

Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases

(Act No. 114 of October 2, 1998)

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Supplementary Provisions

Humankind has over time experienced hardships due to various diseases, including infectious diseases. The spread of plagues, smallpox, cholera and other infectious diseases has often plunged human civilization into a state of crisis. The eradication of infectious diseases has in particular been a long-sought-after goal of humankind.

Advances in medical science and medical care and considerable improvement of hygiene standards have enabled people to overcome a variety of infectious diseases. However, infectious diseases still remain a threat to humankind in new forms due to the emergence of new infectious diseases, due to the resurgence of known infectious diseases, or as a result of increased international interactions.

Meanwhile, in the past in Japan there was groundless discrimination or prejudice against patients and other people suffering from leprosy, acquired immunodeficiency syndrome (AIDS), and similar infectious diseases. The Japanese public must take these facts seriously and turn them into a moral lesson for the future.

In light of these changing circumstances surrounding infectious diseases and the situation surrounding patients with infectious diseases and other persons in similar situations, it is necessary to ensure high-quality and adequate medical care for those persons and to swiftly and adequately address infectious diseases while respecting those persons' human rights.

From this standpoint, this Act is established to fundamentally overhaul conventional measures for preventing infectious diseases and to promote integrated measures for preventing infectious diseases and medical care for patients with infectious diseases.

Chapter I General Provisions

(Purpose)

Article 1 The purpose of this Act is to provide for necessary measures for preventing infectious diseases and medical care for patients with infectious diseases in order to prevent outbreaks and the spreading of infectious diseases, thereby improving and promoting public hygiene.

(Basic Principles)

Article 2 Measures implemented by the national and local governments for the

purpose of preventing outbreaks and the spread of infectious diseases are to be promoted in an integrated and systematic manner by gaining an in-depth understanding of the circumstances surrounding patients with infectious diseases and other persons in similar situations, while respecting the human rights of those persons, so that those governments can address new infectious diseases or other infectious diseases swiftly and adequately by promptly responding to the changing circumstances surrounding health and medical care and dealing with increased international interactions, while taking into account international trends related to the measures implemented for the that purpose.

(Responsibilities of the National and Local Governments)

- Article 3 (1) The national and local governments must disseminate correct knowledge about infectious diseases through educational, publicity-related, and other similar activities, and must gather, organize, analyze, and provide information on infectious diseases, promote research on infectious diseases, enhance the capability to examine pathogens and toxins, and educate personnel engaged in the prevention of infectious diseases and improve their professional qualities, while endeavoring to implement the necessary measures to enable patients with infectious diseases to receive high-quality and adequate medical care, while giving due regard to coordinated liaison with social welfare and other related measures. In this regard, the national and local governments must respect the human rights of patients with infectious diseases and other persons in similar situations.
- (2) The national and local governments must mutually coordinate and pay due regard to regional characteristics in order to ensure that the measures to prevent infectious diseases are implemented in an integrated and timely manner.
- (3) The national government must endeavor to establish systems for gathering and studying information on infectious diseases and pathogens and toxins, and to promote research and development of medicines, ensure a stable supply of those medicines for the medical care of infectious diseases, and facilitate the examination of pathogens and toxins for medical care of infectious diseases, as well as to ensure international coordination, while endeavoring to offer the necessary technical and financial assistance to local governments to encourage them to adequately fulfill the responsibilities referred to in the preceding two paragraphs.

(Responsibilities of the Public)

- Article 4 The public must endeavor to acquire accurate knowledge on infectious diseases and to exercise vigilance in order to prevent infectious diseases, and

must be careful not to infringe on the human rights of patients with infectious diseases and other persons in similar situations.

(Responsibilities of Physicians)

Article 5 (1) Physicians and other medical personnel must cooperate in the measures implemented by the national and local governments to prevent infectious diseases, and endeavor to contribute to the prevention of infectious diseases, while striving to provide high-quality and adequate medical care based on an in-depth understanding of the circumstances surrounding patients with infectious diseases and other persons in similar situations, and obtaining their consent by providing adequate explanations about the relevant medical care.

(2) Proprietors and administrators of hospitals, clinics, and organizations that examine pathogens and toxins, welfare facilities for the elderly, or other similar facilities must implement the necessary measures to prevent any outbreaks or spreading of infectious diseases in their facilities.

(Responsibilities of Veterinarians)

Article 5-2 (1) Veterinarians and other personnel engaged in veterinary practice must cooperate in the measures implemented by the national and local governments to prevent infectious diseases and endeavor to contribute to the prevention of infectious diseases.

(2) Operators of businesses handling animals or similar businesses (meaning persons engaged in the business of importing, storing, leasing, or selling animals or animal corpses or displaying them at amusement parks, zoos, exhibitions, or other facilities and places visited by an unspecified, large number of persons) must endeavor to acquire the knowledge and skills necessary to prevent infectious diseases, properly handle animals or animal corpses, and implement other necessary measures to prevent the transmission of infectious diseases from the animals or animal corpses imported, stored, leased, sold, or displayed to people.

(Definitions)

Article 6 (1) The term "infectious disease" as used in this Act means class I, class II, class III, class IV, and class V infectious diseases, a novel and reemerging influenza or coronavirus infection, a designated infectious disease, and a new infectious disease.

(2) The term "class I infectious disease" as used in this Act means any of the following infectious diseases:

- (i) Ebola haemorrhagic fever;
- (ii) Crimean-Congo haemorrhagic fever;

- (iii) smallpox;
 - (iv) South American haemorrhagic fever;
 - (v) plague;
 - (vi) Marburg virus disease;
 - (vii) Lassa fever.
- (3) The term "class II infectious disease" as used in this Act means any of the following infectious diseases:
- (i) acute poliomyelitis;
 - (ii) tuberculosis;
 - (iii) diphtheria;
 - (iv) severe acute respiratory syndrome (limited to the one caused by the SARS coronavirus as a pathogen in the genus Betacoronavirus);
 - (v) Middle East respiratory syndrome (limited to the one caused by the MERS coronavirus as a pathogen in the genus Betacoronavirus); and
 - (vi) avian influenza (limited to the one caused by any influenza A virus as a pathogen in the genus Influenzavirus A and involving a serosubtype which is specified by Cabinet Order as being highly likely to mutate into a pathogen of a novel and reemerging influenza or coronavirus infection (excluding the novel coronavirus infections listed in paragraph (7), item (iii) and the reemerging coronavirus infections listed in item (iv) of that paragraph. The same applies in paragraph (6), item (i) and paragraph (25), item (i.) (referred to below as "specified avian influenza" in paragraph (5), item (vii))).
- (4) The term "class III infectious disease" as used in this Act means any of the following infectious diseases:
- (i) cholera;
 - (ii) shigellosis;
 - (iii) enterohaemorrhagic Escherichia coli infection;
 - (iv) typhoid fever;
 - (v) paratyphoid fever.
- (5) The term "class IV infectious disease" as used in this Act means any of the following infectious diseases:
- (i) hepatitis E;
 - (ii) hepatitis A;
 - (iii) yellow fever;
 - (iv) Q fever;
 - (v) rabies;
 - (vi) anthrax;
 - (vii) avian influenza (excluding specified avian influenza);
 - (viii) botulism;
 - (ix) malaria;
 - (x) tularaemia;

- (xi) beyond what is stated in the preceding items, any known infectious diseases specified by Cabinet Order as diseases which are transmissible to humans through animals or animal corpses, food or drink, clothing, bedding, or other items and which are likely to affect public health as seriously as the diseases stated in the preceding items.
- (6) The term "class V infectious disease" as used in this Act means any of the following infectious diseases:
- (i) influenza (excluding avian influenza and a novel and reemerging influenza or coronavirus infection);
 - (ii) viral hepatitis (excluding hepatitis E and hepatitis A);
 - (iii) cryptosporidiosis;
 - (iv) acquired immunodeficiency syndrome (AIDS);
 - (v) genital chlamydia infection;
 - (vi) syphilis;
 - (vii) measles;
 - (viii) methicillin-resistant *Staphylococcus aureus* infection;
 - (ix) beyond what is stated in the preceding items, any known infectious disease (excluding class IV infectious diseases) specified by Order of the Ministry of Health, Labour and Welfare as a disease which is likely to affect public health as seriously as the diseases stated in the preceding items.
- (7) The term "novel and reemerging influenza or coronavirus infection" as used in this Act means any of the following infectious diseases:
- (i) novel influenza (meaning a type of influenza caused by a virus that has recently become transmissible from person to person as a pathogen and which is found to be likely to seriously affect the lives of the people and public health in the event of its rapid spread across the country because the general public is not immunized against this infectious disease);
 - (ii) reemerging influenza (meaning a type of influenza specified by the Minister of Health, Labour and Welfare as a pathogen which once caused a global pandemic but which has not caused a global pandemic in a long time, and which is found to be likely to seriously affect the lives of the people and public health in the event of its rapid spread across the country because a large majority of the general public is currently not immunized against this infectious disease).
 - (iii) novel coronavirus disease (meaning a type of disease caused by a coronavirus that has recently become transmissible from person to person as a pathogen and which is found to be likely to seriously affect the lives of the people and public health in the event of its rapid spread across the country because the general public is not immunized against this infectious disease);
and
 - (iv) reemerging coronavirus disease (meaning a type of infectious disease

specified by the Minister of Health, Labour and Welfare as a pathogen which once caused a global pandemic but which has not caused a global pandemic in a long time and which is found to be likely to seriously affect the lives of the people and public health in the event of its rapid spread across the country because a large majority of the general public is currently not immunized against this infectious disease).

- (8) The term "designated infectious disease" as used in this Act means a known infectious disease (excluding class I, class II, and class III infectious diseases and novel and reemerging influenza and coronavirus infections) specified by Cabinet Order as a disease which would be likely to seriously affect public health in the event of its spread if the provisions of Chapters III through VII, in whole or in part, did not apply *mutatis mutandis*.
- (9) The term "new infectious disease" as used in this Act means a disease which is found to be transmissible from person to person, which involves pathological conditions or therapeutic outcomes that are clearly different from those of any known infectious disease, and which could cause severe symptoms if infected, and which is found to be likely to seriously affect the lives of the people and public health if the disease spreads.
- (10) The term "suspected disease carrier" as used in this Act means a person who is suspected to have contracted an infectious disease based on their pathological condition.
- (11) The term "asymptomatic carrier" as used in this Act means a person who carries any pathogen capable of causing an infectious disease and exhibits no symptoms of the infectious disease.
- (12) The term "designated medical institution for infectious diseases" as used in this Act means a designated medical institution for specified infectious diseases, a designated medical institution for class I infectious diseases, a designated medical institution for class II infectious diseases, a designated medical Institution for class I agreement, a designated medical institution for class II agreement, or a designated medical institution for tuberculosis.
- (13) The term "designated medical institution for specified infectious diseases" as used in this Act means a hospital designated by the Minister of Health, Labour and Welfare as a medical institution in charge of hospitalization of a person with symptoms of a new infectious disease or patients with a class I or class II infectious disease, or a novel and reemerging influenza or coronavirus infection.
- (14) The term "designated medical institution for class I infectious diseases" as used in this Act means a hospital designated by a prefectural governor as a medical institution in charge of hospitalization of patients with a class I or class II infectious disease, or a novel and reemerging influenza or coronavirus infection.
- (15) The term "designated medical institution for class II infectious diseases" as

- used in this Act means a hospital designated by a prefectural governor as a medical institution in charge of hospitalization of patients with a class II infectious disease or a novel and reemerging influenza or coronavirus infection.
- (16) The term "designated medical institution for class I agreement" as used in this Act means a hospital or clinic designated by a prefectural governor as a medical institution that provides necessary medical care by hospitalizing a patient with a novel and reemerging influenza or coronavirus infection or a designated infectious disease, or a person with symptoms of a new infectious disease based on a notification pursuant to the provisions of Article 36-2, paragraph (1) (limited to notifications that include the measures listed in item (i) of that paragraph) or a medical care agreement prescribed in Article 36-3, paragraph (1) (limited to medical care agreements that include the measures stated in that item).
- (17) The term "designated medical institution for class II agreement" as used in this Act means a hospital, clinic (including those specified by Cabinet Order as equivalents to these medical institutions; the same applies in the following paragraph, Article 38, paragraph (2), Article 42, paragraph (1), Article 44-3-3, paragraph (1), and Article 50-4, paragraph (1)), or pharmacy designated by a prefectural governor as a medical institution that, based on a notification pursuant to the provisions of Article 36-2, paragraph (1) (limited to notifications that include the measures listed in items (ii) or (iii) of that paragraph) or a medical care agreement pursuant to Article 36-3, paragraph (1) (limited to medical care agreements that include the measures listed in Article 36-2, paragraph (1), items (ii) or (iii)), provides medical services pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare prescribed in Article 44-3-2, paragraph (1) (including cases where it is applied mutatis mutandis by Cabinet Order based on the provisions of Article 44-9, paragraph (1)) or Article 50-3, paragraph (1).
- (18) The term "designated medical institution for tuberculosis" as used in this Act means a hospital or clinic or a pharmacy designated by a prefectural governor as a medical institution in charge of proper medical care for patients with tuberculosis.
- (19) The term "pathogens and toxins" as used in this Act means infectious disease-causing pathogens and toxins.
- (20) The term "toxin" as used in this Act means a substance which is produced by a pathogen causing an infectious disease and which is capable of causing the onset of disease or death, if it enters the human body, including substances such as those artificially synthesized, and representing a structural formula identical to that of a certain natural toxin (referred to below as a "synthetic toxin").
- (21) The term "specified pathogens and toxins" as used in this Act means class I

pathogens and toxins, class II pathogens and toxins, class III pathogens and toxins, and class IV pathogens and toxins.

(22) The term "class I pathogens and toxins " as used in this Act means the pathogens and toxins stated below (excluding pathogens and toxins contained in the medicines or regenerative medical products approved under the provisions of Article 14, paragraph (1), Article 23-2-5, paragraph (1), or Article 23-25, paragraph (1) of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145 of 1960) or certified under the provisions of Article 23-2-23, paragraph (1) of that Act or other pathogens and toxins equivalent to those (referred to below as "medicines or other substances") which are designated by the Minister of Health, Labour and Welfare as substances that are highly unlikely to cause the development of a disease in humans):

- (i) Guaranito virus, Sabia virus, Junin virus, Machupo virus, and Lassa virus, in the genus Arenavirus;
- (ii) Ivory Coast ebolavirus, Zair ebolavirus, Sudan ebolavirus, and Reston ebolavirus, in the genus Ebolavirus;
- (iii) variola virus (also known as the smallpox virus), in the genus Orthopoxvirus;
- (iv) Crimean-Congo haemorrhagic fever virus, in the genus Nairovirus;
- (v) Lake Victoria marburgvirus, in the genus Marburgvirus;
- (vi) beyond what is stated in the preceding items, the pathogens and toxins specified by Cabinet Order as being pathogenic to the same degree as the substances stated in the preceding items and being likely to have extremely serious effects on the lives of the people and public health.

