposition are pending, the proceedings may continue against a transferee, heir, or corporation newly established or surviving the merger: *Provided*, That the same shall not apply where a transferee, heir, or corporation newly established or surviving the merger proves that he/she was not aware of such disposition or any violation as at the time of the transfer or merger. <Amended by Act No. 10789, Jun. 7, 2011; Act No. 13321, May 18, 2015>
- (2) Where a transferee, heir, or corporation newly established or surviving the merger referred to in paragraph (1) transfers, inherits, or merges a child care center, he/she shall confirm whether the former establisher/operator of the child care center is undergoing proceedings for administrative disposition or has previously received any administrative disposition due to the grounds specified in any subparagraph of Article 45 (1), and the Minister of Health and Welfare, the relevant Mayor/Do Governor, or the head of the relevant *Si/Gun/Gu* may issue a confirmation document at the request of the transferee, heir, or corporation newly established or surviving the merger, as prescribed by Ordinance of the Ministry of Health and Welfare. <Newly Inserted by Act No. 13321, May 18, 2015>

[This Article Newly Inserted by Act No. 8851, Jan. 17, 2008]

Article 46 (Suspension of Qualification as Principals of Child Care Centers)

When the principal of a child care center falls under any of the following cases, the Minister of Health and Welfare may suspend his/her qualification for up to one year (or two years if he/she falls under

subparagraph 1 (a) due to child abuse defined in subparagraph 7 of Article 3 of the Child Welfare Act), as prescribed by Ordinance of the Ministry of Health and Welfare: <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 201789, Jun. 7, 2011; Act No. 11858, Jun. 4, 2013; Act No. 13321, May 18, 2015>

1. Where he/she causes harm to an infant or young child by intention or gross negligence as follows, in the course of performing any of his/her duties:
 - (a) Where he/she threatens the life of an infant or young child or causes serious bodily or mental harm to an infant or young child;
 - (b) Where he/she causes harm, in violation of the standards for operation referred to in Article 24;
 - (c) Where he/she causes harm, in violation of the standards for meals determined by Ordinance of the Ministry of Health and Welfare pursuant to Article 33;
 - (d) Where he/she causes other harm;
2. Where he/she hires a unqualified employee to perform any of the duties of a child care teacher, nurse, nutritionist, etc.;
3. Where he/she fails to undergo continuing education referred to in Article 23 on at least three consecutive occasions;
4. Where he/she obtains a subsidy or allowance by fraud or other improper means, or misappropriates a subsidy or allowance;
5. Where he/she takes disadvantageous measures defined in subparagraph 6 of Article 2 of the Protection of Public Interest Reporters Act against child care teachers and staff member, who has filed a public interest report under subparagraph 2 of the same Article.

[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 47 (Suspension of Qualifications as Child Care Teachers)

When a child care teacher falls under any of the following cases, the Minister of Health and Welfare may suspend the qualification of the child care teacher for up to one year (or two years if he/she falls under subparagraph 1 due to child abuse defined in subparagraph 7 of Article 3 of the Child Welfare Act), as prescribed by Ordinance of the Ministry of Health and Welfare: <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11144, Dec. 31, 2011; Act No. 13321, May 18, 2015>

1. Where he/she causes damage, by intention or gross negligence, while performing any of his/her duties in connection with his/her qualification;
2. Where he/she fails to undergo continuing education under Article 23-2 on at least three consecutive occasions.

[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 48 (Revocation of Qualification as Principals or Child Care Teachers of Child Care Centers)

(1) When the principal of a child care center or child care teacher falls under any of the following cases, the Minister of Health and Welfare may revoke his/her qualification: <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10789, Jun. 7, 2011; Act No. 11002, Aug. 4, 2011; Act No. 13321, May 18, 2015>

1. Where he/she is qualified by fraud or other improper means;
2. Where he/she has been sentenced to imprisonment without labor or heavier punishment for causing harm by intention or gross negligence, in the course of performing any of his/her duties in connection with his/her qualification;
3. Where he/she is punished for committing a child abuse-related crime defined in subparagraph 7-2 of Article 3 of the Child Welfare Act;
4. Where he/she lends his/her name, etc., in violation of Article 22-2;
5. Where he/she commits an offence incurring suspension of qualification within three years after the period for suspending his/her qualification expires;

6. Where he/she performs duties related to his/her qualification with a certificate of qualification during the period for suspending his/her qualification;
 7. Where he/she is subject to a disposition of suspending his/her qualification, on at least three occasions;
 8. Where he/she is sentenced to imprisonment without prison labor or heavier punishment because he/she falls under subparagraph 4 of Article 46.
- (2) The Minister of Health and Welfare shall not reissue any qualification to a person whose qualification has been revoked pursuant to paragraph (1), within either of the following periods after revocation of his/her qualification, whichever is relevant: <Newly Inserted by Act No. 12068, Aug. 13, 2013; Act No. 13321, May 18, 2015>
1. Where he/she falls under any subparagraph of paragraph (1), other than subparagraph 3: Two years;
 2. Where he/she falls under paragraph (1) 3: 10 years (Provided, That no qualification shall be reissued to a person for whom twenty years have not elapsed since his/her imprisonment without labor or heavier punishment, declared by a court for committing a child abuse-related crime defined in subparagraph 7-2 of Article 3 of the Child Welfare Act, was completely executed or exempted; or a person for whom 20 years have not elapsed since a suspended sentence of imprisonment without labor or heavier punishment, given for committing a child abuse-related crime defined in subparagraph 7-2 of Article 3 of the Child Welfare Act, was made final and conclusive).

[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 49 (Hearings)

The Minister of Health and Welfare, the Mayor/Do Governor and the head of a *Si/Gun/Gu* shall hold hearings before taking administrative dispositions referred to in Articles 45 through 48. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 49-2 (Official Announcement of Information on Child Care Centers)

- (1) The principal of a child care center shall officially announce the following information that the child care center retains and manages, at least once each year. In such cases, the principal of the child care center shall submit the officially-announced information (hereafter in this Article, referred to as "officially-announced information") to the Mayor of the relevant Special Self-Governing City, the Governor of the relevant Special Self-Governing Province, and the head of the relevant *Si/Gun/Gu*, and the Minister of Health and Welfare may require the submission of materials related to the officially-announced information:
 1. Basic information, such as facilities, the establisher/operator, child care teachers and staff of the child care center;
 2. Matters concerning the child care courses of the child care center referred to in Article 29;
 3. Matters concerning child care fees collected pursuant to Article 38 and other necessary expenses;
 4. Matters concerning accounting, such as the budget and settlement of accounts of the child care center;
 5. Matters concerning health, nutrition, and safety management for infants and young children;
 6. Other matters concerning child care conditions and the operation of child care centers, as prescribed by Presidential Decree.
- (2) Matters necessary for the detailed scope of officially-announced information, the frequency, timing, and method of official announcement, and other matters, shall be determined by Presidential Decree.
- (3) The Minister of Health and Welfare may prepare and disseminate a form necessary for public announcement under paragraph (1) and may collect and manage officially-announced information.

In such cases, the Minister of Health and Welfare may connect and process such officially-announced information to use for formulating child care policy, promoting academic research, compiling statistics, etc.

- (4) Where the principal of a child care center fails or neglects to officially announce the relevant information, the Minister of Health and Welfare, the relevant Mayor/*Do* Governor, or the head of the relevant *Si/Gun/Gu* shall recommend the principal to take corrective measures.
- (5) Where the principal of a child care center publicizes the child care center or places a mark or advertisement under the Act on Fair Labeling and Advertising, he/she shall not give information inconsistent with the information officially announced pursuant to paragraph (1).
- (6) If deemed necessary for confirming whether paragraph (5) has been violated, the Minister of Health and Welfare, the relevant Mayor/*Do* Governor, or the head of the relevant *Si/Gun/Gu* may request the principal of the relevant child care center to submit relevant materials. In such cases, upon receipt of such request, the principal of the relevant child care center shall submit the relevant materials to the Minister of Health and Welfare, the Mayor/*Do* Governor, or the head of the *Si/Gun/Gu* without good cause.

[This Article Newly Inserted by Act No. 11858, Jun. 4, 2013]

Article 49-3 (Publication of Violations)

- (1) Where a child care center for which an administrative disposition referred to in Article 45 or 45-2 has been made falls under any of the following cases, the Minister of Health and Welfare, the relevant Mayor/*Do* Governor, or the head of the relevant *Si/Gun/Gu* shall publish the relevant violation, the details of the disposition, the name of the relevant child care center, the name of its representative, the name of its principal (limited to where the principal is not the representative), and other matters prescribed by Presidential Decree necessary for distinguishing it from other child care centers: *Provided*, That in cases falling under subparagraph 1, the publication shall be limited to the child care center which receives a subsidy or allowance exceeding the amount prescribed by Ordinance of the Ministry of Health and Welfare: <Amended by Act No. 13321, May 18, 2015>
 1. Where it obtains a subsidy or allowance by fraud or other improper means, or misappropriates a subsidy or allowance;
 2. Where it harms the life of an infant or young child or causes serious bodily or mental harm to an infant or young child, in violation of the standards for operation referred to in Article 24 and the standards for meals determined by Ordinance of the Ministry of Health and Welfare pursuant to Article 33.
- (2) With respect to the principal or a child care teacher of a child care center for whom an administrative disposition referred to in Articles 46 through 48 has been taken and who has harmed the life of an infant or young child or has caused serious bodily or mental harm to an infant or young child by committing a child abuse-related crime defined in subparagraph 7 of Article 3 of the Child Welfare Act, the Minister of Health and Welfare, the relevant Mayor/*Do* Governor, or the head of the relevant *Si/Gun/Gu* shall publish the records and list of violations of laws and other matters determined by Presidential Decree. <Amended by Act No. 13321, May 18, 2015>
- (3) The Minister of Health and Welfare, the relevant Mayor/*Do* Governor, or the head of the relevant *Si/Gun/Gu* shall notify the person subject to publication prior to the publication referred to in paragraphs (1) and (2), thereby giving him/her an opportunity to submit explanatory materials or to attend and state his/her opinion.
- (4) Procedures and methods for publication referred to in paragraphs (1) and (2), and other necessary matters shall be determined by Presidential Decree.

[This Article Newly Inserted by Act No. 11858, Jun. 4, 2013]

CHAPTER VIII Supplementary Provisions

Article 50 (Recognition of Career)

- (1) With respect to an employee in a child care center qualified as a kindergarten teacher under the Early Childhood Education Act, his/her child care career experience in such child care center shall be recognized as teaching career experience under the Early Childhood Education Act. *<Amended by Act No. 10789, Jun. 7, 2011>*
 - (2) With respect to an employee in a kindergarten (referring to a kindergarten operating after-school classes under subparagraph 6 of Article 2 of the Early Childhood Education Act) qualified as a child care teacher under this Act, his/her teaching career experience in the kindergarten shall be recognized as child care career experience under this Act. *<Amended by Act No. 11382, Mar. 21, 2012>*
- [This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]*

Article 51 (Delegation of Authority)

The authority of the Minister of Health and Welfare or the Mayor/*Do* Governor under this Act may be partially delegated to the Mayor/*Do* Governor or to the head of a *Si/Gun/Gu*, as prescribed by Presidential Decree.

[This Article Wholly Amended by Act No. 11003, Aug. 4, 2011]

Article 51-2 (Entrustment of Affairs)

- (1) The Minister of Health and Welfare, a Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* may entrust the following affairs to a public institution, civil institution or organization, etc., as prescribed by Presidential Decree. In such cases, he/she may entrust the affairs referred to in subparagraphs 2 and 4 to KCPI: *<Amended by Act No. 11144, Dec. 31, 2011; Act No. 11858, Jun. 4, 2013; Act No. 15892, Dec. 11, 2018>*
 1. Affairs concerning the operation of child care support centers under Article 7 (1);
 2. Affairs concerning the certification of qualification of principals and child care teachers of child care centers under Article 22 (1), and the issuance, etc. of certificates of qualification for child care;
 3. Affairs concerning the provision of continuing education under Articles 23 (1) and 23-2 (1);
 4. Affairs concerning evaluation prescribed in Article 30 (1) and verification and checking prescribed in paragraph (5) of the same Article;
 5. Affairs concerning the provision of voucher under Article 34-3 (1).
- (2) When the Minister of Health and Welfare, a Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* entrusts affairs pursuant to paragraph (1), he/she may subsidize expenses incurred therein, within budgetary limits.
- (3) The Minister of Health and Welfare, a Mayor/*Do* Governor, or the head of a *Si/Gun/Gu* may revoke entrustment under paragraph (1), in any of the following cases:
 1. Where an institution entrusted with affairs uses any subsidy provided pursuant to paragraph (2) for other than the intended purpose;
 2. Where an institution entrusted with affairs is subsidized under paragraph (2) by fraud or other improper means;
 3. Where any other cause prescribed by Presidential Decree exists.

[This Article Newly Inserted by Act No. 11003, Aug. 4, 2011]

Article 51-3 (Business Cooperation between Relevant Agencies)

- (1) The Special Self-Governing City Mayor, the Special Self-Governing Province Governor, and the head of a *Si/Gun/Gu* may request the head of a relevant agency to inquire into criminal history records, etc. to check disqualification referred to in Article 16 or 20.

- (2) To conduct affairs prescribed in Articles 22 (1) and 30 (1), the Minister of Health and Welfare (including persons to whom authority of the Minister of Health and Welfare is entrusted) may request the heads of the relevant agencies, such as State agencies, local governments, and public institutions prescribed in Article 4 of the Act on the Management of Public Institutions, to provide necessary information and materials. *<Newly Inserted by Act No. 15892, Dec. 11, 2018>*
- (3) Upon receipt of a request under paragraph (1) or (2), the head of the relevant agency shall not refuse such request without good cause. *<Amended by Act No. 15892, Dec. 11, 2018>*
[This Article Newly Inserted by Act No. 12697, May 28, 2014]

#Article 52 (Child Care Centers on Islands, in Secluded Places, and in Agricultural and Fishing Communities)

- (1) Where the Special Self-Governing Province Governor or the head of a *Si/Gun/Gu* deems impracticable to apply the standards for establishment of child care centers under Article 15 and the standards for placement of child care teachers and staff under Article 17 (5) to child care centers on islands, in secluded places, in agricultural and fishing communities, etc., he/she may apply separate standards to such child care centers with approval from the competent Mayor/Do Governor, following deliberation by a local child care policy committee under Article 6. *<Amended by Act No. 10789, Jun. 7, 2011; Act No. 11003, Aug. 4, 2011; Act No. 16078, Dec. 24, 2018; Act No. 16404, Apr. 30, 2019>*
- (2) The specific scope of islands, secluded places, agricultural and fishing communities, etc., the standards for establishment of child care centers, and the standards for placement of child care teachers and staff under paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10789, Jun. 7, 2011>*
[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 53 (Federation of Child Care Centers)

- (1) A federation of child care centers may be established to facilitate child care services, balanced development of child care centers, and exchange of information, and promotion of mutual cooperation among child care centers. *<Amended by Act No. 10789, Jun. 7, 2011>*
- (2) Matters necessary for the organizational structure, operation, function, etc. of the Federation of Child Care Centers shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10789, Jun. 7, 2011>*
[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

CHAPTER IX Penalty Provisions

Article 54 (Penalty Provisions)

- (1) Deleted. *<by Act No. 16078, Dec. 24, 2018>*
- (2) Any of the following persons shall be punished by imprisonment with labor for not more than three years, or by a fine not exceeding 30 million won: *<Amended by Act No. 13321, May 18, 2015>*
 1. A person who obtains a subsidy by fraud or other improper means, or misappropriates a subsidy;
 2. A person who arbitrarily manipulates a closed-circuit television for other than its installation purpose, or makes it focus on a place other than the originally intended place, in violation of Article 15-5 (2) 1;
 3. A person who uses a recording function, or stores video information in a device or apparatus other than the storage device prescribed by Ordinance of the Ministry of Health and Welfare, in violation of Article 15-5 (2) 2.

- (3) A person who has video information lost, stolen, leaked, modulated, or damaged due to failure to take measures necessary to secure safety referred to in Article 15-5 (3), shall be punished by imprisonment with labor for not more than two years, or by a fine not exceeding 20 million won. <Newly Inserted by Act No. 13321, May 18, 2015>
- (4) Any of the following persons shall be punished by imprisonment with labor for not more than one year, or by a fine not exceeding 10 million won: <Amended by Act No. 9165, Dec. 19, 2008; Act No. 10789, Jun. 7, 2011; Act No. 11627, Jan. 23, 2013; Act No. 12697, May 28, 2014; Act No. 13321, May 18, 2015>
1. A person who uses the word "child care center" in a trade name, or operates a child care center without authorization for establishment of a child care center pursuant to Article 13 (1);
 2. A person who obtains authorization for establishment of a child care center or the modification thereof under Article 13 (1) by fraud or other improper means;
 3. A person who permits a third person to perform any of the duties of the principal or child care teacher of a child care center by using his/her name or the title of a child care center, or who lends his/her certificate of qualification, in violation of Article 22-2, and his/her counterpart;
 4. A person who obtains a subsidy or helps a third person obtain a subsidy pursuant to Articles 34 and 34-2 by fraud or other improper means;
 5. A person who unjustly uses a voucher for care services referred to in Article 34-3;
 6. An establisher/operator of a child care center who receives child care service fees, etc. referred to in Article 38 by fraud or other improper means;
 7. A person who continues to operate a child care center, in violation of an order to suspend the operation of the child care center or an order to close the child care center pursuant to Article 45 (1);
 8. Deleted. <by Act No. 10789, Jun. 7, 2011>

[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Article 54-2 Deleted. <by Act No. 13321, May 18, 2015>

Article 55 (Joint Penalty Provisions)

When a representative of a corporation, or an agent or, employee of, or other persons employed by a corporation or an individual commits an offence referred to in Article 54 in connection with the affairs of the corporation or the individual, not only shall the offender be punished, but also the corporation or the individual shall be punished by a fine prescribed in the relevant Article: *Provided*, That the same shall not apply when such corporation or individual has not been negligent in giving due attention and supervision regarding the relevant affairs to prevent such offence.

[This Article Wholly Amended by Act No. 10789, Jun. 7, 2011]

Article 56 (Administrative Fines)

- (1) Each person, who closes his/her child care center or suspends operation of his/her child care center for a certain period or resumes operation of his/her child care center without reporting pursuant to Article 43 (1), shall be punished by an administrative fine not exceeding five million won. <Amended by Act No. 10789, Jun. 7, 2011>
- (2) Each of the following persons, shall be punished by an administrative fine not exceeding three million won: <Amended by Act No. 13321, May 18, 2015>
 1. A person who fails to preferentially provide child care services to the vulnerable pursuant to Article 26 (1);
 2. A person who fails to preferentially provide child care services for any infant or young child falling under each subparagraph of Article 28 (1);
 3. A person who fails to conduct a medical checkup, or to take an emergency measure, etc., pursuant to Article 31;

4. A person who fails to install a closed-circuit television or to perform his/her duties to install or manage it pursuant to Article 15-4;
5. A person who fails to comply with a request for inspection pursuant to Article 15-5 (1).
- (3) Administrative fines referred to in paragraphs (1) and (2) shall be imposed and collected by the Minister of Health and Welfare, the relevant Mayor/Do Governor or the head of the relevant *Si/Gun/Gu*, as prescribed by Presidential Decree. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10789, Jun. 7, 2011>*
- (4) through (6) Deleted. *<by Act No. 10789, Jun. 7, 2011>*
[This Article Wholly Amended by Act No. 8654, Oct. 17, 2007]

Addenda

Article 1 (Enforcement Date)

This Act shall enter into force one year after the date of its promulgation.

Article 2 (Transitional Measures for Nursery Information Center and Nursery Instructors)

The nursery information centers and nursery instructors under the former provisions at the time this Act enters into force shall be deemed the child care information centers and child care specialists, respectively, under this Act.

Article 3 (Transitional Measures for Child Care Teacher, etc.)

- (1) The qualifications of the heads of nursery facilities and child care teachers under the former provisions at the time this Act enters into force shall be deemed the qualifications thereof that are recognized under this Act.
- (2) Anyone who is recognized to be qualified as a nursery teacher referred to in paragraph (1), anyone who completes subjects after having majored in such subjects provided for in Article 9 (2) 1 of the previous provisions and anyone who completes educational courses provided for in Article 9 (2) 2 after having studied them at the time this Act comes into force shall all be recognized to be qualified as nursery teachers under this Act.
- (3) Anyone who is recognized to be qualified as a nursery teacher under the provisions of paragraph (1) or (2) may be eligible for the delivery of the certificate of qualifications provided for in Article 22.

Article 4 (Transitional Measures concerning Nurseries)

Any nursery on which a report was made in accordance with the previous provisions at the time this Act comes into force shall be deemed to have been granted authorization under this Act.

Article 5 (Transitional Measures concerning Nursery Federation)

The Nursery Federation that is established under the previous provisions at the time this Act comes into force shall be deemed the Nursery Federation that is established under this Act.

Article 6 (Transitional Measures concerning Administrative Disposition)

Any order issued by, any act performed by, any report made to any administrative agency, etc. under the previous provisions at the time this Act comes into force shall be deemed any act performed by and any act performed to any administrative agency, etc. under this Act.

Article 7 (Transitional Measures concerning Penalty Provisions)

The application of penalty provisions to any act performed prior to the enforcement of this Act shall be governed by the previous provisions.

Article 8 (Relations with Other Statutes)

Where other statutes or regulations cite the provisions of the previous Child Care Act and this Act includes the provisions corresponding thereto, the corresponding provisions of this Act shall be deemed to be cited in lieu of the previous provisions.

Addendum <Act No. 7302, Dec. 31, 2004>

This Act shall enter into force on January 30, 2005.

Addenda <Act No. 7413, Mar. 24, 2005>**Article 1 (Enforcement Date)**

This Act shall enter into force on the date of its promulgation. (Proviso Omitted.)

Articles 2 through 4 Omitted.**Addenda** <Act No. 7785, Dec. 29, 2005>

- (1) (Enforcement Date) This Act shall enter into force three months after the date of its promulgation: *Provided*, That the amended provisions of Articles 21 (1), 22 (1) and (2), 22-2, 46, 48 and 54 (2) shall enter into force one year after the date of its promulgation.
- (2) (Transitional Measures regarding Head of Nursery) Any person who qualified for the head of a nursery under the previous provisions at the time this Act enters into force shall be considered a person who has received a certificate of qualification for the head of a nursery under the amended provisions of Article 21 (1). In this case, he shall meet the requirements referred to in the amended provisions of Article 21 (1) within one year after the enforcement of the amended provisions of Article 21 (1).

Addenda <Act No. 8563, Jul. 27, 2007>

- (1) (Enforcement Date) This Act shall enter into force one year after the date of its promulgation.
- (2) (Transitional Measures for Administrative Disposition) The administrative disposition on a violation committed before this Act enters into force shall be governed by the former provisions.

Addenda <Act No. 8654, Oct. 17, 2007>

- (1) (Enforcement Date) This Act shall enter into force on the date of its promulgation: *Provided*, That the amended provisions of Articles 36 and 45 (1) 1, (2) and (3), subparagraph 4 of Article 46, subparagraph 8 of Article 48 and Article 54 (1) and (2) 5 shall enter into force on July 28, 2008.
- (2) Omitted.

Addenda <Act No. 8655, Oct. 17, 2007>**Article 1 (Enforcement Date)**

This Act shall enter into force three months after the date of its promulgation. (Proviso Omitted.)

Articles 2 through 7 Omitted.**Addendum** <Act No. 8851, Jan. 17, 2008>

This Act shall enter into force three months after the date of its promulgation.

Addenda <Act No. 8852, Feb. 29, 2008>

Article 1 (Enforcement Date)

This Act shall enter into force on the date of its promulgation: *Provided*, That ... (Omitted) among Acts amended pursuant to Article 6 of the Addenda, the Acts which have been promulgated before this Act enters into force, but of which the enforcement dates have yet to arrive shall enter into force on the enforcement date of the relevant Act.

Articles 2 through 7 Omitted.

Addenda <Act No. 9165, Dec. 19, 2008>

Article 1 (Enforcement Date)

This Act shall enter into force on July 1, 2009: *Provided*, That the amended provisions of Articles 34-4 through 34-6 shall enter into force on April 1, 2009.

Article 2 (Model Project)

- (1) The Minister for Health, Welfare and Family Affairs may implement a model project before this Act enters into force for the effective operation of the voucher system for nursing service.
- (2) The Minister for Health, Wealth and Family Affairs or the head of a local government may support the model project under paragraph (1).

Addenda <Act No. 9511, Mar. 20, 2009>

Article 1 (Enforcement Date)

This Act shall enter into force one month after the date of its promulgation. (Proviso Omitted.)

Articles 2 through 9 Omitted.

Addenda <Act No. 9792, Oct. 9, 2009>

Article 1 (Enforcement Date)

This Act shall enter into force on January 1, 2010.

Articles 2 and 3 Omitted.

Addenda <Act No. 9932, Jan. 18, 2010>

Article 1 (Enforcement Date)

This Act shall enter into force two months after the date of its promulgation. (Proviso Omitted.)

Articles 2 through 5 Omitted.

Addenda <Act No. 10012, Feb. 4, 2010>

Article 1 (Enforcement Date)

This Act shall enter into force three months after the date of its promulgation. (Proviso Omitted.)

Articles 2 through 6 Omitted.

Addenda <Act No. 10339, Jun. 4, 2010>

Article 1 (Enforcement Date)

This Act shall enter into force one month after the date of its promulgation. (Proviso Omitted.)

Articles 2 through 5 Omitted.

Addenda <Act No. 10789, Jun. 7, 2011>

Article 1 (Enforcement Date)

This Act shall enter into force six months after the date of its promulgation: *Provided*, That the amended provisions of Articles 5 (3), 22, 28 (1), 30 (6) and (7), 35 (1) and (3), 40-2, 55 and 56 shall enter into force on the date of its promulgation.

Article 2 (Applicability to Fact-Finding Surveys on Child Care)

The first fact-finding survey referred to in the amended provisions of Article 9 shall be conducted in 2012.

Article 3 (Applicability to Imposition of Surcharges)

The amended provisions of Article 45-2 shall apply, starting from the first order to suspend operation of a child care center that must be issued after this Act enters into force.

Article 4 (Transitional Measures concerning Persons Engaging in Child Care, etc.)

Persons engaging in nursery facilities, the heads of nursery facilities and other workers under the former provisions as at the time this Act enters into force shall be deemed child care teachers and staff, principals of child care centers and other employees under the amended provisions of subparagraph 5 of Article 2.

Article 5 (Transitional Measures concerning Child Care Facilities, etc.)

National or public nursery facilities, nursery facilities of corporations, workplace nursery facilities, home-based nursery facilities, parents association nursery facilities and private nursery facilities under the former provisions as at the time this Act enters into force shall be deemed national or public child care centers, child care centers of corporations, workplace child care centers, home-based child care centers, parents association child care centers and private child care centers under the amended provisions of Article 10.

Article 6 Omitted.

Addenda <Act No. 10854, Jul. 14, 2011>

Article 1 (Enforcement Date)

This Act shall enter into force on the date of its promulgation. (Proviso Omitted.)

Articles 2 and 3 Omitted.

Addenda <Act No. 10983, Aug. 4, 2011>

Article 1 (Enforcement Date)

This Act shall enter into force three months after the date of its promulgation. (Proviso Omitted.)

Articles 2 through 4 Omitted.

Addenda <Act No. 11002, Aug. 4, 2011>

Article 1 (Enforcement Date)

This Act shall enter into force one year after the date of its promulgation.

Articles 2 through 7 Omitted.

Addendum <Act No. 11003, Aug. 4, 2011>

This Act shall enter into force six months after the date of its promulgation: *Provided*, That the amended provisions of Article 30 (4) shall enter into force two years after the date of its promulgation.

Addendum <Act No. 11144, Dec. 31, 2011>

This Act shall enter into force six months after the date of its promulgation: *Provided*, That the amended provisions of Articles 15 and 15-3 shall enter into force on the date of its promulgation.

Addenda <Act No. 11382, Mar. 21, 2012>

Article 1 (Enforcement Date)

This Act shall enter into force on the date of its promulgation. (Proviso Omitted.)

Articles 2 and 3 Omitted.

Addenda <Act No. 11627, Jan. 23, 2013>

Article 1 (Enforcement Date)

This Act shall enter into force on March 1, 2013.

Article 2 (Applicability to Standard Child Care Costs)

Matters concerning standard child care costs in the amended provisions of Article 34 shall first apply from January 1, 2014.

Article 3 Omitted.

Addenda <Act No. 11690, Mar. 23, 2013>

Article 1 (Enforcement Date)

(1) This Act shall enter into force on the date of its promulgation.

(2) Omitted.

Articles 2 through 7 Omitted.

Addenda <Act No. 11858, Jun. 4, 2013>

Article 1 (Enforcement Date)

This Act shall enter into force six months after the date of its promulgation: *Provided*, That the amended provisions of subparagraph 1 of Article 46 shall enter into force three months after the date of its promulgation.

Article 2 Omitted.

Addenda <Act No. 11998, Aug. 6, 2013>**Article 1 (Enforcement Date)**

This Act shall enter into force one year after the date of its promulgation.

Articles 2 and 3 Omitted.**Addendum** <Act No. 12068, Aug. 13, 2013>

This Act shall enter into force six months after the date of its promulgation: *Provided*, That the amended provisions of Articles 16, 20, 45, and 48 shall enter into force on the date of its promulgation.

Addenda <Act No. 12251, Jan. 14, 2014>**Article 1 (Enforcement Date)**

This Act shall enter into force on the date of its promulgation.

Articles 2 through 6 Omitted.**Addendum** <Act No. 12619, May 20, 2014>

This Act shall enter into force on January 1, 2015: *Provided*, That the amended provisions of Articles 44-2 and 44-3 shall enter into force on January 1, 2016.

Addenda <Act No. 12697, May 28, 2014>**Article 1 (Enforcement Date)**

This Act shall enter into force on the date of its promulgation: *Provided*, That the amended provisions of Article 45 (1) 5 shall enter into force six months after the date of its promulgation.

Article 2 (Applicability to Disqualification)

The amended provisions of subparagraph 8 of Article 16 shall apply to persons for whom punishment of a fine is made final and conclusive for an offence committed after August 13, 2013.

Article 3 (Applicability to Closure, etc. of Child Care Centers)

The amended provisions of Article 45 (1) 5 shall apply from cases where an infant or young child dies or suffers a serious bodily injury to his/her body prescribed by Ordinance of the Ministry of Health and Welfare due to a traffic accident that occurs after the same amended provisions enter into force.

Article 4 (Transitional Measures concerning Incompetent Persons, etc.)

A person for whom the effect of adjudication of incompetence or quasi-incompetence is maintained under Article 2 of the Addenda to the partially amended Civil Act (Act No. 10429) shall be deemed included in incompetent persons under adult guardianship or quasi-incompetent persons under limited guardianship under the amended provisions of subparagraph 1 of Article 16.

Article 5 (Transitional Measures concerning Disqualification)

Notwithstanding the amended provisions of subparagraphs 6 and 7 of Article 16, the former provisions shall apply to persons to whom a suspended sentence of imprisonment without prison labor or heavier punishment was given for violating Article 17 of the Child Welfare Act and such suspended sentence was made final and conclusive and to persons who received an order for closure under Article 45 before

this Act enters into force.

Addenda <Act No. 13321, May 18, 2015>

Article 1 (Enforcement Date)

This Act shall enter into force four months after the date of its promulgation.

Article 2 (Applicability to Disqualification)

The amended provisions of Article 16 shall apply, starting from a person whose punishment has been made final and conclusive for an offense committed after this Act enters into force, or against whom an order to close a child care center was first issued under Article 45.

Article 3 (Applicability to Period of Stay Overseas)

The period of stay overseas pursuant to the amended provisions of Article 34-2 (3) shall apply from the date on which an infant or young child stays overseas after this Act enters into force.

Article 4 (Transitional Measures concerning Installation of Closed-Circuit Televisions)

Each person, who has established or operates a child care center pursuant to the former provisions as at the time this Act enters into force, shall install a closed-circuit television referred to in the amended provisions of Article 15-4, within three months after the date this Act enters into force: *Provided*, That the same shall not apply where he/she has not installed a closed-circuit television or has installed a network camera pursuant to the proviso to Article 15-4 (1).

Article 5 (Transitional Measures concerning Administrative Disposition)

The former provisions shall apply to administrative dispositions on offenses committed before this Act enters into force.

Article 6 (Transitional Measures concerning Order to Undergo Education)

Notwithstanding the amended provisions of Article 23-3, the former provisions shall apply to an order to undergo education issued against a person to whom the former provisions of Article 16 apply pursuant to Article 2 of the Addenda.

Article 7 (Transitional Measures concerning Reporting of Violations and Protection of Reporting Persons)

Each person, who has filed a report on, or complaint against, a person falling under any subparagraph of Article 42-2 (1) with the relevant administrative or investigative agency before this Act enters into force, shall be deemed filed a report or complaint pursuant to the amended provisions of Article 42-2.

Article 8 (Transitional Measures concerning Penalties or Administrative Fines)

In applying the penal provisions or provisions of administrative fines to offenses committed before this Act enters into force, the former provisions shall govern.

Addenda <Act No. 13323, May 18, 2015>

Article 1 (Enforcement Date)

This Act shall enter into force six months after the date of its promulgation.

Articles 2 through 4 Omitted.

Addenda <Act No. 13498, Aug. 28, 2015>

Article 1 (Enforcement Date)

This Act shall enter into force four months after the date of its promulgation. (Proviso Omitted.)

Articles 2 through 7 Omitted.

Addendum <Act No. 13656, Dec. 29, 2015>

This Act shall enter into force on the date of its promulgation: *Provided*, That the amended provisions of Article 43-2 shall enter into force three months after the date of its promulgation.

Addenda <Act No. 14001, Feb. 3, 2016>

Article 1 (Enforcement Date)

This Act shall enter into force six months after the date of its promulgation: *Provided*, That the amended provisions of Article 32 (5) shall enter into force on the date of its promulgation.

Article 2 (Transitional Measures concerning Child Care Centers at Parents Associations)

The child care centers at parents associations authorized under the former provisions as at the time this Act enters into force shall be considered as cooperative child care centers prescribed in the amended provisions of subparagraph 6 of Article 10.

Addenda <Act No. 14597, Mar. 14, 2017>

Article 1 (Enforcement Date)

This Act shall enter into force six months after the date of its promulgation: *Provided*, That the amended provisions of subparagraph 4 of Article 10, and Article 12 shall enter into force on the date of its promulgation.

Article 2 (Applicability to Types of Child Care Centers)

The amended provisions of subparagraph 4 of Article 10 shall also apply to workplace child care centers established and operated by the State or local governments under the former provisions as at the time the amended provisions enter into force.

Addenda <Act No. 15270, Dec. 19, 2017>

Article 1 (Enforcement Date)

This Act shall enter into force on July 1, 2019. (Proviso Omitted.)

Articles 2 and 3 Omitted.

Addenda <Act No. 15892, Dec. 11, 2018>

Article 1 (Enforcement Date)

This Act shall enter into force six months after the date of its promulgation: *Provided*, That the amended provisions of subparagraph 2 of Article 16 shall enter into force on the date of its promulgation.

Article 2 (Transitional Measures concerning the Incorporation Foundation, Korea Childcare Promotion Institute)

- (1) The incorporated foundation, Korea Childcare Promotion Institute (hereinafter referred to as the "former corporation") shall request the Minister of Health and Welfare to approve KCPI established under this Act to succeed all the property, rights, and obligations, following a resolution by the board of directors during the period from the date this Act is promulgated to the date this Act enters into force.
- (2) Notwithstanding the provisions of the Civil Act governing the dissolution and liquidation of corporations, the former corporation that has obtained approval from the Minister of Health and Welfare pursuant to paragraph (1) shall be deemed dissolved in concurrence with the establishment of KCPI under this Act, and KCPI shall universally succeed all the property, rights, and obligations that have belonged to the former corporation.
- (3) The executive officers and employees of the former corporation shall become executive officers and employees of KCPI.
- (4) The value of property to be succeeded by KCPI pursuant to paragraph (2) shall be the book value of the date preceding the date of establishment registration of KCPI.

Article 3 (Transitional Measures concerning Degree of Disability)

"Degree of disability" in the amended provisions of Article 28 (1) 4-2 shall be construed as "at least disability grade" before the partially amended Act on Welfare of Persons with Disabilities (Act No. 15270) enters into force.

Article 4 (Transitional Measures concerning Accredited Child Care Centers)

Notwithstanding the amended provisions of Article 30, child care centers accredited pursuant to the former provisions shall be governed by the former provisions during the period of validity of the accreditation.

Article 5 (Transitional Measures concerning Administrative Dispositions)

Notwithstanding the amended provisions of subparagraph 4-6 of Article 44, acts conducted before this Act enters into force shall be governed by the former provisions.

Addenda <Act No. 16078, Dec. 24, 2018>

Article 1 (Enforcement Date)

This Act shall enter into force on the date of its promulgation: *Provided*, That the amended provisions of Article 31-3 shall enter into force three months after the date of its promulgation, and the amended provisions of Articles 12, 34 (6), and 39-2 shall enter into force six months after the date of its promulgation.

Article 2 (Applicability to Establishment of National or Public Child Care Centers in Multi-Family Housing)

The amended provisions of Article 12 shall begin to apply from the first multi-family housing which requests a pre-use inspection prescribed in Article 49 of the Housing Act three months after the same amended provisions enter into force.

Article 3 (Transitional Measures concerning Temporary Child Care Service Providers)

Temporary child care service providers designated pursuant to the former provisions as at the time this Act enters into force shall be deemed part-time child care service providers designated pursuant to the amended provisions of Article 26-2 (2).

Addenda <Act No. 16248, Jan. 15, 2019>

Article 1 (Enforcement Date)

This Act shall enter into force six months after the date of its promulgation. (Proviso Omitted.)

Articles 2 through 6 Omitted.

Addenda <Act No. 16251, Jan. 15, 2019>

Article 1 (Enforcement Date)

This Act shall enter into force one year after the date of its promulgation: *Provided*, That the amended provisions of Article 13 (2) shall enter into force six months after the date of its promulgation.

Article 2 (Applicability to Surveys of Standard Child Care Costs)

The first survey of standard child care costs pursuant to the amended provisions of Article 34 (7) shall be conducted in 2022.

Article 3 (Applicability to Order to Return Costs)

The amended provisions of Article 40 shall begin to apply from the first case where costs prescribed in Article 34 are subsidized by fraud or other improper means after this Act enters into force.

Addenda <Act No. 16404, Apr. 30, 2019>

Article 1 (Enforcement Date)

This Act shall enter into force on March 1, 2020: *Provided*, That the amended provisions of Article 44-3 shall enter into force six months after the date of its promulgation.

Article 2 (Applicability to Imposition of Charges for Compelling Compliance)

The amended provisions of Article 44-3 (2) shall begin to apply from the first imposition of charges for compelling compliance after the same amended provisions enter into force.

Article 3 Omitted.

2.15 Enforcement Decree of The Child Care Act

Presidential Decree No. 29180, Sep. 18, 2018

Article 1 (Purpose)

The purpose of this Decree is to prescribe matters mandated by the Child Care Act and matters necessary for the enforcement thereof.

[This Article Wholly Amended by Presidential Decree No. 21585, Jun. 30, 2009]

Article 2 (Term of Office of Members of Child Care Policy Coordination Committee)

- (1) The term of office of a member, other than a public official referred to in Article 5 (3) 2 of the Child Care Act (hereinafter referred to as the "Act"), among members of the Child Care Policy Coordination Committee established under the jurisdiction of the Prime Minister pursuant to Article 5 (1) of the Act (hereinafter referred to as the "Child Care Policy Coordination Committee") shall be two years, which may be renewed.
- (2) The term of office of a member newly commissioned to fill a vacancy by another member shall be the remainder of his/her predecessor's term of office.

[This Article Wholly Amended by Presidential Decree No. 21585, Jun. 30, 2009]

Article 3 (Operation, etc. of Child Care Policy Coordination Committee)

- (1) The Chairperson of the Child Care Policy Coordination Committee shall represent the Child Care Policy Coordination Committee and exercise overall control over affairs of the Child Care Policy Coordination Committee.
- (2) The Vice Minister of Health and Welfare shall be the Vice Chairperson of the Child Care Policy Coordination Committee, who shall assist the Chairperson and act on his/her behalf if the Chairperson is unable to perform any of his/her duties due to extenuating circumstances. <Amended by Presidential Decree No. 22075, Mar. 15, 2010>
- (3) The Child Care Policy Coordination Committee shall have one secretary assigned to conduct affairs of the Child Care Policy Coordination Committee, who shall be either a Grade III public official in charge of child care policies in the Ministry of Health and Welfare, or a public official in general service belonging to the Senior Civil Service Corps. <Amended by Presidential Decree No. 22075, Mar. 15, 2010>
- (4) The secretary may attend and speak at meetings of the Child Care Policy Coordination Committee.

[This Article Wholly Amended by Presidential Decree No. 21585, Jun. 30, 2009]

Article 4 (Meetings of Child Care Policy Coordination Committee)

- (1) Meetings of the Child Care Policy Coordination Committee shall be called by the Chairperson when deemed necessary or when at least one-third of all incumbent members request the convocation thereof.
- (2) Meetings of the Child Care Policy Coordination Committee shall convene with a majority of all incumbent members present, and resolutions shall be adopted with the concurrent vote of a majority of the members present.
- (3) If deemed necessary to perform his/her duties, the Chairperson may request a relevant institution, organization, etc., to submit relevant materials or their opinions.
- (4) Allowances may be provided, and travel expenses reimbursed, within budgetary limits to members who attend a meeting of the Child Care Policy Coordination Committee: *Provided*, That the same shall not apply where a member who is a public official attends such meeting in direct relation to his/her affairs.

[This Article Wholly Amended by Presidential Decree No. 21585, Jun. 30, 2009]

Article 4-2 (Dismissal of Members of Child Care Policy Coordination Committee)

Where a member prescribed in Article 5 (3) 2 of the Act falls under any of the following, the Chairperson of the Child Care Policy Coordination Committee may dismiss the relevant member:

1. Where a member becomes unable to conduct his/her duties due to mental or physical disorder;
2. Where a member commits a misdeed in connection with his/her duties;
3. Where a member is recognized to be unsuitable to be a member due to neglect of duties, injury to dignity, or other grounds;
4. Where a member himself/herself expresses that he/she has difficulties in conducting his/her duties.

[This Article Newly Inserted by Presidential Decree No. 26703, Dec. 10, 2015]

Article 5 (Detailed Operational Rules of Child Care Policy Coordination Committee)

Except as otherwise expressly prescribed in this Decree, matters necessary for operation of the Child Care Policy Coordination Committee shall be determined by the Chairperson by a resolution of the Child Care Policy Coordination Committee.

[This Article Wholly Amended by Presidential Decree No. 21585, Jun. 30, 2009]

Article 6 (Composition of Child Care Policy Committees)

- (1) The Central Child Care Policy Committee established under the Ministry of Health and Welfare pursuant to the main body of Article 6 (1) of the Act (hereinafter referred to as the "Central Child Care Policy Committee") shall be comprised of not exceeding 20 members, including one chairperson and one vice chairperson, while local child care policy committees (hereinafter referred to as "local child care policy committees") established in a Special Metropolitan City, a Metropolitan City, a *Do*, a Special Self-Governing Province (hereinafter referred to as "City/Do"), and a *Si/Gun/Gu* (referring to an autonomous *Gu*; hereinafter the same shall apply) shall be comprised of not exceeding 15 members, including one chairperson and one vice chairperson.