(23) The term "class II pathogens and toxins " as used in this Act means the pathogens and toxins stated below (excluding the medicines or other substances designated by the Minister of Health, Labour and Welfare as substances that are highly unlikely to cause the development of a disease in humans):

- (i) *Y. pestis* (also known as plague bacillus), in the genus *Yersinia*;
- (ii) *C. botulinum* (also known as *Bacillus botulinus*), in the genus *Clostridium*;
- (iii) SARS coronavirus, in the genus *Betacoronavirus*;
- (iv) *B. anthracis* (also known as *Bacillus anthracis*), in the genus *Bacillus*;
- (v) *F. tularensis* subsp. *holarctica*, in the genus *Francisella*;
- (vi) botulinum toxin (including synthetic toxins with a structural formula that is identical to that of botulinum toxin);
- (vii) beyond what is stated in the preceding items, the pathogens and toxins specified by Cabinet Order as being pathogenic to the same degree as the substances stated in the preceding items and as being likely to seriously affect the lives of the people and public health.

- (24) The term "class III pathogens and toxins" as used in this Act means the pathogens and toxins stated below (excluding the medicines or other substances designated by the Minister of Health, Labour and Welfare as substances that are highly unlikely to cause the development of a disease in humans):
- (i) *C. burnetii*, within the genes Coxiella;
 - (ii) *M. tuberculosis* (also known as tubercle bacillus), within the genes Mycobacterium (limited to substances that are resistant to isonicotinic acid hydrazide, rifampicin, or other drugs specified by Cabinet Order as being available for the medical treatment of tuberculosis);
 - (iii) rabies virus, within the genes Lyssavirus;
 - (iv) beyond what is stated in the preceding three items, the pathogens and toxins specified by Cabinet Order as being pathogenic to the same degree as the substances stated in the preceding three items and as being likely to affect the lives of the people and public health.
- (25) The term "class IV pathogens and toxins" as used in this Act means the pathogens and toxins stated below (excluding the medicines or other substances designated by the Minister of Health, Labour and Welfare as substances that are highly unlikely to cause the development of a disease in humans):
- (i) influenza A viruses, in the genus Influenzavirus A (limited to those involving a serosubtype specified by Cabinet Order (excluding pathogens of novel and reemerging influenza and coronavirus infections) or any pathogen of a novel and reemerging influenza or coronavirus infection);
 - (ii) *E. coli* (also known as coliform bacteria), in the genus *Escherichia* (limited to Enterohaemorrhagic *Escherichia coli*);
 - (iii) poliovirus, in the genus Enterovirus;
 - (iv) *C. parvum*, in the genus *Cryptosporidium* (limited to those representing genotype 1 or genotype 2);
 - (v) *S. enterica*, in the genus *Salmonella* (limited to those involving typhi or paratyphi A as a serosubtype);
 - (vi) Shiga toxin (including the synthetic toxins with a structural formula identical to that of Shiga toxin);
 - (vii) *S. sonnei*, *S. dysenteriae*, *S. flexneri*, and *S. boydii*, in the genus *Shigella* (also known as dysentery bacillus);
 - (viii) *V. cholera* (also known as cholera bacillus), in the genus *Vibrio* (limited to those involving O1 or O139 as a serotype);
 - (ix) yellow fever virus, in the genus Flavivirus;
 - (x) *M. tuberculosis*, in the genus Mycobacterium (excluding the pathogens stated in item (ii) of the preceding paragraph);
 - (xi) beyond what is stated in the preceding items, the pathogens and toxins

specified by Cabinet Order as being pathogenic to the same degree as the substances stated in the preceding items and as being likely to affect public health.

- (26) When the Minister of Health, Labour and Welfare intends to propose to establish, revise, or repeal a Cabinet Order referred to in paragraph (3), item (vi), the Minister must hear the opinion of the Health Science Council in advance.

(Mutatis Mutandis Application of this Act to Designated Infectious Diseases)
Article 7 Deleted

(Application of This Act to Suspected Disease Carriers and Asymptomatic Carriers)

Article 8 (1) Suspected carriers of a class I infectious disease or any class II infectious disease specified by Cabinet Order are deemed patients with the respective diseases, and the provisions of this Act apply.

- (2) If a person is a suspected disease carrier of a novel and reemerging influenza or coronavirus infection and there are reasonable grounds for suspecting that they are infected with that infectious disease, that person is deemed a patient with a novel and reemerging influenza or coronavirus infection and the provisions of this Act apply.

- (3) Asymptomatic carriers of a class I infectious disease or a novel and reemerging influenza or coronavirus infection are deemed patients with the corresponding disease, and the provisions of this Act apply.

Chapter II Basic Guidelines

(Basic Guidelines)

Article 9 (1) The Minister of Health, Labour and Welfare must formulate a basic guideline for promoting the prevention of infectious diseases in an integrated manner (referred to below as "basic guideline").

- (2) The basic guideline is to provide for the following:
- (i) a basic direction for promoting the prevention of infectious diseases;
 - (ii) matters concerning measures to prevent outbreaks of infectious diseases;
 - (iii) matters concerning measures to prevent the spread of infectious diseases;
 - (iv) matters concerning gathering information, surveys, and research on infectious diseases and pathogens and toxins;
 - (v) matters concerning systems for examining pathogens and toxins and the improvement of examination capabilities;
 - (vi) matters concerning securing systems for providing medical care for infectious diseases;

- (vii) matters concerning securing systems for transferring patients with infectious diseases;
 - (viii) matters concerning the promotion of research and development of medicines intended for medical care for infectious diseases;
 - (ix) matters concerning targets related to securing systems for the provision of medical care for infectious diseases, and securing systems specified by Order of the Ministry of Health, Labour and Welfare as necessary for measures to prevent outbreaks of infectious diseases or the spread of infectious diseases;
 - (x) matters concerning securing accommodation facilities prescribed in Article 44-3, paragraph (2) or Article 50-2, paragraph (2);
 - (xi) matters concerning the improvement of the living environment during recuperation for the persons subject to voluntary restraint due to a novel and reemerging influenza or coronavirus infection prescribed in Article 44-3-2, paragraph (1), or the persons subject to voluntary restraint due to a new infectious disease prescribed in Article 50-3, paragraph (1);
 - (xii) matters concerning comprehensive coordination pursuant to the provisions of Article 44-5, paragraph (1) (including cases where it is applied mutatis mutandis pursuant to Article 44-8), Article 51-4, paragraph (1) or Article 63-3, paragraph (1), or the instruction policy pursuant to the provisions of Article 51-5, paragraph (1), Article 63-2 or Article 63-4;
 - (xiii) matters concerning securing materials and supplies required for infectious disease countermeasures prescribed in Article 53-16, paragraph (1);
 - (xiv) matters concerning raising public awareness and dissemination of information on infectious diseases, and matters concerning respecting the human rights of patients with infectious diseases and other persons in similar situations;
 - (xv) matters concerning the development and enhancement of the qualifications of human resources to prevent infectious diseases;
 - (xvi) matters concerning securing health center systems to prevent infectious diseases;
 - (xvii) matters concerning securing systems for correct treatment of specified pathogens and toxins;
 - (xviii) matters concerning measures to prevent outbreaks and the spread of infectious diseases, to examine pathogens and toxins, and to provide medical care in emergencies (including matters concerning securing a system of communications between the national and local governments and among local governments); and
 - (xix) other important matters concerning the prevention of infectious diseases.
- (3) Based on an evaluation of the effectiveness of the measures for preventing infectious diseases, the Minister of Health, Labour and Welfare is to review the

matters listed in items (v), (vi), (x), (xi), (xiii), (xv), (xvi), and (xviii) of the preceding paragraph (referred to below as "specified matters" in this paragraph) at least every three years and the matters other than the specified matters in the preceding items at least every six years, and revise the basic guideline if they find it necessary.

- (4) When the Minister of Health, Labour and Welfare intends to formulate or revise the basic guideline, the Minister must consult with the heads of the relevant administrative organs and hear the opinions of the Health Science Council in advance.
- (5) When the Minister of Health, Labour and Welfare has formulated or revised the basic guideline, the Minister must release it without delay.

(Prevention Programs)

Article 10 (1) Prefectural governments must formulate a program for implementing measures to prevent infectious diseases (referred to below as a "prevention program" in this Article and paragraph (2) of the following Article) in line with the basic guideline.

- (2) The prevention programs in the preceding paragraph are to provide for the following in the relevant prefectural governments:
 - (i) matters concerning measures to prevent outbreaks and the spread of a infectious diseases based on regional circumstances;
 - (ii) matters concerning gathering information, surveys, and research on infectious diseases and pathogens and toxins;
 - (iii) matters concerning systems for examining pathogens and toxins and the improvement of examination capabilities;
 - (iv) matters concerning securing systems for providing medical care for infectious diseases;
 - (v) matters concerning securing systems for transferring patients with infectious diseases;
 - (vi) matters concerning targets related to securing systems for the provision of medical care for infectious diseases, and securing the systems specified by Order of the Ministry of Health, Labour and Welfare as necessary for measures to prevent outbreaks of infectious diseases or the spread of infectious diseases;
 - (vii) matters concerning securing the accommodation facilities prescribed in Article 44-3, paragraph (2) or Article 50-2, paragraph (2);
 - (viii) matters concerning the improvement of the living environment during recuperation for the persons subject to voluntary restraint due to a novel and reemerging influenza or coronavirus infection prescribed in Article 44-3-2, paragraph (1), or the persons subject to voluntary restraint due to a new infectious disease prescribed in Article 50-3, paragraph (1).

- (ix) matters concerning the policy for comprehensive coordination pursuant to the provisions of Article 63-3, paragraph (1) or instructions pursuant to the provisions of Article 63-4;
 - (x) matters concerning the development and enhancement of the qualifications of human resources to prevent infectious diseases;
 - (xi) matters concerning securing health center systems to prevent infectious diseases; and
 - (xii) matters concerning measures to prevent outbreaks and the spread of infectious diseases, to examine pathogens and toxins, and to provide medical care in emergencies (including securing systems for coordination with the national government and communications among local governments).
- (3) In the prevention program described in paragraph (1), in addition to the matters listed in the items of the preceding paragraph, efforts are to be made to prescribe matters concerning the dissemination of knowledge on infectious diseases in the prefectural government.
- (4) If the basic guideline is revised, prefectural governments are to review the relevant prevention programs they established and revise those programs when it is found to be necessary. The same applies whenever a prefectural government finds it necessary to revise its prevention program as a result of surveying, analyzing and evaluating the status of implementation of the prevention program.
- (5) The Minister of Health, Labour and Welfare may provide prefectures with the necessary advice concerning the methods of preparing prevention programs and other technical matters important for preparing prevention programs.
- (6) When a prefectural government intends to formulate or revise a prevention program, the prefectural government must discuss the matter with the prefectural coordination council prescribed in paragraph (1) of the following Article in advance in order to ensure the consistency of measures for preventing infectious diseases in its area and to utilize its expert knowledge.
- (7) When a prefectural government intends to formulate or revise a prevention program, the prefectural government must hear the opinion of municipal governments (excluding cities and special wards with a public health center (referred to below as "cities and special wards with a public health center")) in advance.
- (8) When formulating or revising a prevention program, the prefectural government must endeavor to ensure consistency with the medical care plan prescribed in Article 30-4, paragraph (1) of the Medical Care Act (Act No. 205 of 1948) and the prefectural action plan prescribed in Article 7, paragraph (1) of the Act on Special Measures Against Novel and Reemerging Influenza or Coronavirus Infection (Act No. 31 of 2012).
- (9) When a prefectural government has formulated or revised a prevention

- program, the prefectural government is to submit its revised version to the Minister of Health, Labour and Welfare without delay.
- (10) When the Minister of Health, Labour and Welfare finds it necessary, they may give advice, recommendations, or assistance to a prefectural government concerning the prevention program submitted pursuant to the provisions of the preceding paragraph.
- (11) A prefectural government must make a report to notify the Minister of Health, Labour and Welfare of the progress regarding the matters listed in paragraph (2), item (vi) every fiscal year, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (12) When the Minister of Health, Labour and Welfare receives a report pursuant to the provisions of the preceding paragraph, the Minister is to release the contents of that report as necessary pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (13) The provisions of paragraph (10) apply mutatis mutandis to reports received pursuant to the provisions of paragraph (11).
- (14) Cities and special wards with a public health center must establish a prevention program in accordance with the basic guidelines and the prevention program established by the prefectural government with jurisdiction over those cities and wards.
- (15) The prevention programs described in the preceding paragraph provide for the following matters in those cities and special wards with a public health center:
- (i) matters referred to in items (i), (iii), (v), (viii), and items (x) through (xii) of paragraph (2); and
 - (ii) matters concerning targets related to securing systems for facilitating examinations of pathogens and toxins, and to securing systems specified by Order of the Ministry of Health, Labour and Welfare as necessary for measures to prevent outbreaks or the spread of infectious diseases;
- (16) In the prevention program referred to in paragraph (14), in addition to the matters listed in the items of the preceding paragraph, efforts are to be made to provide for the matters listed in paragraph (2), items (ii) and (vii) in cities and special wards with a public health center and matters concerning the dissemination of knowledge on infectious diseases.
- (17) When formulating or revising a prevention program, cities and special wards with a public health center must endeavor to ensure consistency with the municipal action plan prescribed in Article 8, paragraph (1) of the Act on Special Measures Against Novel and Reemerging Influenza or Coronavirus Infection.
- (18) The provisions of paragraphs (4) through (6) and (9) through (13) will apply mutatis mutandis to the prevention programs established by cities and special

wards with a public health center. In this case, the term "basic guideline" in paragraph (4) is deemed to be replaced with "basic guideline or the prevention program established by the prefectural government that has jurisdiction over those cities and wards with a public health center," the term "the Minister of Health, Labour and Welfare" in paragraph (9) is deemed to be replaced with "the prefectural government; in this case, the prefectural government that has received the program must submit it to the Minister of Health, Labour and Welfare without delay," the term "the Minister of Health, Labour and Welfare" in paragraphs (10) and (11) is deemed to be replaced with "the prefectural government," the term "paragraph (2), item (vi)" in the latter paragraph is deemed to be replaced with "paragraph (15), item (ii)," the term "pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare" in that paragraph is deemed to be replaced with "pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare; in this case, the prefectural government that received the report must report its contents to the Minister of Health, Labour and Welfare without delay," and the term "the preceding paragraph" in paragraph (12) is deemed to be replaced with "the second sentence of the preceding paragraph is applied mutatis mutandis pursuant to paragraph (18) following the deemed replacement of terms."