<Amended by Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 23909, Jun. 29, 2012>

- (2) The Vice Minister of Health and Welfare shall be the Chairperson of the Central Child Care Policy Committee, and the Vice Chairperson shall be appointed from among its members, who shall be any of the following persons: *<Amended by Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 23356, Dec. 8, 2011>*

1. A person commissioned by the Minister of Health and Welfare from among child care specialists, principals of child care centers, representatives of child care teachers, representatives of guardians, and persons representing the public interest, referred to in Article 6 (2) of the Act;
2. A Grade III public official in charge of child care policies in the Ministry of Health and Welfare, or a public official in general service belonging to the Senior Civil Service Corps.

- (3) The chairperson and vice chairperson of a local child care policy committee shall be elected from among its members, and its members shall be commissioned or appointed by the head of a local government to which the relevant local child care policy committee belongs, from among child care experts, principals of child care centers, representatives of child care teachers, representatives of guardians, persons representing the public interest, and relevant public officials (excluding members of the relevant local council) referred to in Article 6 (2) of the Act. In such cases, the membership composition ratio shall be as follows: *<Amended by Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 23356, Dec. 8, 2011; Presidential Decree No. 23909, Jun. 29, 2012>*

1. Representatives of guardians and persons representing the public interest: At least 45/100 of the entire members;
2. Child care specialists: Not exceeding 20/100 of all members;

3. Relevant public officials: Not exceeding 15/100 of the all members;
4. Principals of child care centers: Not exceeding 10/100 of the entire members;
5. Representatives of child care teachers: Not exceeding 10/100 of the entire members.

[This Article Wholly Amended by Presidential Decree No. 21585, Jun. 30, 2009]

Article 7 (Functions of Child Care Policy Committees)

- (1) The Central Child Care Policy Committee shall deliberate on the following: *<Amended by Presidential Decree No. 23356, Dec. 8, 2011; Presidential Decree No. 24904, Dec. 4, 2013>*
 1. Matters on formulation of child care plans referred to in Article 11 of the Act and of annual implementation plans referred to in Article 19 (2) of this Decree;
 2. Matters on development of child care courses referred to in Article 29 of the Act;
 3. Matters on accreditation of child care centers referred to in Article 30 of the Act;
 - 3-2. Deleted; *<by Presidential Decree No. 26525, Sep. 15, 2015>*
 4. Other matters referred by the Chairperson to its meeting in relation to child care, such as entrustment with child care-related affairs.
- (2) A local child care policy committee shall deliberate on the following: *<Amended by Presidential Decree No. 22263, Jul. 9, 2010; Presidential Decree No. 23356, Dec. 8, 2011; Presidential Decree No. 23618, Feb. 3, 2012; Presidential Decree No. 23909, Jun. 29, 2012; Presidential Decree No. 24904, Dec. 4, 2013>*
 1. Deleted; *<by Presidential Decree No. 23909, Jun. 29, 2012>*
 2. Matters on formulation of child care plans referred to in Article 11 of the Act and of annual implementation plans referred to in Article 19 (2) of this Decree;
 3. Matters on establishment of public child care centers referred to in Article 12 of the Act and entrustment with operation of public child care centers referred to in Article 24 (2) of the Act: *Provided*, That matters which may not undergo deliberation by the relevant local child care policy deliberation committee among matters concerning entrustment with operation of public child care centers, as prescribed by Ordinance of the Ministry of Health and Welfare, shall be excluded herefrom;
 4. Matters on designation of educational and training facilities referred to in Article 21 (2) 2 of the Act;
 5. Matters on entrustment with implementation of refresher education referred to in Articles 23 (1) and 23-2 (1) of the Act;
 6. Matters on child care fees, etc., to be paid by users of child care centers referred to in Article 38 of the Act;
 7. Deleted; *<by Presidential Decree No. 26525, Sep. 15, 2015>*
 8. Deleted; *<by Presidential Decree No. 23909, Jun. 29, 2012>*
 9. Matters on the standards for establishment of child care centers and staffing standards of child care teachers and staff on islands, in remote places, in agricultural and fishing communities, etc., referred to in Article 52 of the Act;
 10. Other matters referred by the Chairperson to its meeting in relation to child care.

[This Article Wholly Amended by Presidential Decree No. 21585, Jun. 30, 2009]

Article 8 (Term of Office of Child Care Policy Committee Members)

- (1) The term of office of private members among members of the Central Child Care Policy Committee and local child care policy committees (hereinafter referred to as "relevant child care policy committee") shall be two years, but may be renewed only once.
- (2) The term of office of a member newly commissioned to fill a vacancy by another member shall be the remainder of his/her predecessor's term of office.

[This Article Wholly Amended by Presidential Decree No. 21585, Jun. 30, 2009]

Article 9 (Operation, etc., of Child Care Policy Committees)

- (1) The chairperson of each child care policy committee shall represent the relevant committee and exercise overall control over affairs of the committee.
- (2) The vice chairperson of each child care policy committee shall assist the chairperson and act on his/her behalf if the chairperson is unable to perform any of his/her duties due to extenuating circumstances.
- (3) Each child care policy committee shall have one secretary assigned to conduct affairs of the child care policy committee, who shall be appointed by the head of an institution or local government to which each child care policy committee belongs, from among public officials under his/her management. In such cases, the secretary shall prepare minutes of its meetings.

[This Article Wholly Amended by Presidential Decree No. 21585, Jun. 30, 2009]

Article 10 (Meetings of Child Care Policy Committees)

- (1) Meetings of each child care policy committee shall be called by the chairperson when the head of an institution or local government to which the relevant child care policy committee belongs or at least one third of all incumbent members request the convocation thereof, or when the chairperson deems it necessary.
- (2) Meetings of each child care policy committee shall convene with the a majority of all incumbent members present, and resolutions shall be adopted with the concurrent vote of a majority of the members present.
- (3) Article 4 (4) shall apply *mutatis mutandis* to the payment, etc. of allowances and travel expenses to members who attend a meeting of each child care policy committee.
- (4) In principles, outcomes and details of meetings of each child care policy committee shall be made public. In such cases, the method of disclosure thereof shall be prescribed by the detailed operational rules of each child care policy committee.

[This Article Wholly Amended by Presidential Decree No. 21585, Jun. 30, 2009]

Article 10-2 (Exclusion, Challenge, or Refrainment of Members)

- (1) Where a member of each child care policy committee falls under any of the following cases, he/she shall be excluded from deliberations on the relevant agenda item: *<Amended by Presidential Decree No. 23909, Jun. 29, 2012>*
 1. Where a member, or his/her current or former spouse is a party to an agenda, or is related to a party to the agenda as a joint holder of any right or liability;
 2. Where a member is related to a party to an agenda as a relative;
 3. Where a member or a corporation, organization, etc., to which he/she belongs is, or has been, involved as an agent of a party to an agenda;
 4. Other cases where a member has a direct interest with a party to an agenda item.
- (2) Where any circumstances make it impracticable to expect a fair deliberation from a member, a party to an agenda under deliberation by each child care policy committee may request to challenge him/her.
- (3) Where a member falls under paragraph (1) or (2), he/she shall voluntarily refrain from deliberations on the relevant agenda. *<Amended by Presidential Decree No. 26703, Dec. 10, 2015>*

[This Article Newly Inserted by Presidential Decree No. 21585, Jun. 30, 2009]

Article 10-3 (Appointment and Dismissal of Members of Each Child Care Policy Committee)

- (1) Where a member of the Central Child Care Policy Committee prescribed in Article 6 (2) 1 falls under any of the following, the Minister of Health and Welfare may dismiss the relevant member:
 1. Where a member becomes unable to conduct his/her duties due to mental or physical disorder;
 2. Where a member commits a misdeed in connection with his/her duties;

3. Where a member is recognized to be unsuitable to be a member due to neglect of duties, injury to dignity and other grounds;
 4. Where a member fails to evade even though he/she falls under any subparagraph of Article 10-2 (1);
 5. Where a member himself/herself expresses that he/she has difficulties in conducting his/her duties.
- (2) Where a member of a local child care policy committee prescribed in Article 6 (3) falls under any of the following, the head of the local government may dismiss the relevant member:
1. Where a member becomes unable to conduct his/her duties due to mental or physical disorder;
 2. Where a member commits a misdeed in connection with his/her duties;
 3. Where a member is recognized to be unsuitable to be a member due to neglect of duties, injury to dignity and other grounds;
 4. Where a member fails to evade even though he/she falls under any of the subparagraphs of Article 10-2 (1);
 5. Where a member himself/herself expresses that he/she has difficulties in conducting his/her duties.

[This Article Newly Inserted by Presidential Decree No. 26703, Dec. 10, 2015]

Article 11 (Detailed Operational Rules of Child Care Policy Committees)

@Article 5 shall apply *mutatis mutandis* to the detailed operational rules of each child care policy committee.

[This Article Wholly Amended by Presidential Decree No. 21585, Jun. 30, 2009]

Article 12 (Establishment of Child Care Support Centers)

A data room, counseling room, training room, etc., shall be established in the Central Child Care Support Center established and operated by the Minister of Health and Welfare (hereinafter referred to as "Central Child Care Support Center") and in local child care support centers (hereinafter referred to as "local child care support centers") established and operated by each Special Metropolitan City Mayor, each Metropolitan City Mayor, the Metropolitan Autonomous City Mayor, each *Do* Governor, the Special Self-Governing Province Governor (hereinafter referred to as "Mayor/*Do* Governor"), and the head of a *Si/Gun/Gu* (referring to the head of an autonomous *Gu*; hereinafter the same shall apply), pursuant to Article 7 (1) of the Act. *<Amended by Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 24904, Dec. 4, 2013; Presidential Decree No. 25164, Feb. 11, 2014>*

[This Article Wholly Amended by Presidential Decree No. 21585, Jun. 30, 2009]

Article 13 (Functions of Child Care Support Centers)

- (1) The Central Child Care Support Center and local child care support centers (hereinafter referred to as "each child care support center") shall perform the following functions: *<Amended by Presidential Decree No. 23356, Dec. 8, 2011; Presidential Decree No. 24904, Dec. 4, 2013>*
1. Providing temporary nursing services;
 - 1-2. Collecting and providing information on child care;
 2. Providing or lending child care programs and teaching materials or aids;
 3. Providing counseling to child care teachers and staff, and information on recruitment and job seeking;
 4. Counseling and consultation on establishment, operation, etc., of a child care center;
 5. Providing information on child care for the vulnerable, including child care for disabled children;
 6. Counseling and education for parents;
 7. Providing experience and play spaces to infants and young children;
 8. Educating parents of infants and young children and child care teachers and staff on preventing abuse of infants and young children;
 9. Other matters necessary for the operation of child care centers, support for home nurseries, etc.

- (2) The Central Child Care Support Center shall assist local child care support centers in their affairs, while local child care support centers shall render services based on the local characteristics to child care centers and child care users in their jurisdictional areas. *<Amended by Presidential Decree No. 23356, Dec. 8, 2011; Presidential Decree No. 24904, Dec. 4, 2013>*

[This Article Wholly Amended by Presidential Decree No. 21585, Jun. 30, 2009]

Article 14 (Qualification and Duties of Heads of Child Care Support Centers)

- (1) The head of each child care support center shall have at least five-year work experience in child care business after being qualified as a child care expert referred to in Article 15 (1). *<Amended by Presidential Decree No. 24904, Dec. 4, 2013; Presidential Decree No. 28132, Jun. 20, 2017>*
- (2) The head of each child care support center shall represent the relevant child care support center and exercise overall control over affairs of such center. *<Amended by Presidential Decree No. 24904, Dec. 4, 2013>*
- (3) The head of each child care support center shall serve on a full-time basis. *<Amended by Presidential Decree No. 24904, Dec. 4, 2013>*

[This Article Wholly Amended by Presidential Decree No. 21585, Jun. 30, 2009]

Article 15 (Qualifications and Duties of Child Care Experts)

- (1) A child care expert referred to in Article 7 (2) of the Act shall be either of the following persons:
1. A person qualified as a Grade I child care teacher specified in attached Table 1;
 2. A person with at least three years' experience in child care business after obtaining qualification as a Grade I social welfare worker under the Social Welfare Services Act.
- (2) A child care expert shall conduct affairs of a child care support center referred to in Article 13, and a senior child care expert shall act on behalf of the head of a child care support center if he/she is unable to perform his/her duties due to extenuating circumstances. *<Amended by Presidential Decree No. 24904, Dec. 4, 2013>*

[This Article Wholly Amended by Presidential Decree No. 21585, Jun. 30, 2009]

Article 16 (Qualifications for Counseling Experts)

A counseling expert referred to in Article 7 (2) of the Act shall be either of the following:

1. A person qualified as a clinical psychology practitioner of at least Grade II under the National Technical Qualifications Act;
2. A person who has received a bachelor's degree in counseling or psychology from a school defined in any subparagraph of Article 2 of the Higher Education Act (including persons deemed to have a similar school career or higher under the relevant statutes) and has at least three years' work experience in relation to counseling.

[This Article Newly Inserted by Presidential Decree No. 26525, Sep. 15, 2015]

Article 17 Deleted. *<by Presidential Decree No. 23618, Feb. 3, 2012>*

Article 18 (Entrustment with Research, etc., on Child Care)

- (1) The Minister of Health and Welfare may outsource the following affairs to a research institute, corporation, or organization specified in paragraph (2), pursuant to Article 8 (1) of the Act. In such cases, he/she shall publicly announce the details of an outsourced institution and outsourced affairs: *<Amended by Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 23356, Dec. 8, 2011; Presidential Decree No. 24904, Dec. 4, 2013>*

1. Research on child care policies, and provision of information on child care;
2. Development of child care programs and teaching materials;
3. Development of teaching materials and training for child care teachers and staff;

4. Formulation of evaluation criteria for child care centers;
 5. Other affairs deemed necessary by the Minister of Health and Welfare for child care business, such as evaluation of child care support centers, educational and training facilities, etc.
- (2) The Minister of Health and Welfare may entrust the affairs specified in any subparagraph of paragraph (1), to the following research institute, corporation, or organization. In such cases, he/she shall publicly notify the standards, procedures, method, etc., for outsourcing on the bulletin board or website of the Ministry of Health and Welfare: *<Amended by Presidential Decree No. 24904, Dec. 4, 2013>*
1. A Government-funded research institute established under the Act on the Establishment, Operation and Fostering of Government-Funded Research Institutes;
 2. A university or junior college defined under Article 2 of the Higher Education Act, which has a department related to child care or child welfare;
 3. Other non-profit corporation or organization related to child care.
- (3) A research institute, corporation, or organization entrusted with affairs pursuant to paragraph (1), shall prepare and submit a plan and a budget bill for the relevant affairs, to the Minister of Health and Welfare before the relevant business year. *<Amended by Presidential Decree No. 22075, Mar. 15, 2010>*
- (4) The Minister of Health and Welfare may subsidize a research institute, corporation, or organization outsourced with affairs pursuant to paragraph (1), expenses incurred in conducting the outsourced affairs, within budgetary limits. *<Amended by Presidential Decree No. 22075, Mar. 15, 2010>*
[This Article Wholly Amended by Presidential Decree No. 21585, Jun. 30, 2009]

Article 18-2 (Types of Child Care Centers of Corporations, Organizations, etc.)

"Child care centers prescribed by Presidential Decree" referred to in subparagraph 3 of Article 10 of the Act means any of the following child care centers:

1. A child care center established and operated by a corporation or school corporation under the Early Childhood Education Act, the Elementary and Secondary Education Act, or the Higher Education Act;
2. A child care center established and operated by a religious organization;
3. A child care center established and operated by Korea Workers' Compensation and Welfare Service under the Industrial Accident Compensation Insurance Act;
4. A child care center established and operated by educational and training facilities under Article 21 (2) 2 of the Act;
5. A child care center equivalent to the child care centers under subparagraphs 1 through 4 and prescribed by the Minister of Health and Welfare.

[This Article Newly Inserted by Presidential Decree No. 23618, Feb. 3, 2012]

Article 19 (Details of, and Formulation Timing and Procedures for, Child Care Plans)

- (1) The Minister of Health and Welfare, a Mayor/Do Governor, and the head of a *Si/Gun/Gu* shall, pursuant to Article 11 (1) of the Act, formulate child care plans containing the following: *<Amended by Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 23356, Dec. 8, 2011>*
1. Basic direction-setting for child care services;
 2. Matters on establishment of, and supply and demand for, child care centers;
 3. Matters on child care teachers and staff;
 4. Matters on operation and evaluation of child care centers;
 5. Matters on child care expenses;
 6. Other matters necessary for child care.
- (2) The Minister of Health and Welfare, a Mayor/Do Governor, and the head of a *Si/Gun/Gu* shall formulate child care plans referred to paragraph (1) every five years, and annual implementation

plans by the end of February each year. <Amended by Presidential Decree No. 22075, Mar. 15, 2010>
 [This Article Wholly Amended by Presidential Decree No. 21585, Jun. 30, 2009]

Article 19-2 (Preferential Establishment of National or Public Child Care Centers)

"Fixed number of households prescribed by Presidential Decree" in the latter part of Article 12 of the Act, means 500 households.

[This Article Newly Inserted by Presidential Decree No. 25164, Feb. 11, 2014]

Article 20 (Establishment of Workplace Child Care Centers)

- (1) A place of business requiring the business proprietor to establish a workplace child care center pursuant to Article 14 (1) of the Act shall be a place of business which hires at least 300 full-time female workers or at least 500 full-time workers. <Amended by Presidential Decree No. 23356, Dec. 8, 2011>
- (2) In applying paragraph (1), at least two State administrative agencies shall be deemed one place of business, if they jointly use a Government building.
- (3) Where a workplace child care center should be established under paragraph (2), an agency in charge of establishing and managing such child care center, shall be determined in the following order: *Provided*, That it may be determined otherwise through consultation between agencies jointly using a Government building: <Amended by Presidential Decree No. 23356, Dec. 8, 2011>
 1. An agency in charge of managing the relevant Government building (an agency related to the main function of the Government building, if the building is not State property);
 2. An agency where demand for child care is the highest.
- (4) Expenses incurred in operating a workplace child care center established under paragraphs (2) and (3), shall be borne by each relevant agency in proportion to the number of infants and young children using such child care center: *Provided*, That if it is necessary to adjust cost-sharing due to extenuating circumstances, the ratio of expenses to be borne shall be determined through consultation between an agency in charge of establishing and managing the child care center and agencies using it. <Amended by Presidential Decree No. 23356, Dec. 8, 2011>
- (5) If necessary, the business proprietor of a place of business other than those referred to in paragraphs (1) and (2) may establish a workplace child care center to provide child care to employees' children. <Amended by Presidential Decree No. 23356, Dec. 8, 2011; Presidential Decree No. 25929, Dec. 30, 2014>

[This Article Wholly Amended by Presidential Decree No. 21585, Jun. 30, 2009]

Article 20-2 (Research Institution on Performance of Duty to Establish Workplace Child Care Centers, etc.)

- (1) "Institution prescribed by Presidential Decree" in the former part of Article 14-2 (1) of the Act, means any of the following: <Amended by Presidential Decree No. 24454, Mar. 23, 2013; Presidential Decree No. 25929, Dec. 30, 2014>
 1. The Ministry of Education;
 2. The Ministry of Employment and Labor;
 3. Cities/Dos.
- (2) The Minister of Health and Welfare and the head of an institution referred to in each subparagraph of paragraph (1) (hereinafter referred to as "research institution"), shall conduct a fact-finding survey to assess performance of the duty to establish a workplace child care center, etc., referred to in Article 14 (1) of the Act (hereinafter referred to as "fact-finding survey on performance of duties"), for any of the following places of business, as relevant: <Amended by Presidential Decree No. 24454, Mar. 23, 2013; Presidential Decree No. 25164, Feb. 11, 2014; Presidential Decree No. 25929, Dec. 30, 2014>

1. The Minister of Education: Places of business which are schools defined in Article 2 of the Higher Education Act, educational administrative agencies defined in Article 2 (4) of the Educational Officials Act (excluding the Ministry of Education), or educational research institutions defined in Article 2 (5) of the same Act;
 2. The Minister of Employment and Labor: Places of business subscribed to employment insurance;
 3. A Mayor/*Do* Governor: Places of business which are local administrative agencies located in areas under the jurisdiction of the relevant City/*Do* (excluding institutions falling under subparagraph 1);
 4. The Minister of Health and Welfare: Places of business not specified in subparagraphs 1 through 3.
- (3) If necessary to conduct a fact-finding survey to assess performance of duties, the Minister of Health and Welfare and the head of a research institution may request the relevant administrative agency, an institution, organization, etc., subject to the fact-finding survey to assess performance of duties to submit materials, opinions, etc. Upon receipt of such request, the relevant administrative agency, institution, organization, etc., shall comply therewith, except in extenuating circumstances.
- [This Article Newly Inserted by Presidential Decree No. 23909, Jun. 29, 2012]

Article 20-3 (Method, etc. of Fact-Finding Survey on Performance of Duties)

- (1) The Minister of Health and Welfare and the head of a research institution shall conduct a fact-finding survey on performance of duties as at December 31 each year, pursuant to the former part of Article 14-2 (1) of the Act.
- (2) The head of a research institution shall notify the Minister of Health and Welfare of the results of the survey referred to in paragraph (1) by the end of February the following year, pursuant to the latter part of Article 14-2 (1) of the Act.
- (3) Details of a fact-finding survey to assess performance of duties, shall be as follows:
 1. Basic matters on a place of business, such as its name, and the number of full-time workers and full-time female workers;
 2. The number of infants and young children eligible for child care and demand for child care in the relevant place of business;
 3. The actual status of performance of the duty to establish a workplace child care center, etc., referred to in Article 14 of the Act;
 4. If a place of business neglects any of its duties to establish a workplace child care center, etc., referred to in Article 14 of the Act, the ground therefor and a performance plan (including timing to perform such duty).

[This Article Newly Inserted by Presidential Decree No. 23909, Jun. 29, 2012]

Article 20-4 (Timing, Method, etc., of Announcement of Lists)

- (1) The Minister of Health and Welfare shall announce a list of places of business which have breached the obligation to establish a workplace child care center, etc. or have failed to respond to a fact-finding survey, by May 31 each year, pursuant to the main body of Article 14-2 (2) of the Act. *<Amended by Presidential Decree No. 25929, Dec. 30, 2014; Presidential Decree No. 28132, Jun. 20, 2017>*
- (2) The list referred to in paragraph (1) shall include the names and addresses of the relevant places of business, the number of full-time workers, the number of full-time female workers, the number of infants and young children eligible for child care and the grounds for the breach of the obligation or the failure to respond to a fact-finding survey. *<Amended by Presidential Decree No. 25929, Dec. 30, 2014>*

[This Article Newly Inserted by Presidential Decree No. 23909, Jun. 29, 2012]

Article 20-5 (Reasons for Exclusion from Announcement of Lists)

"Where reasons prescribed by Presidential Decree exist" under the proviso to Article 14-2 (2) of the Act,

means any of the following cases:

1. Where one year has not elapsed since the relevant place of business became subject to the obligation to establish a workplace child care center pursuant to Article 20 (1);
2. Where the relevant place of business is establishing a workplace child care center by formulating a plan to establish the workplace child care center and contributing to construction costs;
3. Where it is deemed unnecessary to announce the list, such as where no demand for child care exists in light of the nature of full-time workers of the relevant place of business.

[This Article Newly Inserted by Presidential Decree No. 23909, Jun. 29, 2012]

Article 20-6 (Establishment and Operation of Deliberation Committee on Announcement of List of Workplace Child Care Centers)

- (1) "Person prescribed by Presidential Decree, such as child care specialists" under Article 14-2 (3) 6 of the Act means a person with good knowledge and experience in child care, such as a person who serves as a professor in the child care-related department at a school defined under Article 2 of the Higher Education Act.
- (2) A person falling under Article 14-2 (3) 1 of the Act shall be the chairperson of the deliberation committee on announcement of the list of workplace child care centers referred to in Article 14-2 (3) of the Act (hereinafter referred to as the "committee for deliberation on announcement of list").
- (3) The term of office of a commissioned member of the deliberation committee on announcement of the list shall be two years, but may be renewed only once, and the term of office of a member newly commissioned due to the resignation, etc. of another member shall be the remaining term of office of his/her predecessor. *<Amended by Presidential Decree No. 26703, Dec. 10, 2015>*
- (4) The chairperson of the deliberation committee on announcement of the list shall represent the deliberation committee on announcement of the list and exercise overall control over its affairs.
- (5) Meetings of the deliberation committee on announcement of the list shall be called by the chairperson when deemed necessary or when at least one-third of all incumbent members request the convocation thereof.
- (6) Meetings of the deliberation committee on announcement of the list shall convene with the attendance of a majority of all incumbent members, and resolutions shall be adopted with the consent of a majority of the members present.
- (7) Allowances may be provided, and travel expenses reimbursed, within budgetary limits, to members who attend a meeting of the deliberation committee on announcement of the list: *Provided*, That the same shall not apply where a member who is a public official attends such meeting in direct relation to his/her affairs.
- (8) The deliberation committee on announcement of the list shall have one secretary assigned to conduct affairs of the deliberation committee on announcement of the list, who shall be appointed by the Minister of Health and Welfare from among public officials belonging to the Ministry of Health and Welfare.
- (9) Where a member of the deliberation committee on announcement of the list prescribed in Article 14-2 (3) 2 through 6 of the Act falls under any of the following, the Minister of Health and Welfare may dismiss the relevant member: *<Newly Inserted by Presidential Decree No. 26703, Dec. 10, 2015>*
 1. Where a member becomes unable to conduct his/her duties due to mental or physical disorder;
 2. Where a member commits a misdeed in connection with his/her duties;
 3. Where a member is recognized to be unsuitable to be a member due to neglect of duties, injury to dignity and other grounds;
 4. Where a member himself/herself expresses that he/she has difficulties in conducting his/her duties.
- (10) Except as otherwise expressly prescribed in paragraphs (1) through (9), matters necessary for operating the deliberation committee on announcement of the list shall be determined by the chairperson, subject to deliberation by the deliberation committee on announcement of the list.

<Amended by Presidential Decree No. 26703, Dec. 10, 2015>

[This Article Newly Inserted by Presidential Decree No. 23909, Jun. 29, 2012]

Article 20-7 (Provision of Opportunity to Make Explanatory Statements)

Before announcing a list pursuant to Article 20-4, the Minister of Health and Welfare shall give written notice of the fact of announcement to business proprietors of places of business subject to announcement of the list pursuant to Article 14-2 (4) of the Act, and provide them with an opportunity to submit explanatory materials or to state their opinions at a meeting of the deliberation committee on announcement of the list of workplace child care centers, within 20 days after receipt of such notice.

[This Article Newly Inserted by Presidential Decree No. 23909, Jun. 29, 2012]

Article 20-8 (Measures to Secure Safety of Video Information)

(1) An establisher/operator of a child care center shall take the following measures to ensure the safety of video information pursuant to Article 15-5 (3) of the Act:

1. Measures to keep records of access and to prevent forgery or modulation thereof, in order to address any infringement on video information;
2. Measures to control access to video information and to restrict rights to access thereto;
3. Measures to formulate and implement internal management plans for safely processing video information;
4. Physical measures, such as preparing storage facilities for safe keeping of video information and installing locking devices.

(2) Details of the measures necessary to ensure the safety of video information referred to in paragraph (1), shall be prescribed and publicly announced by the Minister of Health and Welfare.

[This Article Newly Inserted by Presidential Decree No. 26525, Sep. 15, 2015]

Article 21 (Standards for Qualifications for Principals, Child Care Teachers, and Staff of Child Care Centers)

The standards for qualifications for principals, child care teachers, and staff of child care centers referred to in Article 21 (1) and (3) of the Act shall be as specified in attached Table 1. *<Amended by Presidential Decree No. 23356, Dec. 8, 2011>*

[This Article Wholly Amended by Presidential Decree No. 21585, Jun. 30, 2009]

Article 21-2 (Scope of Establishment of Child Care Center Operating Committees)

"Child care centers prescribed by Presidential Decree" under the proviso to Article 25 (1) of the Act means all child care centers, excluding child care centers at parents associations referred to in subparagraph 6 of Article 10 of the Act. *<Amended by Presidential Decree No. 23356, Dec. 8, 2011; Presidential Decree No. 23618, Feb. 3, 2012>*

[This Article Wholly Amended by Presidential Decree No. 21585, Jun. 30, 2009]

Article 21-3 (Grounds for Canceling Designation of Temporary Nursing Services Provider)

"Grounds determined by Presidential Decree" under Article 26-2 (4) 3 of the Act means:

1. Where a temporary nursing services provider is designated by fraudulent or other wrongful means;
2. Where the head or an employee of a temporary nursing services provider receives a punishment pursuant to Article 71 (1) of the Child Welfare Act.

[This Article Newly Inserted by Presidential Decree No. 24904, Dec. 4, 2013]

Article 21-4 (Preferential Provision of Child Care)

"Child care centers prescribed by Presidential Decree" in the main body other than each subparagraph of Article 28 of the Act means child care centers of corporations, organizations, etc., in subparagraph 3,

home-based child care centers in subparagraph 5, and private child care centers in subparagraph 7 of Article 10 of the Act.

[This Article Newly Inserted by Presidential Decree No. 23909, Jun. 29, 2012]

Article 21-5 (Permission for Establishment of Mutual Aid Association for Safety of Child Care Centers)

(1) Where it is intended to establish a mutual aid association for safety of child care centers referred to in Article 31-2 (2) of the Act (hereinafter referred to as "mutual aid association"), at least eight promoters shall prepare its articles of association and mutual aid by-laws and file an application with the Minister of Health and Welfare for permission therefor. *<Amended by Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 23356, Dec. 8, 2011>*

(2) When the Minister of Health and Welfare grants permission under paragraph (1), he/she shall publicly announce such fact. *<Amended by Presidential Decree No. 22075, Mar. 15, 2010>*

[This Article Newly Inserted by Presidential Decree No. 21585, Jun. 30, 2009]

Article 21-6 (Particulars to Be Stated in Articles of Association of Mutual Aid Association)

(1) Matters to be provided for in the articles of association referred to in Article 31-2 (6) of the Act shall be as follows: *<Amended by Presidential Decree No. 23356, Dec. 8, 2011>*

1. Objectives;
2. Name;
3. Location of the head office;
4. Matters on business;
5. Matters on the standards for a share in investments;
6. Matters on qualifications, etc., for membership;
7. Matters on executives and employees;
8. Matters on the board of directors;
9. Matters on compensation examinations of mutual aid business for safety of child care centers;
10. Matters on assets and accounting;
11. Matters on amendment to the articles of association;
12. Matters on enactment, amendment, and abolition of by-laws;
13. Matters on the method of making public announcements.

(2) Where a mutual aid association intends to amend its articles of association, it shall obtain authorization thereof from the Minister of Health and Welfare. *<Amended by Presidential Decree No. 22075, Mar. 15, 2010>*

[This Article Newly Inserted by Presidential Decree No. 21585, Jun. 30, 2009]

Article 21-7 (Operation and Supervision of Mutual Aid Associations)

(1) A mutual aid association shall prepare and submit both a business plan and budget bill for each business year one month before the relevant business year, and a settlement of accounts for each business year within two months after the relevant business year, to the Minister of Health and Welfare. *<Amended by Presidential Decree No. 22075, Mar. 15, 2010>*

(2) The Minister of Health and Welfare may issue an order to report mutual aid business, or provide guidance to or supervision over the business or property conditions, and may require rectification, if deemed necessary. *<Amended by Presidential Decree No. 22075, Mar. 15, 2010>*

[This Article Newly Inserted by Presidential Decree No. 21585, Jun. 30, 2009]

Article 21-8 (Eligible Persons and Standards for Subsidization of Home-Care Allowances)

(1) Persons for whom home-care expenses are subsidized under Article 34-2 (1) of the Act shall be the infants and young children of households with an income (referring to an aggregate of an income and

an income-equivalent of property provided by Ordinance of the Ministry of Health and Welfare) not exceeding the amount prescribed by the Minister of Health and Welfare. <Amended by Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 22629, Jan. 20, 2011; Presidential Decree No. 25929, Dec. 30, 2014>

- (2) The scope of income, included in the amount of income pursuant to paragraph (1), shall be as follows: <Amended by Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 22263, Jul. 9, 2010; Presidential Decree No. 22906, Apr. 22, 2011; Presidential Decree No. 23734, Apr. 17, 2012; Presidential Decree No. 24247, Dec. 21, 2012; Presidential Decree No. 27252, Jun. 21, 2016; Presidential Decree No. 29180, Sep. 18, 2018>
1. Wage and salary income: Income earned by providing labor: *Provided*, That this shall exclude wage and salary income nontaxable in accordance with the Income Tax Act, but shall include the following pay:
 - (a) Pay which is nontaxable pursuant to subparagraph 3 (q) of Article 12 of the Income Tax Act;
 - (b) Pay which is nontaxable pursuant to Article 16 (1) 1 of the Enforcement Decree of the Income Tax Act;
 2. Business income: Any of the following incomes:
 - (a) Agricultural revenue: Revenue obtained from seeds cultivation business, fruit-growing business, horticultural business, sericultural business, seed and nursery business, special crops-producing business, livestock breeding business, breeding stock business or hatching business; and income earned from business incidental thereto;
 - (b) Forestry revenue: Revenue obtained from forest management business, forest goods-producing business or wild bird and animal breeding business; and income earned from business incidental thereto;
 - (c) Fishery revenue: Revenue obtained from fishery business and income earned from business incidental thereto;
 - (d) Other business revenue: Revenue obtained from wholesale business, retail business, manufacturing business or other business;
 3. Property income: Any of the following income:
 - (a) Rental income: Income generated by leasing real estate, movable property, rights or other property;
 - (b) Interest income: Income exceeding the amount prescribed by the Minister of Health and Welfare, out of income generated by interest, dividend, or discount on deposits, shares or bonds;
 - (c) Pension income: Pension or income generated under Article 20-3 (1) 3 through 5 of the Income Tax Act and income generated under Article 4 (1) 1 (b) of the Insurance Business Act;
 4. Public transfer income: Various types of allowances, pensions, pay, or other money or goods provided on a regular basis in accordance with the National Pension Act; the Public Officials Pension Act; the Public Officials' Accident Compensation Act; the Military Pension Act; the Special Post Offices Act; the Pension for Private School Teachers and Staff Act; the Employment Insurance Act; the Industrial Accident Compensation Insurance Act; the Act on the Honorable Treatment of Persons of Distinguished Service to Independence; the Act on the Honorable Treatment and Support for Persons of Distinguished Services to the State; the Act on Assistance to Patients Suffering from Actual or Potential Aftereffects of Defoliants and Establishment of Related Organizations; the Compulsory Motor Vehicle Liability Security Act; the Act on Honorable Treatment of War Veterans and Establishment of Related Associations, etc.: *Provided*, That the following money or goods shall be excluded herefrom:
 - (a) Allowances for adjusting living conditions referred to in Article 14 of the Act on the Honorable Treatment of Persons of Distinguished Service to Independence and Article 14 of the Act on the Honorable Treatment and Support for Persons of Distinguished Service to the

- State;
- (b) War veteran allowances under the Act on Honorable Treatment of War Veterans and Establishment of Related Associations;
 - (c) Rehabilitation subsidies referred to in Article 30 (2) of the Compulsory Motor Vehicle Liability Security Act and Article 21 of the Enforcement Decree of the same Act;
 - (d) Nursing allowances referred to in Article 15 of the Act on the Honorable Treatment and Support for Persons of Distinguished Services to the State.
- (3) The scope of property, included in the amount of income under paragraph (1), shall be as follows: *<Amended by Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 23356, Dec. 8, 2011>*
1. General property: Any of the following property:
 - (a) Land, buildings and housing provided for in subparagraphs 1 through 3 of Article 104 of the Local Tax Act;
 - (b) Aircraft and ships under subparagraphs 4 and 5 of Article 104 of the Local Tax Act;
 - (c) Lease deposits for housing, commercial buildings, etc. (including security money for leases on a deposit basis);
 - (d) Movable property, such as livestock, seeds and seedlings, the value of which exceeds one million won (excluding movable property prescribed by the Minister of Health and Welfare, including rehabilitation aids for disabled persons), and standing timber under subparagraph 11 of Article 6 of the Local Tax Act;
 - (e) Membership under subparagraphs 14 through 17 of Article 6 of the Local Tax Act;
 - (f) The right to acquire a house as an association member pursuant to Article 89 (2) of the Income Tax Act;
 - (g) The right to acquire a building and land incidental thereto when the construction of the building is completed (excluding the right to acquire a house as an association member pursuant to item (f));
 - (h) Fishing right pursuant to subparagraph 13 of Article 6 of the Local Tax Act;
 2. Financial assets: Any of the following assets:
 - (a) Financial assets defined in subparagraph 2 of Article 2 of the Act on Real Name Financial Transactions and Confidentiality;
 - (b) Various insurance products referred to in Article 4 (1) of the Insurance Business Act;
 3. Automobiles referred to in Article 124 of the Local Tax Act: *Provided*, That automobiles used by disabled persons pursuant to Article 39 of the Act on Welfare of Persons with Disabilities and other automobiles prescribed by the Minister of Health and Welfare shall be excluded herefrom, and automobiles prescribed by the Minister of Health and Welfare, including trucks, shall be deemed general property referred to in subparagraph 1.
- (4) The value of property set forth in paragraph (3) shall be calculated by any of the following methods, as relevant, based on the date of the examination referred to in Article 34-5 of the Act (hereinafter referred to as "examination date"): *Provided*, That if it is impracticable to calculate the value of relevant property, the value shall be calculated as prescribed by the Minister of Health and Welfare, taking into account the type, transaction circumstances, etc., of the relevant property: *<Amended by Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 22395, Sep. 20, 2010; Presidential Decree No. 23356, Dec. 8, 2011; Presidential Decree No. 23909, Jun. 29, 2012; Presidential Decree No. 24904, Dec. 4, 2013; Presidential Decree No. 25929, Dec. 30, 2014; Presidential Decree No. 28628, Feb. 9, 2018>*
1. Paragraph (3) 1 (a): The value determined by the Minister of Health and Welfare, taking into account the assessed value pursuant to the proviso to Article 10 (2) of the Local Tax Act;
 2. Paragraph (3) 1 (b): The value determined by the Minister of Health and Welfare, taking into account the assessed value pursuant to the proviso to Article 10 (2) of the Local Tax Act;

3. Paragraph (3) 1 (c): A deposit or security money for lease on a deposit basis stated in a lease contract;
4. Paragraph (3) 1 (d): The current market price in cases of movable property, and the assessed value pursuant to Article 4 (1) 5 of the Enforcement Decree of the Local Tax Act in cases of standing timber;
5. Paragraph (3) 1 (e): The assessed value pursuant to Article 4 (1) 9 of the Enforcement Decree of the Local Tax Act;
6. Paragraph (3) 1 (f): An amount classified as follows:
 - (a) Where liquidation proceeds are paid: An aggregate of a price determined according to a management and disposal plan referred to in Article 74 of the Act on the Maintenance and Improvement of Urban Areas and Dwelling Conditions for Residents (hereinafter referred to as "appraised value of the existing building") and the liquidation proceeds paid;
 - (b) Where liquidation money is received: An amount calculated by deducting liquidation money received from the appraised value of the existing building;
7. Paragraph (3) 1 (g): An amount paid up until the examination date;
8. Paragraph (3) 1 (h): The assessed value under Article 4 (1) 8 of the Enforcement Decree of the Local Tax Act;
9. Paragraph (3) 2: The value by financial property based upon the standards specified in Article 21-9 (1) and (3);
10. Paragraph (3) 3: The value determined by the Minister of Health and Welfare, taking into account the types of automobiles, seating capacity, fixed loading capacity, manufacturing price for each manufacturing year (import price in cases of an imported automobile), transaction price, etc.

[This Article Wholly Amended by Presidential Decree No. 21956, Dec. 31, 2009]

Article 21-9 (Scope of Financial Information, etc.)

- (1) "Average bank account balance and other data or information prescribed by Presidential Decree" referred to in Article 34-4 (2) 1 of the Act means the following: *<Amended by Presidential Decree No. 21956, Dec. 31, 2009; Presidential Decree No. 25929, Dec. 30, 2014>*
 1. On-call deposits, such as ordinary deposits, savings accounts, and free savings accounts: The average balance within the last three months;
 2. Savings deposits, such as term deposits, installment deposits, and installment savings: The account balance or the total amount deposited;
 3. Shares, beneficiary certificates, investments, and investment equities: Final quotations; and in such cases, Article 54 (1) of the Enforcement Decree of the Inheritance Tax and Gift Tax Act shall apply to evaluation of the quotations of unlisted stocks;
 4. Bonds, notes, checks, certificates of debt, and certificates of preemptive right to new stocks: Face value amounts;
 5. Pension savings: The amount paid regularly.
- (2) "Amount of debts and other data or information prescribed by Presidential Decree" referred to in Article 34-4 (2) 2 of the Act means the following:
 1. Loans and details of arrearage;
 2. An unsettled credit card balance.
- (3) "Insurance premiums and other data or information prescribed by Presidential Decree" referred to in Article 34-4 (2) 3 of the Act means the following:
 1. Insurance policies: The amount refundable if insurance is terminated;
 2. Pension insurance: An amount paid on a regular basis.

[This Article Wholly Amended by Presidential Decree No. 21585, Jun. 30, 2009]

Article 21-10 (Request for and Provision of Financial Information, etc.)