(19) Medical institutions, organizations that examine pathogens and toxins, and administrators of accommodation facilities must endeavor to cooperate as necessary to establish the necessary systems in the area to contribute to the promotion of a successful implementation of the prevention program under paragraphs (1) and (14).

(Prefectural Coordination Council)

Article 10-2 (1) In order to develop a system for coordination and cooperation in implementing measures to prevent an outbreak and the spread of an infectious disease, a council (referred to below as a "prefectural coordination council" in this Article) consisting of prefectural governments, cities and special wards with a public health center, designated medical institutions for infectious diseases, groups of persons with relevant knowledge and experience in medical care, and fire defense organizations (meaning the organizations stated in each item of Article 9 of the Fire Defense Organization Act (Act No. 226 of 1947)), and other relevant organizations is to be established.

(2) The prefectural coordination council is to share information on the implementation status of prevention programs established by a prefectural government or cities and special wards with a public health center and useful information for the implementation of those programs by ensuring mutual communication among its members, and is to promote closer coordination among its members.

- (3) When there has been an announcement of an outbreak or related event of a novel and reemerging influenza or coronavirus infection as prescribed in Article 16, paragraph (2), the prefectural government is to hold a prefectural coordination council and endeavor to discuss the implementation of the measures necessary to prevent the outbreak and spread of the infectious disease.
- (4) With regard to the matters agreed upon through consultation at the prefectural coordination council, its members must respect the results of the consultation.
- (5) Beyond what is provided for in each of the preceding paragraphs, necessary matters concerning the prefectural coordination council are specified by the council itself.

(Guidelines on Prevention of Specified Infectious Diseases)

Article 11 (1) With respect to certain infectious diseases which are specified by Order of the Ministry of Health, Labour and Welfare as diseases for which it is particularly necessary to promote preventive measures in an integrated manner, the Minister of Health, Labour and Welfare is to prepare and release the guidelines to facilitate investigations into the causes of those infectious diseases, prevention of their outbreaks and spreading, provision of medical care, promotion of research and development, international coordination, and promotion of other integrated preventive measures customized for each of those infectious diseases (referred to below as "prevention guidelines for specified infectious diseases" in the following paragraph).

- (2) When the Minister of Health, Labour and Welfare intends to formulate or revise the prevention guidelines for specified infectious diseases, the Minister must hear the opinion of the Health Science Council in advance.

Chapter III Gathering and Public Disclosure of Information on Infectious Diseases

(Notification by Physicians)

Article 12 (1) If a physician has diagnosed either of the following persons, the physician must notify the prefectural governor (in the case of a city or special ward with a public health center, the mayor of that city or ward; the same applies below in this Chapter (excluding the following paragraph and paragraph (3), the following Article, paragraphs (3) and (4), Article 14, paragraphs (1) and (6), Article 14-2, paragraphs (1) and (7), Article 15, paragraph (13), and Article 16, paragraphs (2) and (3))) through the chief of the nearest public health center, except in the cases specified by Order of the Ministry of Health, Labour and Welfare, stating the person's name, age, gender

and other information specified by Order of the Ministry of Health, Labour and Welfare immediately if the person is the one stated in item (i), or the person's age, gender and other information specified by Order of the Ministry of Health, Labour and Welfare within seven days if the person is the one stated in item (ii):

- (i) a patient with a class I infectious disease, a patient or asymptomatic carrier of a class II, class III, or class IV infectious disease, a patient with any of the class V infectious diseases specified by Order of the Ministry of Health, Labour and Welfare or a novel and reemerging influenza or coronavirus infection, or a person suspected to be infected with a new infectious disease; or
- (ii) a patient with any of the class V infectious diseases specified by Order of the Ministry of Health, Labour and Welfare (including asymptomatic carriers of any of the class V infectious diseases specified by Order of the Ministry of Health, Labour and Welfare).

(2) A prefectural governor who has received a notification pursuant to the provisions of the preceding paragraph must immediately report the contents of the notification to the Minister of Health, Labour and Welfare by electronic or magnetic means (means a means that utilizes an electronic data processing system or any other means that utilizes the information and communications technology specified by Order of the Ministry of Health, Labour and Welfare; except for Article 15, paragraphs (13) and (14), Article 36-5, paragraphs (4) through (6), Article 36-8, paragraph (3), Article 44-3-5, paragraph (4), and Article 50-6, paragraph (4), the same applies below) with regard to the notification related to a person listed in item (i) of that paragraph and within the period specified by Order of the Ministry of Health, Labour and Welfare with regard to the notification related to a person listed in item (ii) of that paragraph.

(3) When a prefectural governor has received a notification pursuant to the provisions of paragraph (1) with regard to any of the persons listed in the following items, the prefectural governor must notify the persons specified in each of the items of the contents of the notification by electronic or magnetic means:

- (i) a person who resides outside the area under the prefectural jurisdiction: the prefectural governor having jurisdiction over the place of residence (if the place of residence is within a city or special ward with a public health center, the mayor of that city or ward and the prefectural governor having jurisdiction over the place of residence) of the person; and
- (ii) a person who resides in an area under the jurisdiction of the mayor of a city or special ward with a public health center under the prefectural jurisdiction: the mayor of a city or special ward with a public health center having

- jurisdiction over the place of residence of the person.
- (4) The provisions of the preceding two paragraphs will apply *mutatis mutandis* when the mayor of a city or special ward with a public health center receives a notification pursuant to the provisions of paragraph (1). In this case, "the Minister of Health, Labour and Welfare" in paragraph (2) is deemed to be "the Minister of Health, Labour and Welfare and the prefectural governor having jurisdiction over the city or special ward with a public health center (referred to as the "competent prefectural governor" in each item of the following paragraph)", the term "under the prefectural jurisdiction" in items (i) and (ii) of the preceding paragraph is deemed to be replaced with "under the jurisdiction of the competent prefectural governor," and the term "the mayor of a city or special ward with a public health center" in the latter item is deemed to be replaced with "the mayor of a city or special ward with a public health center located outside that city or ward."
 - (5) A physician who is to submit a notification pursuant to the provisions of paragraph (1) (limited to a physician at a designated medical institution for infectious diseases specified by Order of the Ministry of Health, Labour and Welfare) must submit the notification by electronic or magnetic means so that a person who is to report or notify (referred to below as "report or notification" in this Article) the contents of the notification pursuant to the provisions of paragraph (2) or (3) (including cases where these provisions are applied *mutatis mutandis* pursuant to the preceding paragraph), or a person who is to receive the report or notification may inspect it.
 - (6) A physician who is to submit a notification pursuant to the provisions of paragraph (1) (excluding a physician of a designated medical institution for infectious diseases specified by Order of the Ministry of Health, Labour and Welfare stated in the preceding paragraph) must do so using electronic or magnetic means so that a person who is to report or notify the contents of the notification and a person who is to receive the report or notification may inspect it.
 - (7) When a notification under the provisions of paragraph (1) has been submitted by the method prescribed in the preceding two paragraphs, the person who is to make a report or notification is deemed to have made it.
 - (8) A physician who gives patients with any of the chronic infectious diseases specified by Order of the Ministry of Health, Labour and Welfare medical treatment must notify the prefectural governor through the chief of the nearest public health center every fiscal year to report their age, gender, and other information specified by Order of the Ministry of Health, Labour and Welfare, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
 - (9) The provisions of paragraphs (2) through (7) apply *mutatis mutandis* to the

notification in the preceding paragraph. In this case, the phrase "immediately, with regard to the notification related to a person listed in item (i) of the that paragraph and within the period specified by Order of the Ministry of Health, Labour and Welfare, with regard to the notification related to a person listed in item (ii) of that paragraph" in paragraph (2) is deemed to be replaced with "within the period specified by Order of the Ministry of Health, Labour and Welfare."

- (10) The provisions of paragraphs (1) through (7) apply mutatis mutandis when a physician has examined the corpse of a person who had died of an infectious disease prescribed in any item of paragraph (1) (including a person suspected to have died of that infectious disease).

(Notification by Veterinarians)

Article 13 (1) If a veterinarian diagnoses a monkey or another animal specified by Cabinet Order as an animal that is highly likely to transmit diseases to humans with Ebola haemorrhagic fever, Marburg virus disease, or any other infectious disease which is specified by Cabinet Order and is designated as a class I, class II, class III, or class IV infectious disease or a novel and reemerging influenza or coronavirus infection, and that veterinarian determines that the monkey or that other animal is infected or suspected to be infected with those infectious diseases, the veterinarian must immediately notify the prefectural governor through the chief of the nearest public health center, including the name of the owner of the animal (or the person controlling the animal if it is controlled by anyone other than its owner; the same applies below in this Article) and other information specified by Order of the Ministry of Health, Labour and Welfare, by submitting a notification for each of those infectious diseases; provided, however, that this does not apply when the animal is intentionally infected with any of those infectious diseases for the purpose of experimentation.

- (2) The owner of an animal specified by Cabinet Order must submit a notification under the provisions of the preceding paragraph if the owner finds that the animal is infected or suspected of being infected with any of the infectious diseases specified by Cabinet Order as referred to in that paragraph when the animal is not diagnosed by a veterinarian; provided, however, that this does not apply if the animal is intentionally infected with any of those infectious diseases for the purpose of experimentation.
- (3) The prefectural governor receiving a notification submitted under the provisions of either of the preceding two paragraphs must immediately inform the Minister of Health, Labour and Welfare by electronic or magnetic means of the contents of the notification.
- (4) If a prefectural governor receives a notification pursuant to the provisions of

paragraph (1) or paragraph (2) with regard to an animal listed in the following items, the prefectural governor must notify the person specified in each of the items of the contents of the notification by electronic or magnetic means:

- (i) an animal raised outside the area under the prefectural jurisdiction: the prefectural governor having jurisdiction over the location where the animal was raised (if the place is within a city or special ward with a public health center, the mayor of that city or ward and the prefectural governor having jurisdiction over the location); and
 - (ii) an animal raised inside the area under the jurisdiction of the mayor of a city or special ward with a public health center under the prefectural jurisdiction: the mayor of the city or special ward with a public health center having jurisdiction over the location where the animal was raised.
- (5) The provisions of the preceding two paragraphs apply *mutatis mutandis* where the mayor of a city or special ward with a public health center receives a notification pursuant to the provisions of paragraph (1) or paragraph (2). In this case, "the Minister of Health, Labour and Welfare" in paragraph (3) is deemed to be "the Minister of Health, Labour and Welfare and the prefectural governor having jurisdiction over that city or ward (referred to as the "competent prefectural governor" in each item of the following paragraph)," the term "under the prefectural jurisdiction" in items (i) and (ii) of the preceding paragraph is deemed to be replaced with "under the jurisdiction of the competent prefectural governor," and the term "the mayor of the city or special ward with a public health center" in the latter item is deemed to be replaced with "the mayor of a city or special ward with a public health center located outside that city or ward."
- (6) The provisions of paragraph (6) of the preceding Article apply *mutatis mutandis* to a veterinarian who is to submit a notification pursuant to the provisions of paragraph (1), and the provisions of paragraph (7) of that Article apply *mutatis mutandis* to a person who is to submit a report or notification pursuant to the provisions of paragraph (3) or paragraph (4) (including cases where these provisions are applied *mutatis mutandis* pursuant to the preceding paragraph). In this case, the term "report, etc. of the contents" in paragraph (6) of that Article is deemed to be replaced with "report or notification (referred to below as "reports or notifications" in this Article) pursuant to the provisions of paragraph (3) or paragraph (4) of the following Article (including cases where these provisions are applied *mutatis mutandis* pursuant to paragraph (5) of that Article)," the term "paragraph (1)" in paragraph (7) of that Article is deemed to be replaced with "paragraph (1) of the immediately following Article," and the term "the preceding two paragraphs" in paragraph (7) of that Article is deemed to be replaced with "the preceding paragraph applied *mutatis mutandis* pursuant to paragraph (6) of

that Article."

- (7) The provisions from paragraphs (1) and (3) to the preceding paragraph apply mutatis mutandis when a veterinarian who has examined the corpse of an animal specified by Cabinet Order as referred to in paragraph (1) determines in their examination after the death of the animal that the animal was infected or is suspected to have been infected with an infectious disease specified by Cabinet Order as referred to in that paragraph, and the provisions from paragraphs (2) to the preceding paragraph apply mutatis mutandis when the owner of the corpse of an animal specified by Cabinet Order as referred to in paragraph (1) finds that the animal was infected or is suspected to have been infected with an infectious disease specified by Cabinet Order as referred to in that paragraph.

(Ascertaining the Status and Progress of Outbreaks of Infectious Diseases)

Article 14 (1) Pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, prefectural governors will designate the hospitals or clinics, upon obtaining consent from their proprietors, which are to be responsible for submitting notifications of the status of outbreaks of the class V infectious diseases specified by Order of the Ministry of Health, Labour and Welfare or notifications of the suspected cases for the class II infectious diseases, class III infectious diseases, class IV infectious diseases, or class V infectious diseases specified by Order of the Ministry of Health, Labour and Welfare.