- (1) Where the Minister of Health and Welfare or the head of a local government requests the head of a financial institution, etc., (referring to a financial institution, etc. defined in subparagraph 1 of Article 2 of the Act on Real Name Financial Transactions and Confidentiality or a credit information concentration agency defined in subparagraph 6 of Article 2 of the Use and Protection of Credit Information Act; hereinafter the same shall apply) to provide financial information, credit information, or insurance information (hereinafter referred to as "financial information, etc.") of an applicant for expense subsidies, his/her family members, or a person for whom subsidization for expenses has been determined, pursuant to Article 34-6 of the Act, he/she shall do so using a document stating the following: <Amended by Presidential Decree No. 21765, Oct. 1, 2009; Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 23356, Dec. 8, 2011>
1. The relevant person's name and resident registration number;
 2. The scope of financial information, etc., requested, and the base date and period of inquiry.
- (2) When the head of a financial institution, etc., so requested under paragraph (1), provides the relevant financial information, etc., to the Minister of Health and Welfare or the head of the relevant local government, he/she shall do so through a document describing the following: <Amended by Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 23356, Dec. 8, 2011>
1. The relevant person's name and resident registration number;
 2. The name of a financial institution, etc., providing the financial information, etc.;
 3. The name and account number of a financial product subject to information disclosure;
 4. Details of the financial information, etc.
- (3) The Minister of Health and Welfare may request the head of the relevant financial institution, etc., to provide the financial information, etc., referred to in paragraph (1), through the information and communications network of an association, federation, or central association joined by the financial institution, etc. <Amended by Presidential Decree No. 22075, Mar. 15, 2010>
- (4) When the Minister of Health and Welfare requests financial information, etc., of a person for whom subsidization for expenses has been determined under Article 34-6 (2) of the Act, he/she shall do so to the minimal extent necessary to achieve the objective of the examination referred to in Article 34-5 of the Act. <Newly Inserted by Presidential Decree No. 23356, Dec. 8, 2011>

[This Article Wholly Amended by Presidential Decree No. 21585, Jun. 30, 2009]

Article 22 (Details, Scope, etc., of Free Child Care)

- (1) Free care for infants and young children (including those who are disabled children and children of multicultural families referred to in subparagraph 1 of Article 2 of the Multicultural Families Support Act) pursuant to Article 34 (1) of the Act shall be provided to the following: <Amended by Presidential Decree No. 24397, Feb. 28, 2013; Presidential Decree No. 24454, Mar. 23, 2013>
1. Infants and young children who are at least three years of age as of January 1 of the relevant year:

Where they are provided, at child care centers, with common child care and educational courses determined after consultation between the Minister of Health and Welfare and the Minister of Education (hereinafter referred to as "common courses"), among the child care courses referred to in Article 29 of the Act: *Provided*, That this shall include infants and young children who turn three years old during the period between January 2 and March 1 and are provided with common courses at child care centers;
 2. Infants and young children who are younger than three years of age as of January 1 each year:

Where they are provided with child care courses referred to in Article 29 (excluding common courses) of the Act at child care centers.
- (2) Notwithstanding paragraph (1), free child care may be provided for disabled children until they reach twelve years old, if they are provided with child care courses referred to in Article 29 of the Act

at child care centers pursuant to Article 34 (2) of the Act. <Newly Inserted by Presidential Decree No. 24397, Feb. 28, 2013>

- (3) Except as otherwise expressly prescribed in paragraphs (1) and (2), matters necessary for providing free child care shall be determined by the Minister of Health and Welfare. <Amended by Presidential Decree No. 24397, Feb. 28, 2013>

[This Article Wholly Amended by Presidential Decree No. 23192, Sep. 30, 2011]

Article 23 (Expenses for Free Child Care)

- (1) Expenses incurred in providing free child care referred to in Article 22 (1) 1 shall be covered within budgetary limits, pursuant to Article 34 (3) of the Act, and more specifically, with general subsidies under the Local Education Subsidy Act: *Provided*, That such expenses shall be covered by the special accounts for supporting early childhood education prescribed in Article 2 of the Act on the Early Childhood Education Support Special Account during the validity period prescribed in Article 2 of Addenda of the same Act. <Amended by Presidential Decree No. 24397, Feb. 28, 2013; Presidential Decree No. 27732, Dec. 30, 2016>

- (2) Expenses incurred in providing free child care referred to in Article 22 (1) 2 and free child care for disabled children referred to in Article 22 (2) shall be borne by the State and local governments pursuant to Article 34 (3) of the Act, according to the subsidy rate for child care services prescribed in Article 4 and attached Table 1 of the Enforcement Decree of the Subsidy Management Act. <Amended by Presidential Decree No. 23264, Oct. 26, 2011; Presidential Decree No. 24397, Feb. 28, 2013>

- (3) Details of the method, procedures, etc., for subsidizing expenses incurred in providing free child care shall be prescribed by the Minister of Health and Welfare.

[This Article Wholly Amended by Presidential Decree No. 23192, Sep. 30, 2011]

Article 24 (Subsidization of Expenses)

- (1) The State or a local government shall fully or partially subsidize any of the following expenses, within budgetary limits pursuant to Article 36 of the Act. <Amended by Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 23356, Dec. 8, 2011; Presidential Decree No. 23618, Feb. 3, 2012; Presidential Decree No. 24904, Dec. 4, 2013>

1. Expenses incurred in establishing, expanding, reconstructing, improving, or repairing child care centers;
2. Personnel expenses for child care teachers;
3. Expenses for teaching materials and aids;
4. Expenses for establishing and operating local child care support centers;
5. Expenses for employee education and training, such as refresher education;
6. Expenses for providing child care for the vulnerable, such as child care for disabled children;
7. Other expenses deemed necessary for the Minister of Health and Welfare or the head of the relevant local government to operate child care centers, such as vehicle operating expenses.

- (2) Matters necessary for the method, etc. of subsidizing expenses specified in paragraph (1), shall be prescribed by the Minister of Health and Welfare or the head of the relevant local government. <Amended by Presidential Decree No. 22075, Mar. 15, 2010>

[This Article Wholly Amended by Presidential Decree No. 21585, Jun. 30, 2009]

Article 25 (Expenses to Be Borne by Business Proprietor)

A business proprietor who has established a workplace child care center (including where at least two business proprietors jointly establish a workplace child care center) pursuant to Article 14 (1) of the Act or has concluded an outsourcing contract with a local child care center shall bear at least 50/100 of the expenses incurred in operating such child care center and in nursing infants and young children who

receive outsourced child care, pursuant to Article 37 of the Act. <Amended by Presidential Decree No. 22263, Jul. 9, 2010; Presidential Decree No. 23356, Dec. 8, 2011>

[This Article Wholly Amended by Presidential Decree No. 21585, Jun. 30, 2009]

Article 25-2 (Imposition and Refund of Charges for Compelling Execution)

- (1) The standards for imposing a charge for compelling execution referred to in Article 44-3 (1) of the Act shall be as specified in attached Table 1-2.
- (2) Where a disposition of imposition of a charge for compelling the execution is canceled in accordance with an administrative adjudication under the Administrative Appeals Act or a final and conclusive court decision, the relevant Mayor/Do Governor or the head of the relevant *Si/Gun/Gu* shall immediately suspend imposition or collection of the charge for compelling execution either *ex officio* or upon request of the relevant business proprietor, and shall refund the charge for compelling execution already collected.
- (3) When the relevant Mayor/Do Governor or the head of the relevant *Si/Gun/Gu* refunds a charge for compelling the execution, pursuant to paragraph (2), he/she shall refund it by adding, thereto, an amount calculated by multiplying the period from payment to refund of the charge for compelling the execution, by the interest rate prescribed by Ordinance of the Ministry of Health and Welfare.
- (4) Detailed procedures for refunding charges for compelling the execution referred to in paragraph (2) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Presidential Decree No. 26525, Sep. 15, 2015]

Article 25-3 (Criteria for Computing Surcharges)

The amount of a surcharge referred to in Article 45-2 of the Act shall be calculated by applying the criteria specified in attached Table 1-3, and by based upon standards for the disposition of suspension of operation determined by Ordinance of the Ministry of Health and Welfare, taking into account the type and seriousness of a violation. <Amended by Presidential Decree No. 26525, Sep. 15, 2015>

[This Article Newly Inserted by Presidential Decree No. 23356, Dec. 8, 2011]

Article 25-4 (Procedures for Imposing and Collecting Surcharges)

- (1) Where the Minister of Health and Welfare, a Mayor/Do Governor, or the head of a *Si/Gun/Gu* intends to impose a surcharge pursuant to Article 45-2 of the Act, he/she shall give written notice of the payment of a surcharge, specifically stating the type of violation, the amount of surcharge, etc.
- (2) Upon receipt of notice under paragraph (1), the relevant person shall deliver the surcharge to a collecting agency prescribed by the Minister of Health and Welfare, the relevant Mayor/Do Governor, or the head of the relevant *Si/Gun/Gu*, within 20 days after receipt of such notice: *Provided*, That if it is impracticable to pay the surcharge during the period due to a natural disaster, *force majeure*, etc., he/she shall pay the surcharge within seven days from the date such ground ceases to exist.
- (3) The collecting agency, in receipt of a surcharge pursuant to paragraph (2), shall issue a receipt to the payer and notify, without delay, such fact to the Minister of Health and Welfare, the relevant Mayor/Do Governor, or the head of the relevant *Si/Gun/Gu*.
- (4) No surcharge shall be paid in installments.
- (5) Details of the procedures for collecting surcharges shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Presidential Decree No. 23356, Dec. 8, 2011]

Article 25-5 (Scope, Frequency, and Timing of Public Announcement of Information on Child Care Centers)

- (1) "Matters prescribed by Presidential Decree" referred to in Article 49-2 (1) 6 of the Act means the

following: *<Amended by Presidential Decree No. 26525, Sep. 15, 2015>*

1. Matters on completion of refresher education for principals of child care centers referred to in Article 23 of the Act and such education for child care teachers referred to in Article 23-2 of the Act;
 2. Matters on implementation of education for the safety of children referred to in Article 31 of the Child Welfare Act;
 3. Matters on school buses for children operated by child care centers defined in subparagraph 23 of Article 2 of the Road Traffic Act;
 4. Matters on electrical safety inspection referred to in Article 66-2 of the Electric Utility Act.
- (2) The scope, frequency, and timing of public announcements of information to be made by principals of child care centers pursuant to Article 49-2 (1) of the Act (hereinafter referred to as "publicly-announced information") shall be as specified in attached Table 1-4. *<Amended by Presidential Decree No. 26525, Sep. 15, 2015>*

[This Article Newly Inserted by Presidential Decree No. 24904, Dec. 4, 2013]

Article 25-6 (Method, etc., of Public Announcement of Information on Child Care Centers)

- (1) The Minister of Health and Welfare shall establish and operate an information disclosure system through the information and communications network (hereinafter referred to as "information disclosure system") to systematically manage and promptly search for the public information.
- (2) Principals of child care centers shall publish publicly-announced information through the information disclosure system pursuant to Article 49-2 (1) of the Act.
- (3) Where the principle of a child care center submits publicly-announced information to the Minister of Health and Welfare, the Metropolitan Autonomous City Mayor, the Special Self-Governing Province Governor, and the head of the relevant *Si/Gun/Gu* pursuant to the latter part other than the subparagraphs of Article 49-2 (1) of the Act, he/she shall not submit any publicly-announced information inconsistent with the publicly-announced information published through the information disclosure system pursuant to paragraph (2). *<Amended by Presidential Decree No. 26525, Sep. 15, 2015>*
- (4) Except as otherwise expressly prescribed in Article 25-5 and paragraphs (1) through (3), matters necessary for publishing the publicly-announced information shall be prescribed by the Minister of Health and Welfare. *<Amended by Presidential Decree No. 26525, Sep. 15, 2015>*

[This Article Newly Inserted by Presidential Decree No. 24904, Dec. 4, 2013]

Article 25-7 (Violations to Be Publicized, etc.)

- (1) "Matters prescribed by Presidential Decree" under the main sentence of Article 49-3 (1) of the Act means the types and addresses of child care centers referred to in Article 10 of the Act. *<Amended by Presidential Decree No. 26525, Sep. 15, 2015>*
- (2) "Matters prescribed by Presidential Decree" under Article 49-3 (2) of the Act means the following: *<Amended by Presidential Decree No. 26525, Sep. 15, 2015>*
 1. The name and address of a child care center to which the person subject to publication referred to in Article 25-8 (2) belonged when he/she committed the violation;
 2. Details of the violation;
 3. Details of an administrative disposition.

[This Article Newly Inserted by Presidential Decree No. 24904, Dec. 4, 2013]

Article 25-8 (Procedures, Method, etc., for Publication)

- (1) Deleted. *<by Presidential Decree No. 26525, Sep. 15, 2015>*
- (2) Where the Minister of Health and Welfare, a Mayor/Do Governor, or the head of a *Si/Gun/Gu* publicizes violations pursuant to Article 49-3 (1) of the Act, he/she shall give written notice to the

representative, principal, or child care teacher of a child care center determined to be publicized (hereinafter referred to as "person subject to publication") of the fact that he/she is subject to publication, and provide him/her with an opportunity to state his/her opinion. <Amended by Presidential Decree No. 26525, Sep. 15, 2015>

- (3) Where the Minister of Health and Welfare, the relevant Mayor/Do Governor, or the head of the relevant *Si/Gun/Gu* receives opinion from a person subject to publication pursuant to paragraph (2), he/she shall verify whether such person's violations are subject to publication and determine whether to publicize such violations. <Amended by Presidential Decree No. 26525, Sep. 15, 2015>
- (4) Where the Minister of Health and Welfare, a Mayor/Do Governor, or the head of a *Si/Gun/Gu* publicizes violations pursuant to Article 49-3 of the Act, he/she shall do so on the website of the relevant agency during either of the following periods, and may also do so through the information disclosure system or on the website of a child care-related institution, such as child care support center:
 1. Violations causing either closure of a child care center pursuant to Article 45 of the Act or revocation of qualifications for the principal or a child care teacher of a child care center pursuant to Article 48 of the Act: Three years;
 2. Violations causing suspension of operation of a child care center pursuant to Article 45 of the Act (including where a surcharge is imposed in lieu of suspension of operation thereof pursuant to Article 45-2 of the Act), suspension of qualifications for the principal of a child care center pursuant to Article 46 of the Act, or suspension of qualifications for a child care teacher pursuant to Article 47 of the Act: The relevant period for suspension of operation (referring to the period for suspension of operation which has been substituted by the imposition of a surcharge, if the surcharge is imposed in lieu of suspension of operation pursuant to Article 45-2 of the Act), or a period corresponding to twice the period for suspension of qualifications (or six months, if such period is less than six months).
- (5) Where deemed necessary to make an additional publication because a violation subject to publication is serious or repeated, etc., the Minister of Health and Welfare, a Mayor/Do Governor, or the head of a *Si/Gun/Gu* may additionally publicize such violation through a newspaper under the Act on the Promotion of Newspapers, Etc., or through broadcasting under the Broadcasting Act, in addition to the publication pursuant to paragraph (4) during the relevant period referred to in paragraph (4).
- (6) Where a Mayor/Do Governor or the head of a *Si/Gun/Gu* has publicized a violation pursuant to paragraph (4) or (5), the former shall notify, without delay, such fact to the Minister of Health and Welfare and the latter, to the Minister of Health and Welfare through the relevant Mayor/Do Governor.
- (7) Except as otherwise expressly prescribed in paragraphs (1) through (6), matters necessary for the procedures, etc., for publication, shall be prescribed by the Minister of Health and Welfare.

[This Article Newly Inserted by Presidential Decree No. 24904, Dec. 4, 2013]

Article 26 (Delegation of Authority)

- (1) The Minister of Health and Welfare shall delegate his/her authority specified as follows, to a Mayor/Do Governor pursuant to Article 51 of the Act: <Amended by Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 23618, Feb. 3, 2012; Presidential Decree No. 23909, Jun. 29, 2012; Presidential Decree No. 25164, Feb. 11, 2014>
 1. Authority relating to implementation of refresher education referred to in Articles 23 (1) and 23-2 (1) of the Act;
 2. Authority relating to orders to receive education referred to in Article 23-3 of the Act.
- (2) The Minister of Health and Welfare shall delegate the following authority to the Special Self-Governing Province Governor and the head of a *Si/Gun/Gu* pursuant to Article 51 of the Act:

<Amended by Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 23356, Dec. 8, 2011; Presidential Decree No. 23618, Feb. 3, 2012>

1. Authority to suspend qualifications of principals of child care centers referred to in Article 46 of the Act;
2. Authority to suspend qualifications of child care teachers referred to in Article 47 of the Act;
3. Authority to revoke qualifications of principals or child care teachers of child care centers referred to in Article 48 of the Act.

(3) and (4) Deleted. *<by Presidential Decree No. 23618, Feb. 3, 2012>*

[This Article Wholly Amended by Presidential Decree No. 21585, Jun. 30, 2009]

Article 26-2 (Outsourcing of Affairs)

- (1) The Minister of Health and Welfare, a Mayor/Do Governor, or the head of a *Si/Gun/Gu* may entrust affairs specified in Article 51-2 (1) 1 through 4 of the Act to any of the following institutions, organizations, etc. pursuant to Article 51-2 (1) of the Act: *Provided*, That an institution, organization, etc., referred to in subparagraphs 3 and 4 may be entrusted with only the affairs specified in Article 51-2 (1) 3 of the Act: *<Amended by Presidential Decree No. 24904, Dec. 4, 2013>*
 1. A Government-funded research institute established under the Act on the Establishment, Operation and Fostering of Government-Funded Research Institutes;
 2. A university or junior college defined under Article 2 of the Higher Education Act, which has a department related to child care or child welfare;
 3. A child care support center referred to in Article 7 of the Act;
 4. Educational and training facilities referred to in Article 21 (2) 2 of the Act;
 5. Other non-profit corporation or organization related to child care.
- (2) The Minister of Health and Welfare may entrust any of the following affairs, among affairs specified in Article 51-2 (1) 5 of the Act, to a public organization or institution related to social welfare services defined in subparagraph 6 of Article 2 of the Social Welfare Services Act, pursuant to Article 51-2 (1) of the Act:
 1. Providing and managing coupons for nursing services;
 2. Processing and settling expenses relating to amounts spent on coupons for nursing services;
 3. Establishing and operating a computer system designed to conduct affairs on coupons for nursing services;
 4. Other affairs incidental to coupons for nursing services, and prescribed by the Minister of Health and Welfare.
- (3) Where the Minister of Health and Welfare, a Mayor/Do Governor, or the head of a *Si/Gun/Gu* entrusts affairs pursuant to paragraph (1) or (2), he/she shall first publicly announce the standards, procedures, method, etc., for outsourcing on the bulletin board or website of an institution entrusted with such affairs.
- (4) Where the Minister of Health and Welfare, a Mayor/Do Governor, or the head of a *Si/Gun/Gu* has entrusted affairs pursuant to paragraph (1) or (2), he/she shall notify an institution, organization, etc., outsourced with such affairs (hereinafter referred to as "outsourcing institution" in this Article) and details of the entrusted affairs, or shall publicly announce such fact on the bulletin board or website of an entrusting agency.
- (5) "Where any other cause prescribed by Presidential Decree exists" under Article 51-2 (3) 3 of the Act means any of the following: *<Amended by Presidential Decree No. 23909, Jun. 29, 2012; Presidential Decree No. 26525, Sep. 15, 2015>*
 1. Where an entrusted institution becomes bankrupt or is dissolved;
 2. Where an entrusted institution no longer satisfies the standards for entrustment referred to in paragraph (3);
 3. Where an entrusted institution entrusted with affairs specified in Article 51-2 (1) 3 of the Act

conducts refresher education, in violation of the curriculum of refresher education referred to in Articles 23 (4) and 23-2 (3) of the Act and matters on the period, method, etc., of refresher education prescribed by Ordinance of the Ministry of Health and Welfare pursuant to Articles 23 (5) and 23-2 (4) of the Act;

4. Where an entrusted institution entrusted with affairs specified in Article 51-2 (1) 3 of the Act conducts refresher education for, and issues a certificate to, a person unqualified to conduct such education, or issues a certificate to a person failing to meet the standards for recognizing completion of such education.

(6) Matters necessary for application procedures and documents for entrustment of affairs, selection of entrusted institutions, etc., shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Presidential Decree No. 23618, Feb. 3, 2012]

Article 26-3 (Management of Sensitive and Personally Identifiable Information)

(1) If inevitable to conduct the following affairs, the Minister of Health and Welfare (including persons to whom authority of the Minister of Health and Welfare has been delegated under Article 26 or entrusted under Article 26-2) or the head of a local government (including persons to whom relevant authority has been delegated or entrusted, if any) may manage information on health referred to in Article 23 of the Personal Information Protection Act, information that constitutes a criminal history record referred to in subparagraph 2 of Article 18 of the Enforcement Decree of the same Act, and data containing resident registration numbers, passport numbers, or foreigner registration numbers referred to in subparagraph 1, 2, or 4 of Article 19 of the same Decree:

1. Affairs concerning establishment, operation, entrustment, or cancelation of entrustment of child care support centers referred to in Article 7 of the Act;
2. Affairs concerning research, and provision of information, on child care referred to in Article 8 of the Act;
3. Affairs concerning fact-finding surveys on child care referred to in Article 9 of the Act;
4. Affairs concerning authorization for establishment or modification of child care centers referred to in Articles 13 and 14 of the Act;
5. Affairs concerning management of appointment, dismissal, career, etc., of child care teachers and staff referred to in Article 19 of the Act;
6. Affairs concerning qualification examinations for principals or child care teachers of child care centers referred to in Article 21 of the Act, and issuance of qualification certificates referred to in Article 22 of the Act;
7. Affairs concerning designation, cancellation of the designation, of educational and training facilities, operation of curricula, etc., referred to in Article 21 (2) 2 of the Act;
8. Affairs concerning refresher education referred to in Articles 23 and 23-2 of the Act;
9. Affairs concerning orders to receive education referred to in Article 23-3 of the Act;
10. Affairs concerning entrusted operation, etc., of national or public child care centers referred to in Article 24 of the Act;
11. Affairs concerning operation of parental monitoring groups referred to in Article 25-2 of the Act;
12. Affairs concerning provision of, and support for, temporary nursing services referred to in Article 26-2 of the Act;
13. Affairs concerning management of infants and young children eligible to use child care centers referred to in Article 27 of the Act;
14. Affairs concerning preferential provision of child care referred to in Article 28 of the Act;
15. Affairs concerning development, proliferation, etc., of standard child care courses referred to in Article 29 of the Act;
16. Affairs concerning accreditation of child care centers referred to in Article 30 of the Act;

17. Affairs concerning free child care referred to in Article 34 of the Act;
 18. Affairs concerning subsidization for home-care expenses referred to in Article 34-2 of the Act;
 19. Affairs concerning provision and use of coupons for nursing services referred to in Article 34-3 of the Act;
 20. Affairs concerning subsidization for expenses of child care services referred to in Article 36 of the Act;
 21. Affairs concerning refund of expenses and subsidies referred to in Article 40 of the Act;
 22. Affairs concerning recovery of subsidies for expenses referred to in Article 40-2 of the Act;
 23. Affairs concerning closure, suspension, resumption, etc., of the operation of child care centers referred to in Article 43 of the Act;
 24. Affairs concerning orders for rectification or modification referred to in Article 44 of the Act;
 25. Affairs concerning suspension of operation, and closure, of child care centers referred to in Article 45 of the Act;
 26. Affairs concerning the imposition and collection of surcharges referred to in Article 45-2 of the Act;
 27. Affairs concerning suspension or revocation of qualifications for principals or child care teachers of child care centers referred to in Articles 46 through 48 of the Act;
 28. Affairs concerning public announcement of information on child care centers referred to in Article 49-2 of the Act;
 29. Affairs concerning publication of violations referred to in Article 49-3 of the Act.
- (2) If essential to conduct the following affairs, an establisher/operator of a child care center may manage data containing resident registration numbers or foreigner registration numbers referred to in subparagraph 1 or 4 of Article 19 of the Enforcement Decree of the Personal Information Protection Act: <Newly Inserted by Presidential Decree No. 26525, Sep. 15, 2015>
1. Affairs concerning inspection, etc., of video information referred to in Article 15-5 of the Act;
 2. Affairs concerning appointment and dismissal of child care teachers and staff referred to in Article 19 (2) of the Act;
 3. Affairs concerning management of infants and young children eligible to use child care centers referred to in Article 27 of the Act;
 4. Affairs concerning preferential provision of child care referred to in Article 28 of the Act.
- (3) If essential to conduct affairs concerning mutual aid business for safety of child care centers referred to in Article 31-2 (1) of the Act, a mutual aid association may manage data containing resident registration numbers or foreigner registration numbers referred to in subparagraph 1 or 4 of Article 19 of the Enforcement Decree of the Personal Information Protection Act, with the consent of the guardian of the relevant infant or young child, etc. <Amended by Presidential Decree No. 26525, Sep. 15, 2015>

[This Article Wholly Amended by Presidential Decree No. 25929, Dec. 30, 2014]

Article 26-4 (Review of Regulations)

The Minister of Health and Welfare shall assess the appropriateness of the following matters every three years from either of the following base dates (referring to by the day before every third anniversary from the base date), and shall take improvement measures, etc.: <Amended by Presidential Decree No. 26525, Sep. 15, 2015>

1. Criteria for computing surcharges referred to in Article 25-3 and attached Table 1-3: January 1, 2015;
2. Criteria for imposing administrative fines referred to in Article 27 and attached Table 2: January 1, 2014.

[This Article Wholly Amended by Presidential Decree No. 25929, Dec. 30, 2014]

Article 27 (Criteria for Imposing Administrative Fines)

The criteria for imposing administrative fines referred to in Article 56 (1) and (2) of the Act shall be as specified in attached Table 2.

[This Article Wholly Amended by Presidential Decree No. 22906, Apr. 22, 2011]

Addenda <Presidential Decree No. 29180, Sep. 18, 2018>

Article 1 (Enforcement Date)

This Decree shall enter into force on September 21, 2018.

Articles 2 through 19 Omitted.

2.16 School Health Act

Act No. 16339, Apr. 23, 2019

Article 1 (Purpose)

The purpose of this Act is to protect and promote the health of students and teachers and staff by prescribing matters necessary for health management in schools. *<Amended by Act No. 13946, Feb. 3, 2016>*

[This Article Wholly Amended by Act No. 8678, Dec. 14, 2007]

Article 2 (Definitions)

The terms used in this Act are defined as follows: *<Amended by Act No. 8912, Mar. 21, 2008; Act No. 11220, Jan. 26, 2012; Act No. 11384, Mar. 21, 2012>*

1. The term "health examination" means an examination or inspection of the physical developmental conditions and ability, mental health status, and daily habits of a person, whether a person contracts a disease, etc.;
2. The term "school" means respective schools under subparagraph 2 of Article 2 of the Early Childhood Education Act, Article 2 of the Elementary and Secondary Education Act, or Article 2 of the Higher Education Act;
3. Deleted. *<by Act No. 13946, Feb. 3, 2016>*

[This Article Wholly Amended by Act No. 8678, Dec. 14, 2007]

Article 2-2 (Duties of State and Local Governments)

The State and local governments shall formulate and implement a basic plan for the protection and promotion of the health of students and teachers and staff, and formulate policies necessary therefor.

[This Article Wholly Amended by Act No. 8678, Dec. 14, 2007]

Article 3 (Health Facilities)

A founder and a manager of a school shall build a health room, and furnish the facilities, appliances, and goods necessary for health care in schools, as prescribed by Presidential Decree. *<Amended by Act No. 15965, Dec. 18, 2018>*

[This Article Wholly Amended by Act No. 8678, Dec. 14, 2007]

Article 4 (Environmental Sanitation and Food Sanitation in School)

- (1) The head of each school shall, as prescribed by Ordinance of the Ministry of Education, properly maintain and administer environmental sanitation, such as the control of ventilation, lighting, illumination, temperature and humidity, the prevention and management of hazardous substances including hazardous heavy metals, the installation and management of water supply and drainage systems and lavatories, and the prevention and control of air pollution, asbestos, waste, noise, volatile organic compounds, germs, dust, etc., and food sanitation, such as the management of tableware, foodstuffs, and drinking water in a school facility (referring to the site of a school building, a playground, a school building, a gymnasium, a dormitory, a school meal facility, and an auditorium installed in the site of a school building or a playground; hereinafter the same shall apply). *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 11690, Mar. 23, 2013; Act No. 16339, Apr. 23, 2019>*

- (2) The head of a school shall, as prescribed by Ordinance of the Ministry of Education, perform inspections in order to appropriately maintain and administer environmental sanitation and food

sanitation in a school facility pursuant to paragraph (1), and record, maintain, and report the results thereof. In such cases, if a member of a school steering committee or a parent requests participation in an air quality inspection conducted for an inspection of environmental sanitation, such participation shall be permitted. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 11690, Mar. 23, 2013; Act No. 16304, Apr. 2, 2019; Act No. 16339, Apr. 23, 2019>

- (3) The head of a school may, as prescribed by Ordinance of the Ministry of Education, entrust inspection-related affairs prescribed in paragraph (2) to a measuring agency under Article 16 of the Environmental Testing and Inspection Act, or perform such affairs by asking the superintendent of education to provide specialized human resources and other support. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 11690, Mar. 23, 2013>
- (4) Where the results of inspection prescribed in paragraphs (2) and (3) fail to meet the standards prescribed by Ordinance of the Ministry of Education, the head of a school shall take necessary measures, including facility supplementation, and report thereon to the Minister of Education and the superintendent of education. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 11690, Mar. 23, 2013; Act No. 14055, Mar. 2, 2016>
- (5) If deemed necessary to appropriately maintain and administer environmental sanitation and food sanitation under paragraph (1), the Minister of Education or the superintendent of education may have the relevant public official gain access to a school to perform inspections or check the results, etc. thereof under paragraph (2), and if improvement is required, he or she may provide administrative and financial support to the school. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 11690, Mar. 23, 2013>
- (6) The head of a school shall make public results of the inspections of environmental sanitation and food sanitation under paragraph (2) and supplementary measures under paragraph (4) on the website of the school or the website related to publication operated by the Minister of Education. In such cases, measured figures shall include the records of the first measurement and re-measurement. <Newly Inserted by Act No. 14055, Mar. 2, 2016; Act No. 16304, Apr. 2, 2019>
- (7) Where the head of a school performs inspections of environmental sanitation in a school facility under paragraph (2) and confirms that highly hazardous substances can continue to occur, he or she shall request the superintendent of education to conduct a special inspection, and in response to such request, the superintendent of education shall conduct said inspection and formulate and implement countermeasures. <Newly Inserted by Act No. 16339, Apr. 23, 2019>

[This Article Wholly Amended by Act No. 8678, Dec. 14, 2007]

Article 4-2 (Special cases concerning Maintenance and Management of Air Quality)

- (1) The head of a school shall conduct a sanitation inspection of air quality under Article 4 (2) at least once in the first and second half of each year, respectively.
- (2) The head of a school shall regularly conduct an inspection at least once each year with respect to equipment used to measure air quality in a school building under Article 4 (2) and (3), as prescribed by Ordinance of the Ministry of Education.

[This Article Newly Inserted by Act No. 16304, Apr. 2, 2019]

Article 4-3 (Construction of Air Purification Installations)

The head of a school (excluding a school defined in Article 2 of the Higher Education Act) shall construct an air purification installation and a fine dust-measuring device in each classroom to manage air quality in a school building, as prescribed by Ordinance of the Ministry of Education.

[This Article Newly Inserted by Act No. 16304, Apr. 2, 2019]

Article 5 (Preparation of Air Pollution Response Manual)

- (1) The Minister of Education shall prepare and distribute a response manual based on the results of

predicting air pollution levels under Article 7-2 of the Clean Air Conservation Act to effectively deal with air pollution (hereinafter referred to as “air pollution response manual”) after consulting with the Minister of Environment.

- (2) The air pollution response manual shall contain the details prescribed by Presidential Decree, such as guidelines for disseminating information, inspection of conditions for outdoor classes and corresponding measures, and measures to control indoor air quality at each stage of response.
- (3) The head of a school shall formulate a detailed guide to action to be taken by students and teachers and staff in accordance with the air pollution response manual and shall educate them on such detailed guide.
- (4) Other matters necessary for the preparation and distribution of the air pollution response manual and formulation of the detailed guide to action shall be prescribed by Presidential Decree.

[This Article Newly Inserted by Act No. 15965, Dec. 18, 2018]

Articles 6 through 6-3 Deleted. <by Act No. 13946, Feb. 3, 2016>

Article 7 (Health Examinations)

- (1) The head of a school shall require that students and teachers and staff submit to a health examination: *Provided*, That health examinations of teachers and staff may be substituted by health checkups under Article 52 of the National Health Insurance Act. <Amended by Act No. 11141, Dec. 31, 2011>
- (2) In making sure that health examinations are conducted under paragraph (1), the head of a school shall request a health checkup institution under Article 52 of the National Health Insurance Act to conduct a health checkup on any of the following students with regard to matters prescribed by Ordinance of the Ministry of Education in order to examine or inspect whether he or she has contracted a disease, etc.: <Amended by Act No. 8852, Feb. 29, 2008; Act No. 11141, Dec. 31, 2011; Act No. 11384, Mar. 21, 2012; Act No. 11690, Mar. 23, 2013>
 1. First graders and fourth graders of schools under subparagraph 1 of Article 2 of the Elementary and Secondary Education Act, and of special schools and various kinds of schools equivalent thereto: *Provided*, That an oral examination shall be performed on all graders of schools, and matters concerning the methods, expenses, etc. thereof shall be determined by the superintendent of education according to the actual conditions of a community;
 2. First graders in schools under subparagraphs 2 and 3 of Article 2 of the Elementary and Secondary Education Act, and in special schools and various kinds of schools equivalent thereto;
 3. Other students prescribed by Ordinance of the Ministry of Education for the protection and promotion of health.
- (3) The head of a school may ensure that a separate examination, other than a health examination under paragraph (2) is conducted on a student, as prescribed by Ordinance of the Ministry of Education, if deemed necessary to protect and promote the relevant student's health. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 11690, Mar. 23, 2013>
- (4) Notwithstanding the provisions of paragraphs (1) and (2), the head of a school may postpone a health examination or skip all or part of a health examination, as prescribed by Ordinance of the Ministry of Education, where he or she has obtained approval from the superintendent of education, or the head of a district office of education due to any unavoidable cause, such as a natural disaster. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 11690, Mar. 23, 2013>
- (5) An institution which has administered a health examination under paragraph (2) shall notify the relevant student or his or her parents, and the head of the relevant school of the results thereof, as prescribed by Ordinance of the Ministry of Education. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 11690, Mar. 23, 2013>
- (6) With respect to the examination of mental health referred to in subparagraph 1 of Article 2, the head of a school may, if necessary, conduct such examination without obtaining consent of the parent of

the relevant student. In such cases, the head of a school shall notify the relevant parents of the examination to be conducted without delay. <Newly Inserted by Act No. 11386, Mar. 21, 2012; Act No. 14055, Mar. 2, 2016>

- (7) Necessary matters concerning the timing and methods of a health examination, items, procedures, etc. therefor under paragraphs (1) and (2) shall be prescribed by Ordinance of the Ministry of Education. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 11690, Mar. 23, 2013>
[This Article Wholly Amended by Act No. 8678, Dec. 14, 2007]

Article 7-2 (Formulation and Implementation of Health Promotion Plans for Students)

- (1) The superintendent of education shall formulate and implement a health promotion plan for students to improve their physical and mental health. <Newly Inserted by Act No. 12131, Dec. 30, 2013>
 (2) The plan under paragraph (1) shall include ways to administratively and financially support measures taken by the head of a school prescribed in Article 11. <Newly Inserted by Act No. 12131, Dec. 30, 2013>
 (3) The head of a school shall evaluate the results of health examinations under Article 7 and formulate and implement a health promotion plan for students based thereon. <Amended by Act No. 12131, Dec. 30, 2013>
 (4) The head of a school may hold consultation with a school physician or school pharmacist under Article 15 (1) for the evaluation of the results of health examination and the formulation of a health promotion plan for students under paragraph (3). <Amended by Act No. 12131, Dec. 30, 2013>
[This Article Wholly Amended by Act No. 8678, Dec. 14, 2007]

Article 7-3 (Health Examination Records)

- (1) When a health examination has been completed under Article 7, the head of a school shall prepare and administer the results thereof according to the standards prescribed by Ordinance of the Ministry of Education. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 11690, Mar. 23, 2013>
 (2) When the head of a school prepares and administers the results of the health examination under paragraph (1), the data that requires processing by using the educational information system under Article 30-4 of the Elementary and Secondary Education Act shall be as follows: <Amended by Act No. 8852, Feb. 29, 2008; Act No. 11690, Mar. 23, 2013>
 1. Personal details;
 2. Physical developmental status and capacity;
 3. Other matters prescribed by Ordinance of the Ministry of Education within the extent necessary to achieve educational purposes.
 (3) The head of a school shall, when a student under his or her control transfers to another school or enters an advanced high school or lower-level course, transfer the data under paragraph (1) to the head of the relevant school.

[This Article Wholly Amended by Act No. 8678, Dec. 14, 2007]

Article 8 (Suspension from School)

According to the results of the health examination under Article 7 or of a doctor's diagnosis, the head of a school may suspend from school students and teachers and staff who are infected or suspected to be infected, or are likely to be infected with an infectious disease, as prescribed by Presidential Decree. <Amended by Act No. 9847, Dec. 29, 2009>

[This Article Wholly Amended by Act No. 8678, Dec. 14, 2007]

Article 9 (Health Care for Students)

The head of a school shall provide health education to its students and take necessary measures therefor for the purpose of the students' physical development and the enhancement of their physical strength,

the disease treatment and prevention, the prevention of alcohol and tobacco use, of drug misuse and abuse, sex education, the promotion of mental health, etc. of the students. *<Amended by Act No. 8912, Mar. 21, 2008; Act No. 11220, Jan. 26, 2012>*

[This Article Wholly Amended by Act No. 8678, Dec. 14, 2007]

Article 9-2 (Health Education)

- (1) The Minister of Education shall provide health education including education about first aid, such as cardiopulmonary resuscitation, in a systematic manner to all students in kindergartens under subparagraph 2 of Article 2 of the Early Childhood Education Act and in schools referred to in Article 2 of the Elementary and Secondary Education Act. In such cases, matters necessary for the provision of health education, including the timing of education and books used therefor, shall be determined by the Minister of Education. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 11690, Mar. 23, 2013; Act No. 12131, Dec. 30, 2013; Act No. 14402, Dec. 20, 2016>*
- (2) The head of a kindergarten under subparagraph 2 of Article 2 of the Early Childhood Education Act and the head of a school referred to in Article 2 of the Elementary and Secondary Education Act shall provide annual education about first aid, such as cardiopulmonary resuscitation, to teachers and staff, as prescribed by Ordinance of the Ministry of Education. *<Newly Inserted by Act No. 12131, Dec. 30, 2013; Amended by Act No. 14402, Dec. 20, 2016>*
- (3) The head of a kindergarten under subparagraph 2 of Article 2 of the Early Childhood Education Act and the head of a school referred to in Article 2 of the Elementary and Secondary Education Act may entrust the operation of programs related to education on first aid under paragraph (2) and others to relevant specialized institutions or organizations, or experts. *<Newly Inserted by Act No. 14402, Dec. 20, 2016>*

[This Article Newly Inserted by Act No. 8678, Dec. 14, 2007]

Article 10 (Inspection of Completion of Vaccination)

- (1) The head of an elementary school and the head of a secondary school shall receive certificates of vaccination under Article 27 of the Infectious Disease Control and Prevention Act from the head of a *Si/Gun*, or the head of a *Gu* (referring to the head of an autonomous *Gu*; hereinafter the same shall apply) within 90 days from the date when the students enter school, and inspect whether the students have had all the vaccinations under Articles 24 and 25 of the same Act, and then record the results of the inspection in the educational information system. *<Amended by Act No. 9847, Dec. 29, 2009, Act No. 13946, Feb. 3, 2016>*
- (2) The head of an elementary school and the head of a secondary school shall guide new students who, it turns out, after inspection, haven't had all the vaccinations, as a result of the inspections under paragraph (1), to have necessary vaccinations, and if necessary, may ask the head of a relevant public health center for necessary cooperation, such as assistance for vaccinations.

[This Article Wholly Amended by Act No. 8678, Dec. 14, 2007]

Article 11 (Treatment and Preventive Measures)

- (1) The head of a school shall take necessary measures for the medical treatment for and prevention of diseases in students infected or likely to be infected with diseases as a result of health examinations conducted pursuant to Article 7.
- (2) The head of a school shall take the following measures to promote mental health of students, if necessary, as a result of the examination of their mental health defined in subparagraph 1 of Article 2, pursuant to Article 7 (1): *<Newly Inserted by Act No. 12131, Dec. 30, 2013>*
 1. Education for students, their parents, teachers and staff, about the promotion and understanding of mental health;
 2. Consultation with and management of relevant students;

- 3. Connection of specialized consultation agencies or medical agencies with the relevant students;
 - 4. Other measures necessary to promote mental health of students.
- (3) The superintendent of education may subsidize expenses necessary to take measures set forth in each subparagraph of paragraph (2), such as expenses of examination and treatment. <Newly Inserted by Act No. 12131, Dec. 30, 2013>
- (4) If necessary for taking measures referred to in paragraphs (1) and (2), the head of a school may request cooperation from the head of a public health center, and the head of a public health center shall not reject such request without good cause. <Amended by Act No. 12131, Dec. 30, 2013>
- [This Article Wholly Amended by Act No. 8678, Dec. 14, 2007]*

Article 12 (Control of Safety of Students)

In order to prevent safety-related accidents among students, the head of a school shall check out and improve facilities and equipment in the school, provide safety education to students, and take other necessary measures.

[This Article Wholly Amended by Act No. 8678, Dec. 14, 2007]

Article 13 (Health Care for Teachers and Staff)

The head of a school shall, if necessary as a result of health examinations under Article 7 (1) or if necessary as a result of checkups performed in lieu of health examinations, take necessary measures, such as treatment of diseases and the improvement of working conditions of teachers and staff.

[This Article Wholly Amended by Act No. 8678, Dec. 14, 2007]

Article 14 (Prevention of Diseases)

If necessary for the prevention of infectious diseases and for school health, the head of a supervisory agency may issue orders to suspend classes in the relevant school or temporarily close such school (including a kindergarten; hereinafter the same shall apply), and the head of a school may suspend classes, when necessary. <Amended by Act No. 9847, Dec. 29, 2009; Act No. 14055, Mar. 2, 2016>

[This Article Wholly Amended by Act No. 8678, Dec. 14, 2007]

Article 14-2 (Vaccinations against Infectious Diseases)

When the head of a *Si/Gun/Gu* administers required or temporary vaccinations against infectious diseases to the students or teachers and staff of a school pursuant to Articles 24 and 25 of the Infectious Disease Control and Prevention Act, he or she may appoint a school physician or a health teacher (limited to a health teacher who has a nurse's license; hereinafter the same shall apply) as a staff in charge of vaccination and have him or her administer vaccinations to the students or teachers and staff. In such cases, Article 27 (1) of the Medical Service Act shall not apply to the health teacher. <Amended by Act No. 9847, Dec. 29, 2009; Act No. 15043, Nov. 28, 2017; Act No. 15534, Mar. 27, 2018>

[This Article Wholly Amended by Act No. 8678, Dec. 14, 2007]

Article 14-3 (Formulation of Plan for Prevention of Infectious Diseases)

- (1) The Minister of Education shall develop countermeasures to protect students and teachers and staff from infectious diseases (hereinafter referred to as “plan for the prevention of infectious diseases”) including the following. In such cases, he or she shall consult with the Minister of Interior and Safety and the Minister of Health and Welfare: <Amended by Act No. 15043, Nov. 28, 2017>
- 1. Prevention and control of infectious diseases and follow-up measures;
 - 2. Manual on response to infectious diseases;
 - 3. School health and hygiene relating to infectious diseases;
 - 4. Other matters that are prescribed by Presidential Decree and that are related to infectious diseases.
- (2) When the Minister of Education develops a plan for the prevention of infectious diseases pursuant to

paragraph (1), he or she shall notify the Special Metropolitan City Mayor, a Metropolitan City Mayor, a Special Self-Governing City Mayor, a *Do* Governor, a Special Self-Governing Province Governor, the superintendent of education, and schools of such plan.

- (3) The superintendent of education shall develop a detailed plan for the prevention of infectious diseases based on the plan for the prevention of infectious diseases formulated by the Minister of Education, having regard to conditions of the relevant region.
- (4) The Minister of Education and the Minister of Health and Welfare shall build a close cooperative system and share information prescribed by Presidential Decree including information about the current status of infectious disease outbreaks (hereinafter referred to as “infectious disease information”) in order to prevent infectious diseases at school.
- (5) Where students or teachers and staff have been infected or are suspected to have been infected with infectious diseases, the head of a school shall immediately make a report thereon to the Minister of Education via the superintendent of education.
- (6) Where the information under paragraph (4) is shared with or the report under paragraph (5) is made to the Minister of Education, he or she shall promptly make such infectious disease information public to stop their spread.
- (7) Methods and procedures for sharing, reporting, and making public information under paragraphs (4) through (6) shall be prescribed by Ordinance of the Ministry of Education.