- (2) When a physician at a hospital or clinic designated under the provisions of the preceding paragraph (referred to below as "designated notification organization" in this Article) has diagnosed a patient infected with any of the class V infectious diseases specified by Order of the Ministry of Health, Labour and Welfare as referred to in the preceding paragraph (including asymptomatic carriers of the class V infectious diseases specified by Order of the Ministry of Health, Labour and Welfare; the same applies below in this paragraph) or diagnosed a suspected case of any of the class II infectious diseases, class III infectious diseases, class IV infectious diseases, or class V infectious diseases specified by Order of the Ministry of Health, Labour and Welfare, or when a physician of a designated notification organization has conducted an examination after death of the corpse of a person who had died of any of the class V infectious diseases specified by Order of the Ministry of Health, Labour and Welfare as referred to in the preceding paragraph, the administrator of the designated notification organization must notify the prefectural governor having jurisdiction over the location of the designated notification organization pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, to report the age, gender, and other information specified by Order of

- the Ministry of Health, Labour and Welfare on the patient or deceased.
- (3) A prefectural governor receiving a notification submitted under the provisions of the preceding paragraph must report its contents to the Minister of Health, Labour and Welfare by electronic or magnetic means pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (4) The provisions of Article 12, paragraphs (5) and (6) apply mutatis mutandis to the notification pursuant to the provisions of paragraph (2), and the provisions of paragraph (7) of that Article apply mutatis mutandis to the report pursuant to the provisions of the preceding paragraph. In this case, the term "physician who is to" in paragraph (5) and paragraph (6) of same Article is deemed to be replaced with "administrator of a designated notification organization who is to," the term "a report or notification (referred to below as "report or notification" in this Article) of the contents of the notification pursuant to the provisions of paragraph (2) or (3) (including cases where these provisions are applied mutatis mutandis pursuant to the preceding paragraph)" in paragraph (5) of that Article is deemed to be replaced with "report (referred to below as "report" in this Article) on the contents of the notification pursuant to the provisions of Article 14, paragraph (3)," the term "the report, etc." in that paragraph is deemed to be replaced with "the report," the term "report, etc." in paragraphs (6) and (7) of that Article is deemed to be replaced with "report," and the term "paragraph (1)" in the latter paragraph is deemed to be replaced with "Article 14, paragraph (2)."
- (5) A designated notification organization may decline the designation under the provisions of paragraph (1) subject to a notice period of at least 30 days.
- (6) If the administrator of a designated notification organization violates the provisions of paragraph (2) or if a designated notification organization is found to be unsuitable to perform the duty of submitting a notification pursuant to the provisions of that paragraph, the prefectural governor may revoke the designation under the provisions of paragraph (1).
- (7) When the Minister of Health, Labour and Welfare finds that, among suspected cases of class II infectious diseases, class III infectious diseases, class IV infectious diseases or class V infectious diseases, an infectious disease specified by Order of the Ministry of Health, Labour and Welfare referred to in paragraph (1) could cause severe symptoms following infection, or there is an outbreak or risk of an outbreak, the Minister is to notify the prefectural governor of those facts.
- (8) A prefectural governor who has received a notification may, when a physician in a hospital or clinic other than a designated notification organization located within the area under the jurisdiction of the prefectural governor diagnoses a patient with an infectious disease or examines the corpse of a person who has died due to the infectious disease, pursuant to the provisions of Order of the

Ministry of Health, Labour and Welfare, require the physician to report the age, sex, and other information specified by Order of the Ministry of Health, Labour and Welfare on the patient or deceased person. In this case, the physician who is requested to submit the notification must not refuse to do so unless there are reasonable grounds.

- (9) The provisions of paragraph (3) apply mutatis mutandis to the prefectural governor who has received a notification pursuant to the provisions of the preceding paragraph.
- (10) The provisions of Article 12, paragraphs (5) and (6) apply mutatis mutandis to the notification pursuant to the provisions of paragraph (8), and the provisions of paragraph (7) of that Article apply mutatis mutandis to the report pursuant to the provisions of paragraph (3) as applied mutatis mutandis pursuant to the preceding paragraph. In this case, the term "physician who is to" in paragraphs (5) and (6) of that Article is deemed to be replaced with "physician at a hospital or clinic other than a designated notification organization who is to," the term "a report or notification (referred to below as "report or notification" in this Article) of the contents of the notification pursuant to the provisions of paragraph (2) or (3) (including cases where these provisions are applied mutatis mutandis pursuant to the preceding paragraph)" in paragraph (5) of that Article is deemed to be replaced with "report (referred to below simply as "report" in this Article) of the contents of the notification pursuant to the provisions of paragraph (3) of that Article applied mutatis mutandis in Article 14, paragraph (9)," the term "the reports, etc." in that paragraph is deemed to be replaced with "report," the term "reports, etc." in paragraphs (6) and (7) of that Article is deemed to be replaced with "report," and the term "paragraph (1)" in the latter paragraph is deemed to be replaced with "Article 14, paragraph (8)."

Article 14-2 (1) Pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, prefectural governors will designate hospitals or clinics or the hygiene inspection stations, upon obtaining consent of their proprietors, which are to be responsible for submitting specimens sampled from patients infected with any of the class V infectious diseases specified by Order of the Ministry of Health, Labour and Welfare or the pathogens of those infectious diseases.

- (2) The administrator of a hospital or clinic or a hygiene inspection station designated under the provisions of the preceding paragraph (referred to below as "designated submitting organization" in this Article) must submit a part of the specimens sampled from a patient infected with any of the class V infectious diseases specified by Order of the Ministry of Health, Labour and Welfare as referred to in that paragraph or the pathogens of any of those

infectious diseases pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare to the prefectural governor who designated the designated submitting organization pursuant to the provisions of that paragraph whenever a physician of the designated submitting organization (limited to hospitals or clinics) has diagnosed the patient or an employee of the designated submitting organization (limited to hygiene inspection stations) has examined the specimens sampled from the patient or pathogens of those infectious diseases.

- (3) Prefectural governors must conduct an examination of the specimens or the pathogens causing infectious diseases as submitted in accordance with the provisions of the preceding paragraph, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (4) Prefectural governors must report the result of the examination referred to in the preceding paragraph and other matters specified by Order of the Ministry of Health, Labour and Welfare to the Minister of Health, Labour and Welfare by electronic or magnetic means pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (5) When the Minister of Health, Labour and Welfare finds it necessary to personally conduct an examination, the Minister may ask the prefectural governor to submit a part of the specimens or the pathogens of the infectious disease which had been submitted to the prefectural governor pursuant to the provisions of paragraph (2).
- (6) A designated submitting organization may decline the designation under the provisions of paragraph (1) subject to a notice period of at least 30 days.
- (7) If the administrator of a designated submitting organization violates the provisions of paragraph (2) or if a designated submitting organization is found to be unsuitable to perform the duty of submission pursuant to the provisions of that paragraph, the prefectural governor may revoke the designation under the provisions of paragraph (1).

(Investigation into the Status, Progress, and Causes of Outbreaks of Infectious Diseases)

Article 15 (1) When a prefectural governor finds it necessary to prevent an outbreak of an infectious disease or clarify the status of an outbreak, its progress, and the cause of an outbreak, the prefectural governor may direct its relevant officials to interview the patients, suspected disease carriers, or asymptomatic carriers of a class I, class II, class III, class IV, or class V infectious disease or a novel and reemerging influenza or coronavirus infection, a person with symptoms of a new infectious disease, or the owners and managers of animals or their corpses likely to transmit those infectious diseases to humans, and other persons concerned, or to carry out the necessary

investigations.

- (2) When the Minister of Health, Labour and Welfare finds it urgently necessary to prevent an outbreak or the spread of an infectious disease, the Minister may direct relevant officials to interview the patients, suspected disease carriers, or asymptomatic carriers of a class I, class II, class III, class IV, or class V infectious disease or a novel and reemerging influenza or coronavirus infection, a person with symptoms of a new infectious disease, or the owners and managers of animals or their corpses likely to transmit those infectious diseases to humans, and other persons concerned, or to carry out the necessary investigations.
- (3) When a prefectural governor finds it necessary during the investigations carried out under the provisions of paragraph (1), the prefectural governor may direct relevant officials to request that any person stated in the following items submit the specimens or pathogens of the infectious disease prescribed in each of those items or accept the specimens collected by relevant officials, or request that the custodian (meaning a person who exercises parental authority or a guardian; the same applies below) of any person stated in items (i) to (iii) submit the specimens stated in each of those items item or have the persons stated in each of the items accept the specimens collected by relevant officials:
- (i) a patient, suspected disease carrier or asymptomatic carrier of a class I or class II infectious disease or a novel and reemerging influenza or coronavirus infection, or a person who is justifiably suspected of being infected with that infectious disease: specimens sampled from the person;
 - (ii) a patient, suspected disease carrier or asymptomatic carrier of a class III, class IV, or class V infectious disease, or a person who is justifiably suspected of being infected with that infectious disease: specimens sampled from the person;
 - (iii) a person with symptoms of a new infectious disease or a person who is justifiably suspected of being infected with a new infectious disease: specimens sampled from the person;
 - (iv) the owner or administrator of an animal likely to transmit a class I or class II infectious disease or a novel and reemerging influenza or coronavirus infection to humans or the owner or administrator of the corpse of that animal: specimens sampled from the animal or its corpse;
 - (v) the owner or administrator of an animal likely to transmit a class III infectious disease, a class IV infectious disease, or a class V infectious disease to humans or the owner or administrator of the corpse of that animal: specimens sampled from the animal or its corpse;
 - (vi) the owner or administrator of an animal likely to transmit a new infectious disease to humans or the owner or administrator of the corpse of that animal: specimens sampled from the animal or its corpse;

- (vii) a person possessing the specimens referred to in item (i) or pathogens of an infectious disease prescribed in that item separated from those specimens: the specimens or pathogens of the infectious disease;
 - (viii) a person possessing the specimens referred to in item (ii) or pathogens of an infectious disease prescribed in that item separated from those specimens: the specimens or pathogens of the infectious disease;
 - (ix) a person possessing the specimens referred to in item (iii) or pathogens of a new infectious disease separated from those specimens: the specimens or pathogens of that new infectious disease;
 - (x) a person possessing the specimens referred to in item (iv) or pathogens of an infectious disease prescribed in that item separated from those specimens: the specimens or pathogens of the infectious disease;
 - (xi) a person possessing the specimens referred to in item (v) or pathogens of an infectious disease prescribed in that item separated from those specimens: the specimens or pathogens of the infectious disease; or
 - (xii) a person possessing the specimens referred to in item (vi) or pathogens of a new infectious disease separated from those specimens: the specimens or pathogens of that new infectious disease.
- (4) In order to prevent outbreaks of infectious diseases or to prevent the spread of infectious diseases by promptly detecting patients with infectious diseases, the prefectural governor is to review the nature of infectious diseases, consider the medical condition or number of patients with infectious diseases in the area under the jurisdiction of the prefectural governor, the types of facilities or work where infectious diseases occur, the circumstances of the outbreak and spread of the various types of infectious disease, and the risk of spreading infectious diseases to the public and other circumstances, and make requests pursuant to the provisions of the preceding paragraph.
- (5) The prefectural governor must conduct an examination of the specimens or the pathogens of an infectious disease submitted or the specimens collected by relevant officials in accordance with the provisions of paragraph (3), pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (6) The provisions of paragraph (3) apply mutatis mutandis to the necessary investigations carried out under the provisions of paragraph (2).
- (7) A person who has been requested to cooperate in an interview or necessary investigation pursuant to the provisions of paragraph (1) or paragraph (2) (excluding specified patients and persons with symptoms prescribed in the following paragraph) must endeavor to cooperate in the interview or necessary investigation.
- (8) When a person who is a patient with a class 1 or class 2 infectious disease or a novel and reemerging influenza or coronavirus infection, or a person with symptoms of a new infectious disease (referred to below as "specified patients

- and persons with symptoms") does not cooperate in the interview or necessary investigations by the employees pursuant to the provisions of paragraphs (1) and (2) without reasonable grounds if they find it necessary to prevent outbreaks or the spread of those infectious diseases, a prefectural governor or the Minister of Health, Labour and Welfare may order those specified patients and persons with symptoms to cooperate in an interview or the necessary investigations (excluding requests pursuant to the provisions of paragraph (3) (including cases where it is applied mutatis mutandis in paragraph (6), cases where it is applied mutatis mutandis by Cabinet Order pursuant to the provisions of Article 44-9, paragraph (1) (including cases where the period of the Cabinet Order in paragraph (1) of that Article is extended by Cabinet Order in paragraph (2) of that Article), and cases where it is applied mutatis mutandis by Cabinet Order pursuant to the provisions of Article 53, paragraph (1) (including cases where the period of the Cabinet Order in paragraph (1) of that Article is extended by Cabinet Order in paragraph (2) of that Article))).
- (9) The orders of the preceding paragraph are the minimum measures necessary to prevent an outbreak or the spread of an infectious disease based on the risks of spreading the infectious disease to the public, the severity of pathological conditions following infection with the infectious disease, and other circumstances.
- (10) When issuing an order stated in paragraph (8), the prefectural governor or the Minister of Health, Labour and Welfare must, at the same time, notify the recipient of the order in writing of the reason for issuing the order and other matters specified by Order of the Ministry of Health, Labour and Welfare; provided, however, that this will not apply when there is an urgent need for orders to be issued without giving written notice of those matters.
- (11) In the case referred to in the proviso of the preceding paragraph, the prefectural governor or the Minister of Health, Labour and Welfare must, within a reasonable period of time after the order stated in paragraph (8), deliver a document stating the reasons specified in the preceding paragraph and other matters specified by Order of the Ministry of Health, Labour and Welfare.
- (12) Each of the officials referred to in paragraphs (1) and (2) must carry their identification card and present it at the request of any person concerned.
- (13) A prefectural governor and the mayor of a city or special ward with a public health center (referred to below as "prefectural governors and relevant mayors"), pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, must report the findings of the interview or necessary investigations conducted pursuant to the provisions of paragraph (1) by electronic or magnetic means (meaning a method that utilizes an electronic data processing system or any other method that utilizes the information and

communications technology specified by Order of the Ministry of Health, Labour and Welfare; the same applies in the following paragraph, Article 44-3-5, paragraph (4), and Article 50-6, paragraph (4)) to the Minister of Health, Labour and Welfare (in the case of the mayor of a city or special ward with a public health center, the Minister of Health, Labour and Welfare and the prefectural governor having jurisdiction over that city or ward).

- (14) In cases prescribed by Order of the Ministry of Health, Labour and Welfare where a prefectural governor or relevant mayor finds it necessary to prevent the spread of an infectious disease in an area under the jurisdiction of another prefectural governor or relevant mayor, that governor or mayor must notify the other governor or mayor by electronic or magnetic means of the findings of the interview conducted pursuant to the provisions of paragraph (1) or the necessary investigations pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (15) When the Minister of Health, Labour and Welfare finds it necessary to personally conduct an examination, excluding cases involving requests pursuant to the provisions of Article 44-3-5, paragraph (1) or Article 50-6, paragraph (1), the Minister may ask the prefectural governor to submit a part of the specimens or the pathogens of the infectious disease submitted or the specimens collected by the officials under the provisions of paragraph (3).
- (16) When a prefectural governor finds it particularly necessary to conduct an interview or the necessary investigations under the provisions of paragraph (1), the prefectural governor may ask another prefectural governor or the Minister of Health, Labour and Welfare to dispatch an employee or employees of an institute which is engaged in research on the methods of treating infectious diseases, examinations of pathogens and toxins, or other research and development or examinations in connection with infectious diseases (referred to below as "infectious disease research institute") or to provide other necessary assistance.
- (17) The provisions of paragraph (12) apply mutatis mutandis to the employees dispatched pursuant to the provisions of the preceding paragraph.
- (18) Any necessary matters concerning the identification cards referred to in paragraph (12) are specified by Order of the Ministry of Health, Labour and Welfare

(Coordination with Quarantine Station Chiefs)

Article 15-2 (1) If a prefectural governor receives a notice from a quarantine station chief pursuant to the provisions of Article 18, paragraph (3) of the Quarantine Act (Act No. 201 of 1951) (including cases where it is applied mutatis mutandis pursuant to a Cabinet Order based on the provisions of Article 34, paragraph (1) of that Act) stating the instructions given to the

person with a health problem or other matters specified by Order of the Ministry of Health, Labour and Welfare (including cases where that notice is given pursuant to the provisions of Article 34-2, paragraph (3) of that Act), the prefectural governor may direct the prefecture's officials to interview the person with the health problem or other persons concerned or to carry out the necessary investigations.