[This Article Newly Inserted by Act No. 14055, Mar. 2, 2016]

Article 14-4 (Preparation of Infectious Disease Response Manual)

- (1) The Minister of Education shall prepare and distribute a response manual by type of infectious diseases to effectively respond thereto in schools (hereinafter referred to as “infectious disease response manual”) in consultation with the Minister of Health and Welfare.
- (2) Matters necessary for the preparation, distribution, etc. of the infectious disease response manual shall be prescribed by Presidential Decree.

[This Article Newly Inserted by Act No. 14055, Mar. 2, 2016]

Article 15 (School Physician, School Pharmacist, and Health Teacher)

- (1) Each school may employ a medical person defined in Article 2 (1) of the Medical Service Act or a pharmacist defined in subparagraph 2 of Article 2 of the Pharmaceutical Affairs Act, who supports students and teachers and staff with health care needs, as prescribed by Presidential Decree.
<Amended by Act No. 11220, Jan. 26, 2012>
- (2) Every school shall employ a health teacher in charge of health education prescribed in Article 9-2 and health care of students: *Provided*, That schools below a certain size prescribed by Presidential Decree may employ a travelling health teacher.

[This Article Wholly Amended by Act No. 8678, Dec. 14, 2007]

Article 15-2 (First Aid)

- (1) The head of each school (excluding schools referred to in Article 2 of the Higher Education Act; hereafter the same shall apply in this Article) may allow the health teachers or travelling health teachers under Article 15 (2) (hereafter referred to as “health teachers, etc.” in this Article) to provide first-aid services such as administering medicines to students who are in life-threatening conditions such as hypoglycemic shock associated with type 1 diabetes or anaphylactic shock after obtaining consent of their parents and consulting with doctors who have prescribed prescription drugs. In such cases, Article 27 (1) of the Medical Service Act shall not apply to health teachers, etc.
- (2) Where no intention or gross negligence was found on the part of health teachers, etc. for property losses and human casualties that occur as a result of providing first aid to the students in life-threatening conditions under paragraph (1), health teachers, etc. shall not bear civil liability or criminal liability

for bodily injury; and their criminal liability for causing death may be mitigated or remitted.

- (3) The head of each school may have assistant personnel in place for students who need special care or protection due to any illness or disability. In such cases, the roles, requirements, etc. of assistant personnel shall be prescribed by Ordinance of the Ministry of Education.

[This Article Newly Inserted by Act No. 15043, Nov. 28, 2017]

Article 16 (Establishment of Health Organizations)

The superintendent of education or the head of a district office of education may have organizations and public officials under his or her control necessary for school health care, as prescribed by Presidential Decree.

[This Article Wholly Amended by Act No. 8678, Dec. 14, 2007]

Article 17 (School Health Committee)

- (1) A City/Do School Health Committee shall be established under the control of the superintendent of education in order to deliberate on basic plans for and important school health policies under Article 2-2. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 11220, Jan. 26, 2012>

- (2) A City/Do School Health Committee shall be comprised of not more than 15 members who have experience in school health. <Amended by Act No. 11220, Jan. 26, 2012>

- (3) The functions and operations of a City/Do School Health Committee and other necessary matters relating thereto shall be prescribed by Presidential Decree. <Amended by Act No. 11220, Jan. 26, 2012>

[This Article Wholly Amended by Act No. 8678, Dec. 14, 2007]

Article 18 (Subsidizing Expenses)

The State or local governments shall subsidize all or some of expenses incurred in purchasing facilities, appliances, and goods under Article 3, installing an air-purifying facility and a fine dust-measuring device under Article 4-3, and conducting health examinations under Article 7 (1). <Amended by Act No. 15965, Dec. 18, 2018; Act No. 16304, Apr. 2, 2019>

[This Article Wholly Amended by Act No. 8678, Dec. 14, 2007]

Article 18-2 (Prohibition against Divulging Confidential Information)

Any person who performs or performed duties related to the health examination of teachers and staff and students under this Act shall neither divulge confidential information he or she becomes aware of in the course of performing his or her duties to other persons nor use such information for any purpose other than to perform his or her duties.

[This Article Newly Inserted by Act No. 12131, Dec. 30, 2013]

Article 19 (Penalty Provisions)

- (1) In violation of Article 18-2, a person who divulged confidential information he or she became aware of in the course of performing his or her duties to other persons or used them for any purpose other than to perform his or her duties shall be punished by imprisonment with labor for not more than three years or by a fine not exceeding 30 million won. <Newly Inserted by Act No. 12131, Dec. 30, 2013>

- (2) Deleted. <by Act No. 13946, Feb. 3, 2016>

[This Article Wholly Amended by Act No. 8678, Dec. 14, 2007]

Article 20 Deleted. <by Act No. 5618, Dec. 31, 1998>

Addendum

This Act shall enter into force 90 days after the date of its promulgation.

Addendum <Act No. 3006, Jul. 23, 1977>

This Act shall enter into force on the date of its promulgation.

Addendum <Act No. 3374, Feb. 28, 1981>

This Act shall enter into force on the date of its promulgation.

Addenda <Act No. 4268, Dec. 27, 1990>

Article 1 (Enforcement Date)

This Act shall enter into force on the date of its promulgation. (Proviso Omitted.)

Articles 2 through 10 Omitted.

Addendum <Act No. 4349, Mar. 8, 1991>

This Act shall enter into force on the date of its promulgation.

Addenda <Act No. 5069, Dec. 29, 1995>

Article 1 (Enforcement Date)

This Act shall enter into force on March 1, 1996.

Articles 2 through 4 Omitted.

Addendum <Act No. 5454, Dec. 13, 1997>

This Act shall enter into force on January 1, 1998. (Proviso Omitted.)

Addendum <Act No. 5618, Dec. 31, 1998>

This Act shall enter into force on the date of its promulgation.

Addendum <Act No. 6218, Jan. 28, 2000>

This Act shall enter into force on March 1, 2005.

Addenda <Act No. 6400, Jan. 29, 2001>

Article 1 (Enforcement Date)

This Act shall enter into force on the date of its promulgation. (Proviso Omitted.)

Articles 2 through 4 Omitted.

Addenda <Act No. 6716, Aug. 26, 2002>

- (1) (Enforcement Date) This Act shall enter into force on the date of its promulgation.
- (2) (Term of Validity) The amended provisions of Article 6 (1) 5 shall remain effective until December 31, 2004.
- (3) (Special Cases concerning Establishment of Cleanup Zone) If a foreigners' organization registered

with the Ministry of Education and Human Resources Development under Article 39 (1) of the previous Immigration Act (the one before the amendment by Act No. 5755) has obtained authorization for the establishment of a foreigners' school under Article 60-2 of the Elementary and Secondary Education Act by not later than December 31, 2002, Article 5 (1) shall not apply.

Addenda <Act No. 7120, Jan. 29, 2004>

Article 1 (Enforcement Date)

This Act shall enter into force one year after the date of its promulgation.

Articles 2 through 9 Omitted.

Addenda <Act No. 7170, Feb. 9, 2004>

Article 1 (Enforcement Date)

This Act shall enter into force one year after the date of its promulgation.

Articles 2 through 4 Omitted.

Addenda <Act No. 7396, Mar. 24, 2005>

- (1) (Enforcement Date) This Act shall enter into force on the date of its promulgation: *Provided*, That the amended provisions of subparagraph 1 of Article 2, Articles 2-2, 4, 7, 7-2, 7-3, 8, 11 (1), 13, and 17, and the part on "health examination" in the amended provisions of Article 18 shall enter into force on January 1, 2006.
- (2) (Transitional Measures concerning Bicycle Race Tracks) Any facilities established in the school environmental sanitation and cleanup zone as at the time this Act enters into force, which fall under the amended provisions of Article 6 (1) 13, shall be transferred or closed by not later than December 31, 2009: *Provided*, That the same shall not apply where such facilities are recognized by the superintendent of education or any person to whom the superintendent delegates his or her authority pursuant to the proviso of Article 6 (1) by December 31, 2005.
- (3) (Transitional Measures concerning Physical Examination) The physical examination under the previous provisions as at the time this Act enters into force shall be deemed the health examination under the amended provisions of Article 7.

Addenda <Act No. 7700, Dec. 7, 2005>

- (1) (Enforcement Date) This Act shall enter into force on the date of its promulgation.
- (2) (Transitional Measures concerning Charnel Facilities) The amended provisions of Article 6 (1) 3 shall not apply to charnel facilities which have already been set up within a school environmental sanitation and cleanup zone as at the time this Act enters into force.

Addenda <Act No. 7799, Dec. 29, 2005>

Article 1 (Enforcement Date)

This Act shall enter into force three months after the date of its promulgation.

Articles 2 through 4 Omitted.

Addenda <Act No. 8366, Apr. 11, 2007>

Article 1 (Enforcement Date)

This Act shall enter into force on the date of its promulgation. (Proviso Omitted.)

Articles 2 through 21 Omitted.

Addenda <Act No. 8391, Apr. 27, 2007>

- (1) (Enforcement Date) This Act shall enter into force one year after the date of its promulgation.
- (2) (Transitional Measures concerning Establishment of Cleanup Zone on Existing Land Reserved for Establishment of School) With respect to a site for a school determined and publicly notified as part of the urban management plan pursuant to Article 30 of the National Land Planning and Utilization Act and a site secured for the establishment of a kindergarten pursuant to Article 8 of the Early Childhood Education Act and of a special school pursuant to Article 4 of the Elementary and Secondary Education Act as at the time this Act enters into force (in the case of a private kindergarten or special school, referring to a site on which the establishment of a private kindergarten or special school has been approved), the school environmental sanitation and cleanup zone under the amended provision of Article 5 (1) shall be established and publicly notified within 30 days after the enforcement of this Act.
- (3) (Transitional Measures concerning Existing Facilities) Facilities falling under the provisions of Article 6 (1) 1 through 15 as facilities built in the school environmental sanitation and cleanup zone in land reserved for the establishment of a school as at the time this Act enters into force shall be moved or closed down before the opening date of the relevant school: *Provided*, That this shall not apply where approval from the superintendent of education or of any person delegated by the superintendent of education has been obtained pursuant to the proviso of Article 6 (1), and when there are facilities the relocation or closure of which are deemed substantially impracticable before the opening date of a school, the superintendent of education may formulate a separate plan to move or close down such facilities within five years from the opening date of the school.

Addenda <Act No. 8466, May 17, 2007>

Article 1 (Enforcement Date)

This Act shall enter into force six months after the date of its promulgation.

Articles 2 through 5 Omitted.

Addenda <Act No. 8578, Aug. 3, 2007>

- (1) (Enforcement Date) This Act shall enter into force one year after the date of its promulgation.
- (2) (Transitional Measures concerning Existing Facilities) Game facilities falling under Article 6 (1) 13-3 as facilities built in the school environmental sanitation and cleanup zone as at the time this Act enters into force shall be moved or closed down before this Act enters into force: *Provided*, That this shall not apply where approval from the superintendent of education or any person delegated by the superintendent of education has been obtained pursuant to the proviso of Article 6 (1).

Addendum <Act No. 8678, Dec. 14, 2007>

This Act shall enter into force on the date of its promulgation: *Provided*, That the amended provisions of

Articles 2, 4, 5, 6 (3), 6-2, and 19 shall enter into force on April 28, 2008; the amended provisions of Articles 6 (1) and 6-3 shall enter into force on August 4, 2008; and the amended provisions of Articles 9-2 and 15 (2) shall enter into force on March 1, 2009, respectively.

Addenda <Act No. 8852, Feb. 29, 2008>

Article 1 (Enforcement Date)

This Act shall enter into force on the date of its promulgation: *Provided*, That ... <omitted> ... among Acts amended pursuant to Article 6 of the Addenda, the amendments to any Act which was promulgated before this Act enters into force, but the enforcement date of which has yet to arrive shall enter into force on the enforcement date of the relevant Act.

Articles 2 through 7 Omitted.

Addendum <Act No. 8912, Mar. 21, 2008>

This Act shall enter into force on the date of its promulgation: *Provided*, That the amended provisions of subparagraph 3 (b) of Article 2 shall enter into force on April 28, 2008.

Addenda <Act No. 9770, Jun. 9, 2009>

Article 1 (Enforcement Date)

This Act shall enter into force on July 1, 2010. (Proviso Omitted.)

Articles 2 through 7 Omitted.

Addenda <Act No. 9847, Dec. 29, 2009>

Article 1 (Enforcement Date)

This Act shall enter into force one year after the date of its promulgation.

Articles 2 through 22 Omitted.

Addenda <Act No. 9932, Jan. 18, 2010>

Article 1 (Enforcement Date)

This Act shall enter into force two months after the date of its promulgation. (Proviso Omitted.)

Articles 2 through 5 Omitted.

Addenda <Act No. 11048, Sep. 15, 2011>

Article 1 (Enforcement Date)

This Act shall enter into force one year after the date of its promulgation. (Proviso Omitted.)

Articles 2 through 5 Omitted.

Addenda <Act No. 11141, Dec. 31, 2011>

Article 1 (Enforcement Date)

This Act shall enter into force on September 1, 2012. (Proviso Omitted.)

Articles 2 through 22 Omitted.

Addendum <Act No. 11220, Jan. 26, 2012>

This Act shall enter into force on April 1, 2012: *Provided*, That the amended provisions of subparagraph 3 (b) of Article 2 and Articles 6 (3) and 6-3 (2) shall enter into force on July 1, 2012. <Amended by Act No. 11386, Mar. 21, 2012>

Addenda <Act No. 11384, Mar. 21, 2012>

Article 1 (Enforcement Date)

This Act shall enter into force on the date of its promulgation. (Proviso Omitted.)

Article 2 Omitted.

Addendum <Act No. 11386, Mar. 21, 2012>

This Act shall enter into force on April 1, 2012.

Addenda <Act No. 11690, Mar. 23, 2013>

Article 1 (Enforcement Date)

(1) This Act shall enter into force on the date of its promulgation.

(2) Omitted.

Articles 2 through 7 Omitted.

Addendum <Act No. 12131, Dec. 30, 2013>

This Act shall enter into force on the date of its promulgation: *Provided*, That the amended provisions of Articles 9-2, 18-2, and 19 (1) shall enter into force six months after the date of its promulgation.

Addenda <Act No. 13879, Jan. 27, 2016>

Article 1 (Enforcement Date)

This Act shall enter into force one year after the date of its promulgation. (Proviso Omitted.)

Articles 2 through 12 Omitted.

Addenda <Act No. 13946, Feb. 3, 2016>

Article 1 (Enforcement Date)

This Act shall enter into force one year after the date of its promulgation.

Article 2 (Transitional Measure concerning Penalty Provisions)

The previous provisions shall apply to the imposition of penalty provisions for acts committed before this Act enters into force.

Addendum <Act No. 14055, Mar. 2, 2016>

This Act shall enter into force six months after the date of its promulgation: *Provided*, That the amended provisions of Article 7 (6) shall enter into force on the date of its promulgation.

Addendum <Act No. 14402, Dec. 20, 2016>

This Act shall enter into force three months after the date of its promulgation.

Addenda <Act No. 14532, Jan. 17, 2017>**Article 1 (Enforcement Date)**

This Act shall enter into force one year after the date of its promulgation: *Provided*, That, among Acts amended pursuant to Article 6 of the Addenda, the amendments to any Act, which was promulgated before this Act enters into force but the enforcement date of which has yet to arrive, shall enter into force on the enforcement date of the relevant Act.

Articles 2 through 7 Omitted.**Addenda** <Act No. 14839, Jul. 26, 2017>**Article 1 (Enforcement Date)**

This Act shall enter into force on the date of its promulgation: *Provided*, That, among Acts amended pursuant to Article 5 of the Addenda, the amendments to any Act, which was promulgated before this Act enters into force but the enforcement date of which has yet to arrive, shall enter into force on the enforcement date of the relevant Act.

Articles 2 through 6 Omitted.**Addendum** <Act No. 15043, Nov. 28, 2017>

This Act shall enter into force six months after the date of its promulgation.

Addenda <Act No. 15534, Mar. 27, 2018>**Article 1 (Enforcement Date)**

This Act shall enter into force on January 1, 2020: *Provided*, That ... <omitted> ... Article 2 (5) of the Addenda shall enter into force six months after the date of its promulgation.

Article 2 Omitted.**Addendum** <Act No. 15965, Dec. 18, 2018>

This Act shall enter into force six months after the date of its promulgation.

Addenda <Act No. 16304, Apr. 2, 2019>**Article 1 (Enforcement Date)**

This shall enter into force three months after the date of its promulgation.

Article 2 (Applicability to Measured Figures)

The amended provisions of the latter part of Article 4 (6) shall begin to apply from the first figure measured after this Act enters into force.

Addendum <Act No. 16339, Apr. 23, 2019>

This Act shall enter into force six months after the date of its promulgation.

2.17 Enforcement Decree of The School Health Act

Presidential Decree No. 29950, Jul. 2, 2019

CHAPTER I General Provisions

Article 1 (Purpose)

The purpose of this Decree is to prescribe matters mandated by the School Health Act and matters necessary for enforcing said Act.

Article 2 (Standards for Installation of Health Room)

- (1) Standards for the installation of a health room under Article 3 of the School Health Act (hereinafter referred to as the "Act") shall be as follows: *<Amended by Presidential Decree No. 24026, Aug. 13, 2012; Presidential Decree No. 24423, Mar. 23, 2013>*
 1. Location: It shall be located in a place that is readily accessible to students and teachers and staff, who can swiftly receive emergency treatment, etc., and that is well-ventilated and well-lighted;
 2. Area: It shall be at least 66 square meters: *Provided*, That the Minister of Education (applicable only to universities and colleges under Article 1 of the Regulations for the Establishment and Operation of Universities and Colleges) or the superintendent of education of the Special Metropolitan City, a Metropolitan City, a Special Self-Governing City, a *Do*, or of a Special Self-Governing Province (hereinafter referred to as "City/Do") (applicable only to schools under Article 2 of the Regulations for the Establishment and Operation of Schools of the Grades not Higher than High Schools) may relax requirements for such area to the extent that they do not undermine efforts by students and teachers and staff to maintain their health, taking the number of students, etc., into consideration.
- (2) A health room under paragraph (1) shall be furnished with the following facilities, appliances, and goods required for school health: *<Amended by Presidential Decree No. 29859, Jun. 18, 2019>*
 1. Facilities, appliances, and goods required for the health care, emergency treatment, etc., of students and teachers and staff;
 2. Appliances required for the inspection of environmental sanitation and food sanitation in schools.
- (3) Specific standards for facilities, appliances, and goods required in a health room under paragraph (2) shall be prescribed by Ordinance of the Ministry of Education in cases of national schools under Article 3 of the Elementary and Secondary Education Act, and schools under the subparagraphs of Article 2 of the Higher Education Act; and by the Rules of Education of the relevant City/*Do* in cases of public or private schools under Article 3 of the Elementary and Secondary Education Act. *<Amended by Presidential Decree No. 24026, Aug. 13, 2012; Presidential Decree No. 24423, Mar. 23, 2013; Presidential Decree No. 29859, Jun. 18, 2019>*

CHAPTER II Response to Air Pollution

Article 3 (Preparation of Air Pollution Response Manual)

- (1) "Details prescribed by Presidential Decree" in Article 5 (2) of the Act means the following:
 1. Matters regarding work systems to respond to air pollution and roles played by each relevant institution;
 2. Matters regarding guidelines for disseminating information at each stage of response;
 3. Matters regarding the inspection of conditions for outdoor classes and corresponding measures at

- each stage of response;
4. Matters regarding measures to control indoor air quality at each stage of response;
 5. Other matters deemed necessary by the Minister of Education to respond to air pollution.
- (2) The Minister of Education may distribute an air pollution response manual prepared pursuant to Article 5 (1) of the Act in electronic or printed form.
- (3) Detailed guide to action for students and teachers and staff under Article 5 (3) of the Act (hereafter in this Article referred to as “detailed guide to action”) shall include the following:
1. Matters regarding the designation of teachers and staff in charge of responding to air pollution;
 2. Matters regarding the implementation of safety measures at each stage of response, such as the adjustment of school commuting time, shortening of school hours, and management of ill persons;
 3. Matters regarding guidelines for disseminating information at each stage of response, such as the maintenance of teachers and staff’s emergency contacts and the establishment of a system to contact students and their parents;
 4. Matters regarding the inspection of conditions for outdoor classes and corresponding measures at each stage of response, such as the replacement of outdoor classes like physical activities, field-based learning, and school sports day for indoor classes;
 5. Matters regarding the control of indoor air quality at each stage of response, such as the operation of air purification installations, ventilation guidelines, and cleaning;
 6. Other matters deemed necessary by the head of a school to respond to air pollution, in consideration of the school conditions, etc.
- (4) The head of a school may establish and include the detailed guide to action in a school plan for the prevention of accidents at school under Article 4 (6) of the Act on the Prevention of and Compensation for Accidents at School.

[This Article Newly Inserted by Presidential Decree No. 29859, Jun. 18, 2019]

Articles 4 through 8 Deleted. <by Presidential Decree No. 27831, Feb. 3, 2017>

CHAPTER III (Articles 9 through 12) Deleted.

CHAPTER IV (Articles 13 through 19) Deleted.

CHAPTER V (Articles 20 and 21) Deleted.