- (2) The prefectural governor must notify the Minister of Health, Labour and Welfare of the findings of the interview or necessary investigations carried out in accordance with the provisions of the preceding paragraph, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (3) The provisions of paragraph (12) of the preceding Article apply mutatis mutandis when a prefectural governor directs relevant officials to implement a measure prescribed in paragraph (1).

Article 15-3 (1) If a prefectural governor receives a notice from a quarantine station chief pursuant to the provisions of Article 18, paragraph (5) of the Quarantine Act (including cases where it is applied mutatis mutandis pursuant to a Cabinet Order based on Article 34, paragraph (1) of that Act) stating the matters reported with regard to a person prescribed in Article 18, paragraph (4) of that Act pursuant to the provisions of that paragraph (including cases where that notice is given pursuant to the provisions of Article 34-2, paragraph (3) of that Act), the prefectural governor may ask the person to report their body temperature and other facts regarding their state of health during the period specified by the quarantine station chief pursuant to the provisions of Article 18, paragraph (1) of that Act, or direct the prefecture's officials to interview the person.

- (2) If the prefectural governor confirms as a result of a report or interview under the provisions of the preceding paragraph that the person has a health problem, the prefectural governor must, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, immediately report that fact to the Minister of Health, Labour and Welfare, and the prefectural governor may direct relevant officials to interview the person or other persons concerned or to carry out the necessary investigations.
- (3) The prefectural governor must report the findings of the interview or necessary investigations carried out in accordance with the provisions of the preceding paragraph to the Minister of Health, Labour and Welfare, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (4) The provisions of Article 15, paragraph (12) apply mutatis mutandis when a prefectural governor directs relevant officials to implement a measure prescribed in paragraphs (1) and (2).
- (5) When requested by a prefectural governor and after taking into account the

- implementation system of the affairs that the prefectural governor is supposed to handle under the provisions of this Act or Cabinet Order based on this Act and other actual conditions of the region, the Minister of Health, Labour and Welfare is to personally implement the measures prescribed in paragraph (1) on behalf of that prefectural governor if the Minister finds it necessary to prevent the spread of an infectious disease listed in Article 2, item (ii) of the Quarantine Act, an infectious disease designated by Cabinet Order under Article 34, paragraph (1) of that Act (limited to the infectious diseases for which the provisions of Article 18, paragraph (5) of that Act are applied by Cabinet Order), or a new infectious disease prescribed in Article 34-2, paragraph (1) of that Act (limited to the new infectious diseases for which the affairs prescribed in Article 18, paragraph (5) of that Act are carried out according to the provisions of paragraph (3) of that Article) in the area of the prefectural government or the city or special ward with a public health center.
- (6) When the Minister of Health, Labour and Welfare is acting on behalf of the prefectural governor as stipulated in the provisions of paragraph (1) pursuant to the provisions of the preceding paragraph, the Minister is to notify the relevant person of that fact.
- (7) With regard to the application of the provisions of paragraphs (2) and (4) when the Minister of Health, Labour and Welfare is acting on behalf of the prefectural governor as prescribed in the provisions of paragraph (1) pursuant to the provisions of paragraph (5), the term "the prefectural governor" in paragraph (2) is deemed to be "the Minister of Health, Labour and Welfare," the term "report that fact to the Minister of Health, Labour and Welfare and the prefectural governor may direct relevant officials to interview the person" in paragraph (2) is deemed to be "notification of that fact for the prefectural governor having jurisdiction over the location of the residence. In this case, the prefectural governor who has received the notification, may direct relevant officials to interview those persons to whom the notification refers" the term "a prefectural governor" in paragraph (4) is deemed to be "the Minister of Health, Labour and Welfare," the term "paragraphs (1) and (2)" in paragraph (4) is deemed to be "paragraph (1), and when the prefectural governor has the official implement the measures prescribed in paragraph (2)."
- (8) Beyond what is provided for in the preceding two paragraphs, any necessary matters concerning the substitution of the Minister of Health, Labour and Welfare pursuant to the provisions of paragraph (5) are to be specified by Cabinet Order.

(Public Disclosure of Information)

Article 16 (1) The Minister of Health, Labour and Welfare and prefectural governors must analyze the information on infectious diseases gathered

pursuant to the provisions of Article 12 through the preceding Article, and actively release the information on the status, progress, causes of outbreaks of infectious diseases and the information necessary for the prevention and treatment of the infectious diseases in newspapers, by broadcasting via the Internet, or by any other suitable means.

- (2) From the time when an announcement is made pursuant to the provisions of Article 44-2, paragraph (1), Article 44-7, paragraph (1), or Article 44-10, paragraph (1) (referred to below as "announcement of an outbreak or related event of a novel and reemerging influenza or coronavirus infection") until an announcement is made pursuant to the provisions of Article 44-2, paragraph (3) or Article 44-7, paragraph (3), or the abolition of the Cabinet Order of Article 53, paragraph (1) (referred to as "announcement or other official communication that it is no longer recognized as a novel and reemerging influenza or coronavirus infection" in Article 36-2, paragraph (1) and Article 63-4), a prefectural governor may request the necessary cooperation from the mayors of municipalities when it is found to be necessary to raise awareness among residents regarding the information on the situation, progress, and causes of the outbreak of an infectious disease for which the announcement of an outbreak or related event of a novel and reemerging influenza or coronavirus infection has been made.
- (3) When a prefectural governor finds it necessary to make a request for cooperation pursuant to the provisions of the preceding paragraph, the prefectural governor may provide the mayor of the municipality with the information specified by Order of the Ministry of Health, Labor and Welfare, such as the number of patients with a novel and reemerging influenza or coronavirus infection, a designated infectious disease, or symptoms of a new infectious disease (limited to patients who have a place of residence within the area of the prefectural government), the name of the municipality where the person resides, the date and time when it was determined that the person is a patient with a novel and reemerging influenza or coronavirus infection or a designated infectious disease or a person with symptoms of a new infectious disease.
- (4) In the public disclosure of the information pursuant to the provisions of paragraph (1) or the provisions of the information pursuant to the provisions of the preceding paragraph, due regard must be paid to protect personal information.

(Requests for Cooperation and Other Actions)

Article 16-2 (1) When it is found to be urgently necessary to prevent an outbreak or the spread of an infectious disease, the Minister of Health, Labour and Welfare and prefectural governors may establish measures necessary to

prevent an outbreak or the spread of the infectious disease and request physicians, medical institutions, organizations with persons who have the relevant expertise or other medical personnel, or private business operators or any other infectious disease research institutes that carry out examinations of pathogens and toxins and other examinations related to infectious diseases to offer the assistance necessary to implement the measures, taking into consideration the pathological conditions of the patients with the infectious disease, the number of those patients, other circumstances of the outbreak or spread of the infectious disease, and the circumstances of examining pathogens and toxins.

- (2) When the Minister of Health, Labour and Welfare and the prefectural governor make a request for cooperation pursuant to the provisions of the preceding paragraph and if the person requested for cooperation has not responded to the request for cooperation without reasonable grounds, the Minister and the prefectural governor may recommend that the person cooperate in the implementation of the measures prescribed in that paragraph.
- (3) When the Minister of Health, Labour and Welfare and the prefectural governor make a recommendation pursuant to the provisions of the preceding paragraph and the person who receives the recommendation does not follow it without reasonable grounds, the Minister and the prefectural governor may make that fact public.

Chapter IV Restrictions on Work Participation and Other Measures

(Collection of Specimens)

- Article 16-3 (1) When a prefectural governor finds it necessary to prevent the spread of a class I or class II infectious disease or a novel and reemerging influenza or coronavirus infection, the prefectural governor may recommend that the person stated in Article 15, paragraph (3), item (i) submit the specimens prescribed in that item or accept the specimens collected by relevant officials, or recommend that the person's custodian submit the specimens or have the person accept the the specimens collected by relevant officials; provided, however, that this does not apply when the prefectural governor is considered to be able to obtain the specimens which are the subject of the intended recommendation (including the pathogens of the infectious disease prescribed in that item which are separated from the specimens that are the subject of the intended recommendation; the same applies below in this paragraph) from the person who possesses the specimens which are the subject of the intended recommendation.
- (2) When the Minister of Health, Labour and Welfare finds it urgently necessary to prevent the spread of a class I or class II infectious disease or a novel and

reemerging influenza or coronavirus infection, the Minister may recommend that a person stated in Article 15, paragraph (3), item (i) submit the specimens prescribed in that item or accept the specimens collected by relevant officials, or recommend that the person's custodian submit the specimens or have the person accept the specimens collected by relevant officials; provided, however, that this does not apply when the Minister of Health, Labour and Welfare is considered to be able to obtain the specimens which are the subject of the intended recommendation (including the pathogens of the infectious disease prescribed in that item which are separated from the specimens that are the subject of the intended recommendation; the same applies below in this paragraph) from the person who possesses the specimens which are the subject of the intended recommendation.

- (3) If the person receiving a recommendation made under the provisions of paragraph (1) does not follow the recommendation, the prefectural governor may, to the minimum extent necessary for examination, direct relevant officials to collect the specimens prescribed in Article 15, paragraph (3), item (i) from the person stated in that item who is the subject of the recommendation.
- (4) If the person receiving a recommendation made under the provisions of paragraph (2) does not follow the recommendation, the Minister of Health, Labour and Welfare may, to the minimum extent necessary for examination, direct relevant officials to collect the specimens prescribed in Article 15, paragraph (3), item (i) from the person stated in that item who is the subject of the recommendation.
- (5) When a prefectural governor recommends the submission or collection of specimens under the provisions of paragraph (1) or implements measures for collecting specimens under the provisions of paragraph (3), the prefectural governor must simultaneously notify the person who receives the recommendation or is subject to the measures of the reason for the recommendation or measures and other matters specified by Order of the Ministry of Health, Labour and Welfare, in writing; provided, however, this does not apply when there is a pressing need to recommend the submission or collection of specimens or to implement a measure that involves collecting specimens before a notification of those matters is submitted in writing.
- (6) In the case referred to in the proviso of the preceding paragraph, the prefectural governor must issue a written document stating the reason and other matters specified by Order of the Ministry of Health, Labour and Welfare as referred to in that paragraph for the person who has received the recommendation or has been subject to the measures, within a reasonable period of time after the recommendation of the submission or collection of specimens or the measures for collecting specimens.

- (7) The prefectural governor must examine the specimens submitted or collected by relevant officials in accordance with the provisions of paragraph (1) or the specimens which the prefectural governor directed relevant officials to collect in accordance with the provisions of paragraph (3), pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (8) The prefectural governor must report the findings of the examination referred to in the preceding paragraph and other matters specified by Order of the Ministry of Health, Labour and Welfare to the Minister of Health, Labour and Welfare, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (9) When the Minister of Health, Labour and Welfare finds it necessary to personally conduct an examination, the Minister may ask a prefectural governor to submit a part of the specimens submitted or collected by relevant officials under the provisions of paragraph (1) or a part of the specimens which the prefectural governor directed relevant officials to collect pursuant to the provisions of paragraph (3).
- (10) When a prefectural governor finds it particularly necessary to recommend the submission or collection of specimens under the provisions of paragraph (1), direct relevant officials to collect specimens under the provisions of paragraph (3), or examine the specimens under the provisions of paragraph (7), the prefectural governor may ask another prefectural governor or the Minister of Health, Labour and Welfare to dispatch an employee or employees of an infectious disease research institute and to provide other necessary assistance.
- (11) The provisions of paragraphs (5) and (6) apply mutatis mutandis when the Minister of Health, Labour and Welfare recommends the submission or collection of specimens pursuant to the provisions of paragraph (2) or directs relevant officials to implement a measure that involves collecting specimens pursuant to the provisions of paragraph (4).

(Medical Examinations)

- Article 17 (1) When a prefectural governor finds it necessary to prevent the spread of a class I, class II, or class III infectious disease or a novel and reemerging influenza or coronavirus infection, the prefectural governor may recommend that a person who is justifiably suspected to be infected with that infectious disease take a medical examination conducted by a physician to ascertain whether the person is infected with that infectious disease or not, or recommend to the custodian of the person who is justifiably suspected to be infected with that infectious disease to take a medical examination.
- (2) If the person receiving a recommendation made under the provisions of the preceding paragraph does not follow the recommendation, the prefectural governor may direct relevant officials to conduct a medical examination of the

person justifiably suspected to be infected with the infectious disease of the recommendation for doing so.

(Restrictions on Work Participation)

- Article 18 (1) When a prefectural governor receives a notification submitted under the provisions of Article 12, paragraph (1) in connection with a patient with a class I infectious disease or a patient or asymptomatic carrier of a class II or class III infectious disease or a novel and reemerging influenza or coronavirus infection, and the prefectural governor finds it necessary to prevent the spread of those infectious diseases, the prefectural governor may notify the person or their custodian of the contents of the notification and other matters specified by Order of the Ministry of Health, Labour and Welfare in writing.
- (2) If a patient or asymptomatic carrier prescribed in the preceding paragraph or their custodian receives written notice given under the provisions of that paragraph, the patient or asymptomatic carrier must not perform any type of work specified by Order of the Ministry of Health, Labour and Welfare for each infectious disease which involves the risk of spreading an infectious disease to the public for the period specified by Order of the Ministry of Health, Labour and Welfare for each infectious disease as the length of time required for the elimination of that risk.
- (3) A person who is subject to the provisions of the preceding paragraph or their custodian may request the prefectural governor to confirm that the person has ceased to be subject to the provisions of that paragraph.
- (4) After receiving a request for confirmation under the provisions of the preceding paragraph, the prefectural governor must confirm whether or not the person to whom the provisions of paragraph (2) are applied and for whom the request is made is a patient or asymptomatic carrier of the infectious disease based on which the provisions of that paragraph are applied, or whether or not the period prescribed in that paragraph has passed.
- (5) When the prefectural governor intends to give notice pursuant to the provisions of paragraph (1), the prefectural governor must, in advance, hear the opinions of the infectious disease examination committee prescribed in Article 24, paragraph (1) established at the public health center that has jurisdiction over the place of residence of the patient or asymptomatic carrier; provided, however, that this does not apply when there is no time to seek the opinions of the infectious disease examination committee in advance in an emergency.
- (6) In the case referred to in the proviso of the preceding paragraph, the prefectural governor must promptly report to the infectious disease examination committee the contents of the notice it has given.