CHAPTER VI Assignment of School Physicians and School Health Committee

Article 22 (Suspension from School)

- (1) The head of a school may issue orders requiring any of the following persons, from among the students and teachers and staff under Article 8 of the Act, to be suspended from school: <Amended by Presidential Decree No. 22564, Dec. 29, 2010; Presidential Decree No. 27457, Aug. 29, 2016>
1. Patients with infectious diseases, suspected cases of infectious diseases, and carriers of pathogens (hereinafter referred to as “patients with infectious diseases, etc.”) under Article 2 of the Infectious Disease Control and Prevention Act: *Provided*, That persons diagnosed by a physician

as unlikely to infect others shall be excluded herefrom;

2. Patients, other than those referred to in subparagraph 1, who are diagnosed by a physician to be infected with highly infectious diseases.
- (2) When the head of a school orders them to be suspended from school pursuant to paragraph (1), he or she shall clarify the reasons for such order and the effective period thereof: *Provided*, That if deemed necessary based on symptoms of a disease or aspects of the prevalence of a disease, he or she may reduce or extend such period.

Article 22-2 (Formulation of Plan for Prevention of Infectious Diseases)

- (1) "Matters that are prescribed by Presidential Decree" in Article 14-3 (1) 4 of the Act means any of the following: *<Amended by Presidential Decree No. 29950, Jul. 2, 2019>*
1. Matters regarding education necessary for the prevention and control of infectious diseases;
 2. Matters regarding training for real-life situations such as virtual practice to enhance the ability to respond to infectious diseases;
 3. Matters regarding storing articles and setting up facilities necessary for the prevention of infectious diseases;
 4. Other matters deemed necessary by the Minister of Education for the prevention and control of infectious diseases.
- (2) "Information prescribed by Presidential Decree including information about the current status of infectious disease outbreaks" in Article 14-3 (4) of the Act means the following information regarding a relevant disease where Class 4 infectious diseases under subparagraph 5 of Article 2 of the Infectious Disease Control and Prevention Act emerge domestically or enter the country or where forecasts or alerts more serious than caution under Article 38 (2) of the Framework Act on the Management of Disasters and Safety are issued for infectious diseases publicly notified by the Minister of Health and Welfare under Article 41 (1) of the Infectious Disease Control and Prevention Act:
1. Names of infectious diseases;
 2. Status of outbreak of infectious diseases and how they enter the country;
 3. Date of occurrence in patients with infectious diseases (limited to students and teachers and staff), date of diagnosis, travel route, means of transportation, and status of contacts of patients with infectious diseases, etc. (limited to students and teachers and staff);
 4. Other information deemed necessary for the prevention of the outbreaks of infectious diseases and of the spread thereof by the Minister of Education or the Minister of Health and Welfare.

[This Article Newly Inserted by Presidential Decree No. 27457, Aug. 29, 2016]

Article 22-3 (Preparation and Distribution of Infectious Disease Response Manual)

- (1) A response manual by type of infectious diseases which shall be prepared and distributed under Article 14-4 (1) of the Act (hereinafter referred to as "infectious disease response manual") shall include the following matters:
1. Matters regarding behavioral know-how of students and teachers and staff by type of infectious diseases;
 2. Matters regarding measures by stage of prevention, preparedness, response, and restoration by type of infectious diseases;
- (2) Where the Minister of Education distributes the infectious disease response manual, he or she may distribute it in electronic or printed form.
- (3) Where the superintendent of education of the Special Metropolitan City, a Metropolitan City, a Special Self-Governing City, a *Do*, or of a Special Self-Governing Province (hereinafter referred to as "superintendent of education") and the head of a school promotes business regarding measures of prevention of, preparation for, response to and restoration from infectious diseases, he or she shall utilize the infectious disease response manual. *<Amended by Presidential Decree No. 27831, Feb. 3,*

2017>

- (4) The superintendent of education and the head of a school may add details to or complement the infectious disease response manual reflecting characteristics of each region or school.

[This Article Newly Inserted by Presidential Decree No. 27457, Aug. 29, 2016]

Article 23 (School Physicians, School Pharmacists, and Health Teachers)

- (1) Each school shall employ a school physician (including a dentist and a herb doctor; hereinafter the same shall apply), a school pharmacist, and a health teacher as follows pursuant to Article 15 of the Act:

1. Any elementary school which has at least 18 classes shall employ one school physician, one school pharmacist, and one health teacher, and any elementary school which has less than 18 classes may employ either school physician or school pharmacist, and one health teacher;
2. Any middle school or high school which has at least nine classes shall employ one school physician, one school pharmacist, and one health teacher, and any middle school or high school which has less than nine classes shall employ either school physician or school pharmacist, and one health teacher;
3. Any university (referring to a college in cases of a university which has at least three colleges), college of education, teachers' college, or junior college shall employ one school physician and one school pharmacist;
4. Any high technical school, citizenship training school, citizenship training high school, special school, kindergarten, and schools of various kinds shall employ a school physician, a school pharmacist, and a health teacher corresponding to the relevant school prescribed in subparagraphs 1 through 3.

- (2) A school physician and a school pharmacist under paragraph (1) shall be appointed by the head of a school from among those who hold the relevant licenses.

- (3) Duties of a health teacher, a school physician, and a school pharmacist under paragraph (1) shall be as follows:

1. Duties of a health teacher:

- (a) Formulation of school health plans;
- (b) Matters concerning the maintenance, control, and improvement of environmental sanitation in schools;
- (c) Cooperation in preparing for and conducting health examinations of students and teachers and staff;
- (d) Precautionary measures against all diseases and guidance on health;
- (e) Cooperation in the health observation of students and teachers and staff, the health consultation and health appraisals, etc., by a school physician;
- (f) Health guidance for feeble-bodied students;
- (g) Visit to students' homes for health guidance;
- (h) Cooperation in health education of teachers and health education when necessary;
- (i) Management of facilities, equipment and medicines, etc., in a health room;
- (j) Collection and management of health education materials;
- (k) Administration of students' health records;
- (l) Medical treatments as follows (only applicable to persons holding a nursing license):
 - (i) Medical treatment of patients with an external wound, etc., which is a case usually seen;
 - (ii) First-aid treatment of those who need emergency treatment;
 - (iii) Medical treatment to prevent recurrence of a wound or disease;
 - (iv) Medical care guidance for and management of patients found to have diseases in health examinations;
- (v) Medication according to medical treatment referred to in subitems (i) through (iv);

- (m) Other matters concerning school health administration;
- 2. Duties of a school physician:
 - (a) Advice on the formulation of school health plans;
 - (b) Advice on the maintenance, control, and improvement of environmental sanitation in schools;
 - (c) Health examinations and health appraisal of students and teachers and staff;
 - (d) Precautionary measures against all diseases and health guidance;
 - (e) Health consultations for students and teachers and staff;
 - (f) Other guidance on school health administration;
- 3. Duties of a school pharmacist:
 - (a) Advice on the formulation of school health plans;
 - (b) Advice on the maintenance, control, and improvement of environmental sanitation in schools;
 - (c) Advice on the management of medical supplies and toxic chemicals used in school;
 - (d) Tests and inspection of medical supplies and toxic chemicals used in school;
 - (e) Other guidance on school health administration.

Article 24 (Functions of Health Committee)

- (1) Deleted. <by Presidential Decree No. 24026, Aug. 13, 2012>
- (2) A City/Do School Health Committee under Article 17 (1) of the Act (hereinafter referred to as the "Health Committee") shall deliberate on the following matters: <Amended by Presidential Decree No. 24026, Aug. 13, 2012>
 - 1. The medium- and long-term basic plan for a City/Do to improve the health of students and teachers and staff;
 - 2. Proposals for the enactment of or amendment to ordinances of a City/Do or educational regulations related to school health;
 - 3. Matters concerning school health policies, etc., submitted to a meeting by the superintendent of education;
 - 4. Deleted. <by Presidential Decree No. 27831, Feb. 3, 2017>

Article 25 (Organization of Health Committee)

- (1) The Health Committee shall have one chairperson and one vice-chairperson, who shall be elected from among and by its members, respectively. <Amended by Presidential Decree No. 24026, Aug. 13, 2012>
- (2) Deleted. <by Presidential Decree No. 24026, Aug. 13, 2012>
- (3) The superintendent of education shall appoint or commission members of the Health Committee from among public officials at the director-general level of the relevant Office of Education or persons who have knowledge of or experience in school health. <Amended by Presidential Decree No. 24026, Aug. 13, 2012>
- (4) Each member commissioned pursuant to paragraph (3) shall hold office for a term of two years and may be appointed consecutively: *Provided*, That the term of office of a member filling a vacancy shall be the remainder of his or her predecessor's term of office. <Amended by Presidential Decree No. 24026, Aug. 13, 2012>

Article 26 (Duties of Chairperson)

- (1) The chairperson of the Health Committee shall represent the Health Committee and exercise general supervision over the affairs concerning meetings of the committee.
- (2) When the chairperson is unable to perform his or her duties due to any unavoidable reason, the vice-chairperson shall act on behalf of the chairperson.

Article 27 (Meetings)

- (1) The chairperson of the Health Committee shall convene and preside over meetings of the committee in any of the following cases: *<Amended by Presidential Decree No. 24026, Aug. 13, 2012>*
 1. Cases where the superintendent of education requests him or her to convene a meeting;
 2. Cases where at least 1/3 of the members requests him or her to convene a meeting;
 3. Other cases deemed necessary by the chairperson in order to deliberate on the matters for the protection and improvement of the health of students and teachers and staff.
- (2) A majority of the members of the Health Committee shall constitute a quorum, and any decision thereof shall require the concurring vote of at least a majority of those present.

Article 28 (Subcommittees)

- (1) Subcommittees by special field may be established in the Health Committee.
- (2) Each subcommittee shall deliberate on matters delegated by the Health Committee among the matters to be deliberated by the Health Committee.
- (3) The superintendent of education shall determine the assignment of the members of the Health Committee to each subcommittee. *<Amended by Presidential Decree No. 24026, Aug. 13, 2012>*
- (4) Each subcommittee shall have one chairperson, each of whom shall be elected from among its members.
- (5) Article 27 shall apply *mutatis mutandis* to subcommittee meetings.

Article 29 (Executive Secretary and Clerk)

- (1) The Health Committee shall have one executive secretary and several clerks.
- (2) The executive secretary and clerks of the Health Committee shall be appointed by the superintendent of education from among public officials under his or her control. *<Amended by Presidential Decree No. 24026, Aug. 13, 2012>*
- (3) The executive secretary shall perform the administrative affairs of the Committee upon instruction of the chairperson, and clerks shall assist the executive secretary.

Article 30 (Request for Cooperation)

The Minister of Education or the superintendent of education may request any non-profit corporation related to health sanitation in schools, non-profit medical institution, or national or public health and medical institution to render cooperation necessary to protect and improve the health of students and teachers and staff. *<Amended by Presidential Decree No. 24423, Mar. 23, 2013>*

Article 31 (Hearing Opinions of Experts)

- (1) The Health Committee and subcommittees may, if necessary, hear the opinions of relevant experts.
- (2) The Health Committee and subcommittees may, if necessary, request the relevant public official to present the relevant materials or to attend a meeting to answer questions, and the relevant public official shall comply with the request of the Protection Committee or subcommittees without a compelling reason not to do so.

[This Article Wholly Amended by Presidential Decree No. 27831, Feb. 3, 2017]

Article 31-2 (Allowances and Travel Expenses)

Allowances, travel expenses, and other necessary expenses may be paid to members of the committee or the relevant experts, etc., attending a meeting of the Health Committee within the budget: *Provided*, That this shall not apply where a public official attends a committee meeting in direct connection with his or her affairs.

[This Article Newly Inserted by Presidential Decree No. 27831, Feb. 3, 2017]

Article 31-3 (Operating Rules)

Except as provided in this Decree, matters necessary for the operation of the Health Committee and subcommittees shall be determined by the chairperson after a resolution of the Health Committee.

[This Article Newly Inserted by Presidential Decree No. 27831, Feb. 3, 2017]

CHAPTER VII Supplementary Provisions

Article 32 Deleted. *<by Presidential Decree No. 27831, Feb. 3, 2017>*

Article 32-2 (Management of Sensitive Information and Personally Identifiable Information)

- (1) Where unavoidable to perform affairs concerning health examinations under Article 7 of the Act, the head of a school may manage information on health under Article 23 of the Personal Information Protection Act or data containing resident registration numbers or foreigner registration numbers under subparagraph 1 or 4 of Article 19 of the Enforcement Decree of the same Act. *<Amended by Presidential Decree No. 27457, Aug. 29, 2016>*
- (2) Where unavoidable to perform affairs concerning the inspection of completion of vaccination under Article 10 of the Act, the head of an elementary or secondary school may manage information on health under Article 23 of the Personal Information Protection Act or data containing resident registration numbers or foreigner registration numbers under subparagraph 1 or 4 of Article 19 of the Enforcement Decree of the same Act. *<Amended by Presidential Decree No. 27457, Aug. 29, 2016>*
- (3) When unavoidable to perform affairs concerning vaccinations against infectious diseases under Article 14-2 of the Act, the head of a *Si/Gun/Gu* (referring to the head of an autonomous *Gu*, including a person delegated or entrusted with the relevant authority, where the authority of the head of the *Si/Gun* or the head of the autonomous *Gu* has been delegated or entrusted) may manage information on health under Article 23 of the Personal Information Protection Act or data containing resident registration numbers or foreigner registration numbers under subparagraph 1 or 4 of Article 19 of the Enforcement Decree of the same Act. *<Amended by Presidential Decree No. 27457, Aug. 29, 2016; Amended by Presidential Decree No. 27831, Feb. 3, 2017>*
- (4) Where unavoidable to perform the following affairs, the Minister of Education, the Minister of Health and Welfare, the superintendent of education or the head of a school may manage information on health under Article 23 of the Personal Information Protection Act or data containing resident registration numbers or foreigner registration numbers under subparagraph 1 or 4 of Article 19 of the Enforcement Decree of the same Act: *<Newly Inserted by Presidential Decree No. 27457, Aug. 29, 2016>*
 1. Affairs regarding sharing of infectious disease information under Article 14-3 (4) of the Act;
 2. Affairs regarding report on infectious disease information under Article 14-3 (5) of the Act;
 3. Affairs regarding making infectious disease information public under Article 14-3 (6) of the Act.

[This Article Newly Inserted by Presidential Decree No. 25532, Aug. 6, 2014]

Article 33 (Re-Examination of Regulation)

The Minister of Education shall examine the appropriateness of the following matters every three years, counting from each base date specified in the following (referring to the period that ends on the day before the base date of every third year) and shall take measures, such as making improvements:

1. Standards for the installation of a health room and standards for equipment and apparatuses required in a health room under Article 2: January 1, 2016;
2. Standards for the placement of, qualifications and duties of school physicians, school pharmacists, and health teachers under Article 23: January 1, 2014.

[This Article Wholly Amended by Presidential Decree No. 27831, Feb. 3, 2017]

Addenda

Article 1 (Enforcement Date)

This Decree shall enter into force on August 4, 2008.

Article 2 (Transitional Measures concerning Existing Facilities)

Facilities approved by the superintendent of education or any person designated by him or her pursuant to the following before this Decree enters into force shall be deemed facilities approved by the superintendent of education or any person designated by him or her pursuant to the proviso of Article 6 (1) of the Act following deliberation by the Cleanup Committee in accordance with this Decree:

1. Paragraph (3) of Addenda to the amended Enforcement Decree of the School Health Act, Presidential Decree No. 10481;
2. Paragraph (2) of Addenda to the amended Enforcement Decree of the School Health Act, Presidential Decree No. 13214;
3. Paragraph (2) of Addenda to the amended Enforcement Decree of the School Health Act, Presidential Decree No. 13982;
4. Paragraph (2) of Addenda to the amended Enforcement Decree of the School Health Act, Presidential Decree No. 15607.

Article 3 (Relationship to Other Statutes or Regulations)

Where the provisions of the Enforcement Decree of the School Health Act are cited in other statutes as at the time this Decree enters into force, if the provisions corresponding thereto exist in this Decree, the corresponding provisions in this Decree shall be deemed to have been cited in place of the previous provisions.

Addenda <Presidential Decree No. 22075, Mar. 15, 2010>

Article 1 (Enforcement Date)

This Decree shall enter into force on March 19, 2010. (Proviso Omitted.)

Article 2 Omitted.

Addendum <Presidential Decree No. 22232, Jun. 29, 2010>

This Decree shall enter into force on September 1, 2010.

Addenda <Presidential Decree No. 22564, Dec. 29, 2010>

Article 1 (Enforcement Date)

This Decree shall enter into force on December 30, 2010. (Proviso Omitted.)

Articles 2 through 8 Omitted.

Addenda <Presidential Decree No. 23718, Apr. 10, 2012>

Article 1 (Enforcement Date)

This Decree shall enter into force on April 15, 2012. (Proviso Omitted.)

Articles 2 through 15 Omitted.

Addendum <Presidential Decree No. 23928, Jul. 4, 2012>

This Decree shall enter into force on the date of its promulgation. (Proviso Omitted.)

Addenda <Presidential Decree No. 24026, Aug. 13, 2012>

Article 1 (Enforcement Date)

This Decree shall enter into force on the date of its promulgation: *Provided*, That the amended provisions of Articles 7 and 7-2 shall enter into force three months after the date of its promulgation.

Articles 2 (Applicability to Term of Office of Members of the Cleanup Committee)

- (1) The amended provisions of Article 7-2 shall apply to a person who is commissioned as a member of the Cleanup Committee (including the renewal of his or her term of office) after this Decree enters into force.
- (2) Where the amended provisions of Article 7-2 are applied pursuant to paragraph (1), a member who is in the midst of his or her first term of office after being commissioned before this Decree enters into force may be eligible for the renewal of his or her term of office once after the completion of such first term of office, and no member who is in the midst of his or her term of office after renewal thereof at least once before this Decree enters into force shall be eligible for the renewal thereof after the completion of such renewed term of office.

Addenda <Presidential Decree No. 24423, Mar. 23, 2013>

Article 1 (Enforcement Date)

This Decree shall enter into force on the date of its promulgation. (Proviso Omitted.)

Articles 2 through 7 Omitted.

Addenda <Presidential Decree No. 24666, Jul. 22, 2013>

Article 1 (Enforcement Date)

This Decree shall enter into force on the date of its promulgation.

Articles 2 (Applicability to Omission of Some Details of Assessment Report)

The amended provisions of Articles 9 (2) and 10 (3) shall begin to apply from the first case where the selector of a school site submits the assessment report to the superintendent of education after this Decree enters into force.

Addendum <Presidential Decree No. 25050, Dec. 30, 2013>

This Decree shall enter into force on January 1, 2014. (Proviso Omitted.)

Addenda <Presidential Decree No. 25255, Mar. 18, 2014>

Article 1 (Enforcement Date)

This Decree shall enter into force on the date of its promulgation.

Article 2 (Transitional Measures concerning Existing Facilities)

Any facility established in the school environmental sanitation and cleanup zones before this Decree enters into force, which is the facility for providing multiple types of visual materials under the amended provisions of subparagraph 6 of Article 6, shall be transferred or closed before February 28, 2019: Provided, That, facilities recognized by the superintendent of education or any person to whom the superintendent delegates his or her authority under the proviso of Article 6 (1) of the Act, shall be excluded herefrom.

Addendum <Presidential Decree No. 25532, Aug. 6, 2014>

This Decree shall enter into force on August 7, 2014.

Addenda <Presidential Decree No. 25840, Dec. 9, 2014>

Article 1 (Enforcement Date)

This Decree shall enter into force on January 1, 2015.

Articles 2 through 16 Omitted.

Addenda <Presidential Decree No. 26571, Oct. 6, 2015>

Article 1 (Enforcement Date)

This Decree shall enter into force on the date of its promulgation.

Article 2 (Applicability to Omission of Review of Assessment Report)

The amendment of the proviso of Article 10 (3) shall also apply where the procedures related to the approval under Article 6-2 (2) of the Act are being conducted as at the time this Decree enters into force.

Addendum <Presidential Decree No. 26855, Dec. 31, 2015>

This Decree shall enter into force on the date of its promulgation.

Addendum <Presidential Decree No. 27457, Aug. 29, 2016>

This Decree shall enter into force on September 3, 2016.

Addendum <Presidential Decree No. 27831, Feb. 3, 2017>

This Decree shall enter into force on February 4, 2017.

Addendum <Presidential Decree No. 29859, Jun. 18, 2019>

This Decree shall enter into force on June 19, 2019.

Addendum <Presidential Decree No. 29950, Jul. 2, 2019>

This Decree shall enter into force on the date of its promulgation. (Proviso Omitted.)

Korean Statutes related to COVID-19

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History

- 2019's**
 - Website of Korea Law Translation Center complete reorganization
 - Korean-Chinese Legal Translation Advisory Committee established
 - Law Translation Management System (LTMS) instituted
- 2018's**
 - Korean-English Legal Translation Advisory Committee and Advisory Groups on Legal Terminology by Field established
- 2015's**
 - "Standards for Law Translation into English" (1st edition) published (currently 3rd edition)
 - Legal term management solution introduced
- 2014's**
 - Open API Service for English translations of Korean legislation
- 2012's**
 - Korean-English Statutory Translation Advisory Committee set up
 - Mobile platform for English translation of Korean legislation launched
- 2010's**
 - Free online service for English translation of Korean legislation
- 2008's**
 - In-house development of English-Korean Law Management System (ELMS)
- 2001's**
 - "Korean-English Glossary of Legal Terms" (1st edition) published (currently 4th edition)
- 2000's**
 - Online service for English translations of Korean legislation (service charge)
- 1997's**
 - New edition of the English version of the "Statutes of the Republic of Korea" published
- 1996's**
 - Compilation Committee for new edition of the English version of the "Statutes of the Republic of Korea" set up
- 1994's**
 - Korean legislation database provided through PC communication service
- 1992's**
 - First edition of the English version of the "Statutes of the Republic of Korea" published
- 1992's**
 - English translation of Korean legislation transferred from the Ministry of Government Legislation to Korea Legislation Research Institute
- 1982's**
 - English version of the "Statutes of the Republic of Korea" published by the Ministry of Government Legislation

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