(Hospitalization)

- Article 19 (1) When a prefectural governor finds it necessary to prevent the spread of a class I infectious disease, the prefectural governor may recommend that a patient with that infectious disease be hospitalized or recommend to their custodian that the patient be hospitalized in a designated medical institution for specified infectious diseases or a designated medical institution for class I infectious diseases; provided, however, that in an emergency or under other unavoidable circumstances, the prefectural governor may recommend that the patient be hospitalized or recommend to their custodian that the patient be hospitalized in a hospital or clinic found suitable by the prefectural governor other than a designated medical institution for specified infectious diseases or a designated medical institution for class I infectious diseases.
- (2) When a prefectural governor makes a recommendation under the provisions of the preceding paragraph, the prefectural governor must give adequate explanations to the patient who is subject to the recommendation or their custodian and endeavor to help them understand the situation.
- (3) If the person receiving a recommendation made under the provisions of paragraph (1) does not follow the recommendation, the prefectural governor may hospitalize the patient who is subject to the recommendation at a designated medical institution for specified infectious diseases or a designated medical institution for class I infectious diseases (or if the person does not follow a recommendation made under the proviso of that paragraph, at a hospital or clinic found suitable by the prefectural governor other than a designated medical institution for specified infectious diseases or a designated medical institution for class I infectious diseases).
- (4) The period of hospitalization under paragraph (1) or the preceding paragraph must not exceed 72 hours.
- (5) In an emergency or under other unavoidable circumstances, a prefectural governor may hospitalize a patient who has been hospitalized pursuant to the provisions of paragraph (1) or (3) at another hospital or clinic which the prefectural governor finds to be suitable.
- (6) The total period of hospitalization under the provisions of paragraph (1) or (3) and the period of hospitalization under the provisions of the preceding paragraph must not exceed 72 hours.
- (7) When issuing a recommendation under the provisions of paragraph (1) or implementing a measure that involves hospitalization under the provisions of paragraph (3), the prefectural governor must, without delay, make a report to the infectious disease examination committee prescribed in Article 24, paragraph (1) established at the public health center that has jurisdiction over

the location of the hospital or clinic where that patient is hospitalized.

- Article 20 (1) When a prefectural governor finds it necessary to prevent the spread of a class I infectious disease, the prefectural governor may recommend that a patient with that infectious disease who is hospitalized pursuant to the provisions of the preceding Article be hospitalized or recommend to their custodian that the patient be hospitalized at a designated medical institution for specified infectious diseases or a designated medical institution for class I infectious diseases for a specified period of not more than 10 days; provided, however, that in an emergency or under other unavoidable circumstances, the prefectural governor may recommend that the patient be hospitalized or recommend to their custodian that the patient be hospitalized in a hospital or clinic found suitable by the prefectural governor other than a designated medical institution for specified infectious diseases or a designated medical institution for class I infectious diseases for a specified period of not more than 10 days.
- (2) If the person receiving a recommendation made under the provisions of the preceding paragraph does not follow the recommendation, the prefectural governor may hospitalize the patient who is subject to the recommendation at a designated medical institution for specified infectious diseases or a designated medical institution for class I infectious diseases (or if the person does not follow a recommendation made under the proviso of that paragraph, at a hospital or clinic found suitable by the prefectural governor other than a designated medical institution for specified infectious diseases or a designated medical institution for class I infectious diseases) for a specified period of not more than 10 days.
- (3) In an emergency or under other unavoidable circumstances, a prefectural governor may hospitalize a patient who has been hospitalized pursuant to the provisions of the preceding two paragraphs at a hospital or clinic found suitable by the prefectural governor other than the one where the patient is currently hospitalized for a specified period of not more than 10 days from the date on which the patient was hospitalized under the provisions of the preceding two paragraphs.
- (4) After the end of the period of the hospitalization referred to in the preceding three paragraphs, if the prefectural governor finds it necessary to continue the hospitalization of the patient who has been hospitalized, the prefectural governor may extend the period of hospitalization for a specified period of not more than 10 days. The same applies when the period of hospitalization is to be further extended after the end of the previously extended period.
- (5) If the prefectural governor intends to make a recommendation under the provisions of paragraph (1) or to extend the period of the hospitalization

pursuant to the provisions of the preceding paragraph, the prefectural governor must, in advance, hear the opinions of the infectious disease examination committee prescribed in Article 24, paragraph (1) established at the public health center that has jurisdiction over the location of the hospital or clinic where that patient is hospitalized.

- (6) If the prefectural governor intends to make a recommendation under the provisions of paragraph (1), the prefectural governor must give adequate explanations to the patient or their custodian and endeavor to help them understand the situation, and must afford them an opportunity to express their opinions to the official designated by the prefectural governor. In this case, the prefectural governor must give advance notice to the patient or their custodian of the date and time and the place set for that opportunity to express their opinions and the facts underlying the grounds for the recommendation.
- (7) The patient or their custodian receiving a notice given under the provisions of the preceding paragraph may have an agent appear and submit evidence in their favor.
- (8) The official who hears the opinions expressed under the provisions of paragraph (6) must prepare a hearing report and submit it to the prefectural governor.

(Patient Transfers)

Article 21 The prefectural governor must transfer the patient who is to be hospitalized in accordance with the provisions of the preceding two Articles to the hospital or clinic where the patient is to be hospitalized, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Discharge from Hospital)

- Article 22 (1) If it is confirmed that a patient who has been hospitalized pursuant to the provisions of Article 19 or 20 is not carrying the pathogens of the class I infectious disease for which the patient was hospitalized, the prefectural governor must discharge the hospitalized patient.
- (2) When the administrator of the hospital or clinic has confirmed that a patient hospitalized pursuant to the provisions of Article 19 or 20 is not carrying the pathogens of the class I infectious disease for which the patient was hospitalized, the administrator of the hospital or clinic must notify the prefectural governor of that fact.
 - (3) A patient hospitalized pursuant to the provisions of Article 19 or 20 or their custodian may request the prefectural governor to approve the discharge of the patient.
 - (4) After receiving a request for discharge under the provisions of the preceding paragraph, the prefectural governor must confirm whether or not the patient is

carrying the pathogens of the class I infectious disease for which the patient was hospitalized.

(Minimum Necessary Measures)

Article 22-2 The measures implemented pursuant to the provisions of Articles 16-3 through 21 are the minimum necessary measures to prevent an outbreak or the spread of an infectious disease based on the risk of spreading the infectious disease to the public, the severity of pathological conditions following infection with the infectious disease, and other circumstances.

(Notice in Writing)

Article 23 The provisions of Article 16-3, paragraphs (5) and (6) apply *mutatis mutandis* when a prefectural governor recommends a medical examination under the provisions of Article 17, paragraph (1), implements a measure that involves a medical examination under the provisions of paragraph (2) of that Article, recommends hospitalization under the provisions of Article 19, paragraph (1) or Article 20, paragraph (1), implements a measure that involves hospitalization under the provisions of Article 19, paragraph (3) or (5) or Article 20, paragraph (2) or (3), or extends the period of hospitalization under the provisions of paragraph (4) of that Article.

(Committee for Examining Infectious Diseases)

Article 24 (1) A committee for examination of infectious diseases (referred to below as "infectious disease examination committee" in this Article) will be established at each public health center.

(2) Regardless of the provisions of the preceding paragraph, a prefectural government with two or more health centers may establish a single infectious disease examination committee for two or more public health centers when it is found to be particularly necessary.

(3) The infectious disease examination committee will take charge of the following affairs:

- (i) deliberating necessary matters when consulted by the prefectural governor in connection with notices given under the provisions of Article 18, paragraph (1), recommendations made under the provisions of Article 20, paragraph (1) (including cases where it is applied *mutatis mutandis* in Article 26), extension of the period of hospitalization under the provisions of Article 20, paragraph (4) (including cases where it is applied *mutatis mutandis* in Article 26), and the coverage of expenses based on an application filed under the provisions of Article 37-2, paragraph (1); and
- (ii) stating opinions in connection with the reports made under the provisions of Article 18, paragraph (6) or Article 19, paragraph (7) (including cases

where it is applied mutatis mutandis in Article 26).

- (4) The infectious disease examination committee is to be composed of three or more members.
- (5) Members of the committee must be appointed by the prefectural governor from among the physicians at designated medical institutions for infectious diseases, persons with relevant knowledge and experience in medical care for patients with infectious diseases (excluding physicians at designated medical institutions for infectious diseases), persons with relevant knowledge and experience in law, and persons with relevant knowledge and experience in fields other than medical care and law; provided, however, that a majority of the members must be appointed from among the physicians.
- (6) Beyond what is provided for in this Act, necessary matters concerning the infectious disease examination committee are specified by Prefectural Ordinance.

(Filing Complaints with Prefectural Governors)

- Article 24-2 (1) A patient hospitalized pursuant to the provisions of Article 19 or 20 or their custodian may file a complaint with the prefectural governor, in writing or orally, with regard to the way the patient was treated.
- (2) If the patient prescribed in the preceding paragraph or their custodian intends to file a complaint under that paragraph orally, the prefectural governor may direct their designated officials to hear the details of the complaint.
 - (3) After receiving a complaint filed, the prefectural governor must handle the complaint in good faith and notify the person who filed the complaint of the results.

(Special Provisions for Requests for Administrative Review)

- Article 25 (1) A patient hospitalized pursuant to the provisions of Article 20, paragraph (2) or (3) for a period exceeding 30 days or their custodian may file a request for administrative review (including a request for re-examination and a request for further examination; the same applies below in this Article) with the Minister of Health, Labour and Welfare, in writing or orally, with regard to the hospitalization measure prescribed in paragraph (2) or (3) of that Article.
- (2) When a request for administrative review is filed under the preceding paragraph, the Minister of Health, Labour and Welfare must make a determination on the request within five days from the date on which the request was filed.
 - (3) If a patient hospitalized pursuant to the provisions of Article 20, paragraph (2) or (3) whose period of hospitalization does not exceed 30 days or their custodian files a request for administrative review with the Minister of Health,

Labour and Welfare, the Minister must make a determination on the request within 35 days from the day on which the patient for whom the request is filed was hospitalized pursuant to the provisions of paragraph (2) or (3) of that Article.

- (4) If a patient hospitalized pursuant to the provisions of Article 20, paragraph (2) or (3) whose period of hospitalization does not exceed 30 days or their custodian files a request for administrative review with the prefectural governor, and subsequently the period of hospitalization of the patient exceeds 30 days, the prefectural governor must immediately transfer the case to the Minister of Health, Labour and Welfare and notify the person who has filed the request of that fact.
- (5) When a case is transferred pursuant to the provisions of the preceding paragraph, the request for administrative review is deemed to have been filed originally with the Minister of Health, Labour and Welfare, and the provisions of paragraph (3) apply.
- (6) When the Minister of Health, Labour and Welfare intends to make a determination referred to in paragraph (2) or a determination referred to in paragraph (3) (limited to those for patients whose period of hospitalization exceeds 30 days), the Minister must hear the opinion of the councils and other relevant organizations (meaning an organ prescribed in Article 8 of the National Government Organization Act (Act No. 120 of 1948)) specified by Cabinet Order, in advance.
- (7) The provisions of Chapter II, Section 4 of the Administrative Appeal Act (Act No. 68 of 2014) do not apply to requests for administrative review filed with regard to a measure that involves hospitalization implemented pursuant to the provisions of Article 19, paragraph (3) or (5).

(Application Mutatis Mutandis)

Article 26 (1) The provisions of Articles 19 through 23, Article 24-2, and the preceding Article apply mutatis mutandis to the patients with a class II infectious disease. In this case, the phrase "a designated medical institution for specified infectious diseases or a designated medical institution for class I infectious diseases" in Article 19, paragraphs (1) and (3) and Article 20, paragraphs (1) and (2) is deemed to be replaced with "a designated medical institution for specified infectious diseases, a designated medical institution for class I infectious diseases, or a designated medical institution for class II infectious diseases," the phrase "a designated medical institution for specified infectious diseases or a designated medical institution for class I infectious diseases" in Article 19, paragraph (3) and Article 20, paragraph (2) is deemed to be replaced with "a designated medical institution for specified infectious diseases, a designated medical institution for class I infectious diseases, or a

designated medical institution for class II infectious diseases," the phrase "must transfer" in Article 21 is deemed to be replaced with "may transfer," the phrase "is not carrying the pathogens of the class I infectious disease" in Article 22, paragraphs (1) and (2) is deemed to be replaced with "is not carrying the pathogens of the class II infectious disease or ceases to have the symptoms of that infectious disease," the phrase "whether or not the patient is carrying the pathogens of the class I infectious disease" in paragraph (4) of that Article is deemed to be replaced with "whether or not the patient is carrying the pathogens of the class II infectious disease, or ceases to have the symptoms of that infectious disease" and, in addition to the above, the necessary technical replacements of terms in connection with these provisions are specified by Cabinet Order.

- (2) The provisions of Articles 19 through 23, Article 24-2, and the preceding Article apply mutatis mutandis to patients with a novel and reemerging influenza or coronavirus infection. In this case, the term "a patient" in Article 19, paragraph (1) is deemed to be replaced with "a patient (for patients with a novel and reemerging influenza or coronavirus infection (limited to those specified by Order of the Ministry of Health, Labour and Welfare based on the severity of their symptoms), limited to those specified by Order of the Ministry of Health, Labour and Welfare based on the infectious disease or the risk that the symptoms following infection with the infectious disease will become severe, and those other than relevant persons who have not responded to the request for cooperation pursuant to the provisions of Article 44-3, paragraph (2))," the phrase "a designated medical institution for specified infectious diseases or a designated medical institution for class I infectious diseases" in that paragraph and paragraph (3) of that Article and Article 20, paragraphs (1) and (2) is deemed to be replaced with "a designated medical institution for specified infectious diseases, a designated medical institution for class I infectious diseases, a designated medical institution for class II infectious diseases, or a designated medical institution for class I agreement," the phrase "a designated medical institution for specified infectious diseases or a designated medical institution for class I infectious diseases" in Article 19, paragraph (3) and Article 20, paragraph (2) is deemed to be replaced with "a designated medical institution for specified infectious diseases, a designated medical institution for class I infectious diseases, a designated medical institution for class II infectious diseases, or a designated medical institution for class I agreement," the phrase "must transfer" in Article 21 is deemed to be replaced with "can transfer," and, in addition to the above, the necessary technical replacements of terms in connection with these provisions are specified by Cabinet Order.

(Special Provisions for the Hospitalization of Tuberculosis Patients)

Article 26-2 To apply the provisions of Articles 19 and 20 as applied mutatis mutandis pursuant to the provisions of the preceding Article, paragraph (1) following the deemed replacement of terms for tuberculosis patients, the phrase "the location of the hospital or clinic where that patient is hospitalized" in Article 19, paragraph (7) is deemed to be replaced with "the place of residence of that patient," the phrase "not more than 10 days" in the main clause of Article 20, paragraph (1) is deemed to be replaced with "not more than 30 days," the phrase "not more than 10 days" in paragraph (4) of that Article is deemed to be replaced with "not more than 10 days (or not more than 30 days, in case of hospitalization under the main clause of paragraph (1))," the phrase "the location of the hospital or clinic where that patient is hospitalized" in paragraph (5) of that Article is deemed to be replaced with "the place of residence of that patient."

Chapter V Disinfection and Other Measures

(Forcible Collection of Specimens)

- Article 26-3 (1) When a prefectural governor finds it necessary to prevent an outbreak or the spread of a class I or class II infectious disease or a novel and reemerging influenza or coronavirus infection, the prefectural governor may order a person stated in Article 15, paragraph (3), item (vii) or (x) to submit the specimens or pathogens of the infectious disease prescribed in the relevant item.
- (2) When the Minister of Health, Labour and Welfare finds it urgently necessary to prevent an outbreak or the spread of a class I or class II infectious disease or a novel and reemerging influenza or coronavirus infection, the Minister may order a person stated in Article 15, paragraph (3), item (vii) or (x) to submit the specimens or pathogens of the infectious disease prescribed in the relevant item.
- (3) If the person receiving an order made under the provisions of paragraph (1) does not follow the order, the prefectural governor may, to the minimum extent necessary for examination, direct relevant officials to forcibly collect the specimens or pathogens of the infectious disease prescribed in Article 15, paragraph (3), item (vii) or (x), without compensation, from the person stated in that item who has received the order.
- (4) If the person receiving an order made under the provisions of paragraph (2) does not follow the order, the Minister of Health, Labour and Welfare may, to the minimum extent necessary for examination, direct relevant officials to forcibly collect the specimens or pathogens of the infectious disease prescribed in Article 15, paragraph (3), item (vii) or (x), without compensation, from the person stated in that item who has received the order.

- (5) The prefectural governor must conduct an examination of the specimens or the pathogens of the infectious disease submitted in accordance with the provisions of paragraph (1) or the specimens or pathogens of the infectious disease forcibly collected by the officials in accordance with the provisions of paragraph (3), pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (6) The prefectural governor must report the result of the examination referred to in the preceding paragraph and other matters specified by Order of the Ministry of Health, Labour and Welfare to the Minister of Health, Labour and Welfare, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (7) If the Minister of Health, Labour and Welfare finds it necessary to personally conduct an examination, the Minister may ask the prefectural governor to submit a part of the specimens or the pathogens of the infectious disease submitted under the provisions of paragraph (1) or a part of the specimens or the pathogens of the infectious disease forcibly collected by the officials under the provisions of paragraph (3).
- (8) If a prefectural governor finds it particularly necessary to order the submission of the specimens or the pathogens of the infectious disease under the provisions of paragraph (1), direct relevant officials to implement forcible collection of the specimens or the pathogens of the infectious disease under the provisions of paragraph (3), or conduct an examination of the specimens or the pathogens of the infectious disease under the provisions of paragraph (5), the prefectural governor may ask another prefectural governor or the Minister of Health, Labour and Welfare to dispatch an employee or employees of an infectious disease research institute and to provide other necessary assistance.

(Collection of Specimens)

- Article 26-4 (1) If a prefectural governor finds it necessary to prevent an outbreak or the spread of a class I or class II infectious disease or a novel and reemerging influenza or coronavirus infection, the prefectural governor may order a person stated in Article 15, paragraph (3), item (iv) to submit the specimens prescribed in that item or to accept the specimens collected by relevant officials.
- (2) If the Minister of Health, Labour and Welfare finds it urgently necessary to prevent an outbreak or the spread of a class I or class II infectious disease or a novel and reemerging influenza or coronavirus infection, the Minister may order a person stated in Article 15, paragraph (3), item (iv) to submit the specimens prescribed in that item or to accept the specimens collected by relevant officials.
 - (3) If the person receiving an order made under the provisions of paragraph (1)

does not follow the order, the prefectural governor may, to the minimum extent necessary for examination, direct relevant officials to collect the specimens prescribed in Article 15, paragraph (3), item (iv) from the animal or its corpse which is prescribed in that item and which is the subject of the order.

- (4) If the person receiving an order made under the provisions of paragraph (2) does not follow the order, the Minister of Health, Labour and Welfare may, to the minimum extent necessary for examination, direct relevant officials to collect the specimens prescribed in Article 15, paragraph (3), item (iv) from the animal or its corpse which is prescribed in that item and which is the subject of the order.
- (5) The prefectural governor must conduct an examination of the specimens which were submitted in accordance with the provisions of paragraph (1) or which the officials collected in accordance with those provisions, or the specimens collected by the officials based on the prefectural governor's direction in accordance with the provisions of paragraph (3), pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (6) The prefectural governor must report the result of the examination referred to in the preceding paragraph and other matters specified by Order of the Ministry of Health, Labour and Welfare to the Minister of Health, Labour and Welfare, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (7) When the Minister of Health, Labour and Welfare finds it necessary to personally conduct an examination, the Minister may ask the prefectural governor to submit a part of the specimens which were submitted under the provisions of paragraph (1) or which the officials collected in accordance with those provisions, or a part of the specimens collected by the officials based on the prefectural governor's direction under the provisions of paragraph (3).
- (8) When a prefectural governor finds it particularly necessary to order the submission or collection of the specimens under the provisions of paragraph (1), direct relevant officials to implement a measure that involves collecting the specimens under the provisions of paragraph (3), or examine the specimens under the provisions of paragraph (5), the prefectural governor may ask another prefectural governor or the Minister of Health, Labour and Welfare to dispatch an employee or employees of an infectious disease research institute and to provide other necessary assistance.

(Disinfection of Areas Contaminated with the Pathogens of an Infectious Disease)

Article 27 (1) When a prefectural governor finds it necessary to prevent an outbreak or the spread of a class I, class II, class III, or class IV infectious disease or a novel and reemerging influenza or coronavirus infection, the

prefectural governor may order, with regard to the places where a patient with that infectious disease stays or stayed or where there is or was the corpse of a person who died of that infectious disease, and other areas contaminated or suspected to have been contaminated with the pathogens of that infectious disease, the patient or their custodian or the person responsible for administration of the places in question or their agent to disinfect those places or areas pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

- (2) When a prefectural governor finds that it would be too difficult to prevent an outbreak or the spread of a class I, class II, class III, or class IV infectious disease or a novel and reemerging influenza or coronavirus infection by issuing an order prescribed in the preceding paragraph, the prefectural governor may instruct relevant municipal governments or direct the prefecture's officials to disinfect the places where the patient with that infectious disease stays or stayed or where there is or was the corpse of the person who had died of that infectious disease, and other areas contaminated or suspected to have been contaminated with the pathogens of that infectious disease pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Extermination of Rodents or Insects)

Article 28 (1) When a prefectural governor finds it necessary to prevent an outbreak or the spread of a class I, class II, class III, or a class IV infectious disease, the prefectural governor may designate the areas where rodents, insects, or other animals which are contaminated or suspected to have been contaminated with the pathogens of that infectious disease are present, and order the persons responsible for administration of those areas or the persons acting on their behalf to exterminate those rodents, insects, or other animals pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

- (2) When a prefectural governor finds that it would be too difficult to prevent an outbreak or the spread of a class I infectious disease, a class II infectious disease, a class III infectious disease, or a class IV infectious disease by issuing an order prescribed in the preceding paragraph, the prefectural governor may designate the areas where rodents, insects, or other animals which are contaminated or suspected to have been contaminated with the pathogens of that infectious disease are present, and instruct relevant municipal governments who have jurisdiction over those areas or direct the prefecture's officials to exterminate those rodents, insects, or other animals pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Measures Regarding Items)

Article 29 (1) When a prefectural governor finds it necessary to prevent an outbreak or the spread of a class I, class II, class III, or class IV infectious disease or a novel and reemerging influenza or coronavirus infection, the prefectural governor may, with regard to food or drink, clothing, bedding, and other items contaminated or suspected to have been contaminated with the pathogens of that infectious disease, order the holders of those items to restrict or prohibit their relocation, to disinfect or discard them, or to implement other necessary measures for preventing an outbreak or the spread of that infectious disease pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(2) When a prefectural governor finds that it would be too difficult to prevent an outbreak or the spread of a class I, class II, class III, or class IV infectious disease or a novel and reemerging influenza or coronavirus infection by issuing an order prescribed in the preceding paragraph, the prefectural governor may instruct relevant municipal governments to disinfect food or drink, clothing, bedding, and other items contaminated or suspected to have been contaminated with the pathogens of that infectious disease, or direct the prefecture's officials to disinfect or discard them or implement other necessary measures for preventing an outbreak or the spread of those infectious diseases pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Restrictions on the Relocation of Corpses)

Article 30 (1) When a prefectural governor finds it necessary to prevent an outbreak or the spread of a class I, class II, or class III infectious disease or a novel and reemerging influenza or coronavirus infection, the prefectural governor may restrict or prohibit relocating the corpses contaminated or suspected to have been contaminated with the pathogens of those infectious diseases.

(2) The corpses contaminated or suspected to have been contaminated with the pathogens of a class I, class II, or class III infectious disease or a novel and reemerging influenza or coronavirus infection must be cremated; provided, however, that the burial of those corpses may be allowed if adequate disinfection has been completed and the permission of the prefectural governor has been obtained.

(3) The corpses contaminated or suspected to have been contaminated with pathogens of a class, class II, or class III infectious disease or a novel and reemerging influenza or coronavirus infection may be either cremated or buried within 24 hours.

(Restrictions on the Use of Water for Daily Use)

Article 31 (1) When a prefectural governor finds it necessary to prevent an

outbreak or the spread of a class I, class II, or class III infectious disease, the prefectural governor may order the administrator responsible for the water for daily use that has been contaminated or suspected to have been contaminated with the pathogens of that infectious disease to restrict or prohibit the use or supply of that water for a specified period.

- (2) If a prefectural governor orders to restrict or prohibit the use or supply of water for daily use pursuant to the provisions of the preceding paragraph, the municipal governments in the prefecture must supply the users of water for daily use with an alternative source of water for daily use for the period prescribed in that paragraph, in accordance with the prefectural governor's instructions.

(Measures Taken for Buildings)

Article 32 (1) When a prefectural governor finds it necessary to prevent an outbreak or the spread of a class I infectious disease, and it is too difficult to achieve that by disinfection, the prefectural governor may restrict or prohibit entry into the buildings contaminated or suspected to have been contaminated with the pathogens of that infectious disease for a specified period pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

- (2) If the spread of a class I infectious disease cannot be prevented even by implementing the measure prescribed in the preceding paragraph, the prefectural governor may seal off the buildings contaminated or suspected to have been contaminated with the pathogens of the infectious disease or implement other necessary measures concerning the buildings in order to prevent the spread of the infectious disease, in accordance with the standards specified by Cabinet Order, only when it is found to be urgently necessary.

(Restriction or Blocking of Traffic)

Article 33 If a prefectural governor finds it urgently necessary to prevent the spread of a class I infectious disease and it is too difficult to achieve that by disinfection, the prefectural governor may restrict or block the traffic in places where patients with that infectious disease stay and other places contaminated or suspected to have been contaminated with the pathogens of that infectious disease, in accordance with the standards specified by Cabinet Order, for a specified period of not more than 72 hours.

(Minimum Necessary Measures)

Article 34 The measures implemented pursuant to the provisions of Article 26-3 through the preceding Article must be the minimum necessary measures to prevent an outbreak or the spread of an infectious disease.

(Interviews and Investigations)

- Article 35 (1) When a prefectural governor finds it necessary to implement any of the measures prescribed in Articles 26-3 through 33, the prefectural governor may direct relevant officials to enter the places where patients with a class I, class II, class III, or class IV infectious disease or a novel and reemerging influenza or coronavirus infection stay or previously stayed, the places where there are or were the corpses of persons who died of those infectious diseases, the places where there are or were animals likely to transmit those infectious diseases to humans, the places where there are or were the corpses of those animals which died of those infectious diseases, and other areas contaminated or suspected to have been contaminated with the pathogens of those infectious diseases, and interview the patients, suspected disease carriers, or asymptomatic carriers of a class I, class II, class III, or class IV infectious disease or a novel and reemerging influenza or coronavirus infection, the owners and managers of the animals or their corpses likely to transmit those infectious diseases to humans, and other persons concerned, or carry out the necessary investigations.
- (2) Each of the officials referred to in the preceding paragraph must carry their identification card and present it at the request of any person concerned.
- (3) The provisions of paragraph (1) must not be construed as being granted for criminal investigation purposes.
- (4) The provisions of the preceding three paragraphs apply *mutatis mutandis* when the Minister of Health, Labour and Welfare finds it necessary to implement or direct relevant officials to implement a measure prescribed in Article 26-3, paragraph (2) or (4) or Article 26-4, paragraph (2) or (4). In this case, the phrase ", a class III infectious disease, a class IV infectious disease or" in paragraph (1) is deemed to be replaced with "or."
- (5) The provisions of paragraphs (1) through (3) apply *mutatis mutandis* when a mayor of a municipality finds it necessary to implement a measure prescribed in Article 27, paragraph (2), Article 28, paragraph (2), Article 29, paragraph (2), or Article 31, paragraph (2).
- (6) Necessary matters concerning the identification cards referred to in paragraph (2) are specified by Order of the Ministry of Health, Labour and Welfare.

(Notice in Writing)

- Article 36 (1) If a prefectural governor implements or directs relevant officials to implement a measure prescribed in Article 26-3, paragraph (1) or (3), Article 26-4, paragraph (1) or (3), Article 27, paragraph (1) or (2), Article 28, paragraph (1) or (2), Article 29, paragraph (1) or (2), Article 30, paragraph (1), or Article 31, paragraph (1), the prefectural governor must notify the addressee

of the measure or their custodian in writing of the implementation of the measure, the reasons for that measure, and other matters specified by Order of the Ministry of Health, Labour and Welfare; provided, however, that this does not apply when there is a pressing need to implement the measure before a notification of those matters is submitted in writing.

- (2) In the case referred to in the proviso of the preceding paragraph, the prefectural governor must issue a written document stating that the measure has been implemented, the reasons for that measure, and other matters specified by Order of the Ministry of Health, Labour and Welfare as referred to in that paragraph to the addressee of the measure or their custodian within a reasonable period of time after implementing the measure.
- (3) The provisions of the preceding two paragraphs apply mutatis mutandis when the Minister of Health, Labour and Welfare implements or directs relevant officials to implement a measure prescribed in Article 26-3, paragraph (2) or (4) or Article 26-4, paragraph (2) or (4).
- (4) If a prefectural governor implements or directs relevant officials to implement a measure prescribed in Article 32 or 33, the prefectural governor must post a statement declaring that the measure has been implemented, the reasons for that measure, and other matters specified by Order of the Ministry of Health, Labour and Welfare in a suitable place.
- (5) The provisions of paragraphs (1) and (2) apply mutatis mutandis when a mayor of a municipality directs relevant officials to implement a measure prescribed in Article 27, paragraph (2), Article 28, paragraph (2), or Article 29, paragraph (2).

Chapter VI Medical Care

Section 1 Medical Care Agreements

(Obligation of Public Medical Institutions, Regional Medical Care Support Hospitals, and Advanced Treatment Hospitals to Provide Medical Care)

Article 36-2 (1) A prefectural governor is to, in order to swiftly and adequately take the necessary measures to establish a system for the provision of medical care for a novel and reemerging influenza or coronavirus infection, designated infectious disease, or new infectious disease during the period from the announcement of an outbreak or related event of a novel and reemerging influenza or coronavirus infection, until the announcement or other official communication that it is no longer considered a novel and reemerging influenza or coronavirus infection (referred to below as the "publicly announced period for an outbreak or related event of a novel and reemerging influenza or coronavirus infection" in this paragraph, paragraph (1) of the following Article, and Article 36-6, paragraph (1)), pursuant to the provisions of Order of the

Ministry of Health, Labour and Welfare, notify the administrators of medical institutions established by the persons listed in each item of Article 7-2, paragraph (1) of the Medical Care Act, the National Hospital Organization, the Japan Organization of Occupational Health and Safety, and medical institutions established by the national government or corporations specified by Order of the Ministry of Health, Labour and Welfare (referred to below as "public or other relevant medical institutions"), located within the jurisdiction of the prefectural governor, and regional medical care support hospitals (this refers to regional medical care support hospitals as stated in Article 4, paragraph (1) of that Act; the same applies below) and advanced treatment hospitals (this refers to advanced treatment hospitals stated in Article 4-2, paragraph (1) of that Act; the same applies below), of those measures listed below that need to be taken by the relevant medical institutions during the announcement period of an outbreak of a novel and reemerging influenza or coronavirus infection (with regard to the measures listed in items (i) through (v), limited to those specified by Order of the Ministry of Health, Labour and Welfare as those that swiftly and adequately take necessary measures to establish a system for the provision of medical care for a novel and reemerging influenza or coronavirus infection, designated infectious diseases, or new infectious diseases), the method of covering the expenses necessary for the measures, and other matters specified by Order of the Ministry of Health, Labour and Welfare:

- (i) hospitalizing a patient with a novel and reemerging influenza or coronavirus infection or a designated infectious disease, or a person with symptoms of a new infectious disease, and providing the necessary medical care;
- (ii) providing medical care for a suspected patient with a novel and reemerging influenza or coronavirus infection or a designated infectious disease, or a person who is justifiably suspected to have one of those infectious diseases, or a person who is justifiably suspected to have a new infectious disease;
- (iii) providing medical services specified by Order of the Ministry of Health, Labour and Welfare stated in Article 44-3-2, paragraph (1) (including cases where it is applied mutatis mutandis by Cabinet Order pursuant to the provisions of Article 44-9, paragraph (1)) or Article 50-3, paragraph (1) and requesting a report of the body temperature and other facts regarding the state of health of a patient with a novel and reemerging influenza or coronavirus infection or a designated infectious disease, or a person with symptoms of a new infectious disease pursuant to the provisions of Article 44-3, paragraph (2) (including cases where it is applied mutatis mutandis by Cabinet Order pursuant to the provisions of Article 44-9, paragraph (1)) or Article 50-2, paragraph (2).

- (iv) providing medical care on behalf of a medical institution that takes the measures listed in the preceding three items to a patient other than a patient with a novel and reemerging influenza or coronavirus infection or a designated infectious disease, or a person with symptoms of a new infectious disease;
 - (v) securing medical care personnel for novel and reemerging influenza or coronavirus infections prescribed in Article 44-4-2, paragraph (1), persons involved in the prevention of novel and reemerging influenza or coronavirus infections prescribed in that paragraph, medical care personnel for designated infectious diseases prescribed in that paragraph as applied mutatis mutandis by replacing terms pursuant to Article 44-8, persons involved in the prevention of designated infectious diseases prescribed in that paragraph as applied mutatis mutandis by replacing terms pursuant to that Article, medical care personnel for new infectious diseases prescribed in Article 51-2, paragraph 1, or persons involved in the prevention of new infectious diseases prescribed in that paragraph, and dispatching those persons to medical institutions or other institutions; or
 - (vi) implementing other measures specified by Order of the Ministry of Health, Labour and Welfare.
- (2) When the administrator of a public or other relevant medical institution, regional medical care support hospital, and advanced treatment hospital has received a notice pursuant to the provisions of the preceding paragraph, the administrator must take measures based on the notice.
- (3) When a prefectural governor has given a notice pursuant to the provisions of paragraph (1), the prefectural governor is to release the contents of the notice pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Conclusion of Agreements with Medical Institutions and Other Related Matters)

Article 36-3 (1) In order to swiftly and adequately take the necessary measures to establish a system for providing medical care related to a novel and reemerging influenza or coronavirus infection, designated infectious disease, or new infectious disease during the publicly announced period for an outbreak or related event of a novel and reemerging influenza or coronavirus infection, the prefectural governor is to consult with the administrators of medical institutions within the area under their jurisdiction, and, when an agreement is reached, conclude an agreement (referred to below as "medical care agreement") that includes the following matters as specified by Order of the Ministry of Health, Labour and Welfare:

- (i) those measures listed in the items of paragraph (1) of the preceding Article

- that need to be taken by the medical institution during the publicly announced period for an outbreak or related event of a novel and reemerging influenza or coronavirus infection;
- (ii) in cases prescribed for stockpiling personal protective equipment as provided for in Article 53-16, paragraph (1), the details of those matters;
 - (iii) the method of covering the expenses necessary for the measures stated in the preceding two items;
 - (iv) the term of the medical care agreement;
 - (v) measures in the event the medical care agreement is violated; and
 - (vi) other matters specified by Order of the Ministry of Health, Labour and Welfare as necessary matters concerning the implementation of the medical care agreement.
- (2) The administrator of a medical institution who has been requested to consult pursuant to the provisions of the preceding paragraph must respond to the request.
- (3) When the prefectural governor fails to reach an agreement on a medical care agreement with the administrator of a medical institution through consultation as prescribed in paragraph (1), the prefectural governor may hear the opinion of the Prefectural Council on Medical Service Facilities prescribed in Article 72, paragraph (1) of the Medical Care Act.
- (4) The prefectural governor and the administrator of a medical care institution must respect the opinion of the Prefectural Council on Medical Service Facilities under the provisions of the preceding paragraph.
- (5) When a prefectural governor has concluded a medical care agreement, the prefectural governor is to release the contents of the agreement pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (6) Beyond what is prescribed in the preceding paragraphs, necessary matters concerning the conclusion of a medical care agreement are to be prescribed by Order of the Ministry of Health, Labour and Welfare.

(Instructions and Directives by a Prefectural Governor)

- Article 36-4 (1) When a prefectural governor finds that an administrator of a public or other relevant medical institution has not taken any of the following measures without reasonable grounds, the prefectural governor may give instructions to the administrator to take the necessary measures:
- (i) measures based on notices given under the provisions of paragraph (1), Article 36-2; and
 - (ii) when the reference public or other relevant medical institutions conclude medical care agreements, measures based on the relevant medical care agreement.
- (2) When a prefectural governor finds that an administrator of a medical

institution (excluding public or other relevant medical institution; the same applies below in this Article) has not taken any of the following measures without reasonable grounds, the prefectural governor may recommend to the administrator to take the necessary measures:

- (i) measures based on notices given under the provisions of paragraph (1), Article 36-2; and
 - (ii) when the reference medical institutions conclude medical care agreements, measures based on the relevant medical care agreements.
- (3) If the administrator of a medical institution does not follow the recommendation prescribed in the preceding paragraph without reasonable grounds, the prefectural governor may give the necessary instructions to the administrator if the prefectural governor finds it necessary.
- (4) When the prefectural governor has given instructions pursuant to the provisions of paragraph (1) or the preceding paragraph, if the public or other relevant medical institution or the administrator of the medical institution who received these instructions does not follow the instructions without reasonable grounds, the prefectural governor may make that fact public.

(Reports on the Status of Implementation of Measures under Medical Care Agreements)

Article 36-5 (1) A prefectural governor, when the prefectural governor finds it necessary, may request the administrator of a public or other relevant medical institution, regional medical care support hospital, or advanced treatment hospital to report on the following matters, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare:

- (i) the status of the implementation of the measures based on the notification pursuant to the provisions of paragraph (1) of Article 36-2, the status of the operation of the medical institution involved in the implementation of those measures, and other matters; and
 - (ii) if the medical institution has concluded a medical care agreement, the status of the implementation of the measures based on the medical care agreement, the status of operation of the medical institution involved in the implementation of those measures, and other matters.
- (2) A prefectural governor, when the prefectural governor finds it necessary, may, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, request the administrator of a medical institution (excluding medical institutions prescribed in the preceding paragraph) that has concluded a medical care agreement to report on the status of the implementation of the measures based on the medical care agreement, the status of the operation of the medical institution involved in the implementation of those measures, and other matters.

- (3) When a prefectural governor requests a report pursuant to the provisions of the preceding two paragraphs, the administrator of a medical institution must promptly report the matters listed in the items of paragraph (1) or the matters prescribed in the preceding paragraph, except when there are reasonable grounds.
- (4) A prefectural governor who has received a report pursuant to the provisions of the preceding paragraph must report on the contents of the report by electronic or magnetic means (meaning a method that utilizes an electronic data processing system or any other method that utilizes the information and communications technology specified by Order of the Ministry of Health, Labour and Welfare; the same applies below in the following paragraph and paragraph (6)) to the Minister of Health, Labour and Welfare and make that report public.
- (5) The administrator of a medical institution (limited to designated medical institution for infectious diseases specified by Order of the Ministry of Health, Labour and Welfare) that is to make a report pursuant to the provisions of paragraph (3) must make the report by an electronic or magnetic means that allows the person who is to make the report pursuant to the provisions of the preceding paragraph and the person who is to receive the report to view the contents of the report.
- (6) The administrator of a medical institution (excluding a designated medical institution for infectious diseases specified by Order of the Ministry of Health, Labour and Welfare in the preceding paragraph) that is to make a report pursuant to the provisions of paragraph (3) must endeavor to make the report by an electronic or magnetic means that allows the person who is to make the report pursuant to the provisions of paragraph (iv) and the person who is to receive the report to view the contents of the report.
- (7) When an administrator of a medical institution that is to make a report as prescribed in paragraph (3) has made a report by the methods prescribed in the preceding two paragraphs, the prefectural governor who has received the report is to deem it as a report as prescribed in paragraph (4).
- (8) When the Minister of Health, Labour and Welfare finds it necessary, they may provide the necessary advice or assistance to a prefectural governor with regard to the matters listed in the items of paragraph (1) or the matters prescribed in paragraph (2) for which a report (including cases where a report is deemed to have been made pursuant to the provisions of the preceding paragraph; the same applies in the following paragraph, Article 44-4-2, paragraph (4), and Article 51-2, paragraph (4)) pursuant to the provisions of paragraph (4) was received.
- (9) When the Minister of Health, Labour and Welfare has received a report pursuant to the provisions of paragraph (4) or has given advice or assistance

pursuant to the provisions of the preceding paragraph, the Minister is to, as necessary, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, release the contents of the report.

(Conclusion of Agreements with Organizations that Examine Pathogens and Toxins)

Article 36-6 (1) In order to swiftly and adequately take necessary measures to establish a system for providing medical care related to an infectious disease such as examinations concerning a novel and reemerging influenza or coronavirus infection, designated infectious disease, or new infectious disease during the publicly announced period for an outbreak or related event of a novel and reemerging influenza or coronavirus infection, to secure accommodation facilities, and to take other measures, the prefectural governor or relevant mayor is to consult with the administrators of organizations that examine pathogens and toxins, accommodation facilities, and other organizations or facilities specified by Order of the Ministry of Health, Labour and Welfare (referred to below as "organizations that examine pathogens and toxins"), and, when an agreement is reached, conclude an agreement (referred to below as "agreement on examination and other measures") that includes the following matters as specified by Order of the Ministry of Health, Labour and Welfare:

- (i) measures prescribed in (a) through (c) below, which are to be taken by organizations that examine pathogens and toxins during the publicly announced period for an outbreak or related event of a novel and reemerging influenza or coronavirus infection, according to the categories of those organizations listed in (a) through (c) below:
 - (a) Organizations that examine pathogens and toxins: collecting a specimen or conducting an examination of a specimen from a suspected patient with a novel and reemerging influenza or coronavirus infection or a designated infectious disease, or a person who is justifiably suspected to have one of those infectious diseases, or a person who is justifiably suspected to have a new infectious disease;
 - (b) Accommodation facilities: securing of accommodation facilities prescribed in Article 44-3, paragraph (2) or Article 50-2, paragraph (2); and
 - (c) Organizations or institutions other than those listed in (a) and (b): implementing measures specified by Order of the Ministry of Health, Labour and Welfare.
- (ii) in cases prescribed for stockpiling personal protective equipment as provided for in Article 53-16, paragraph (1), the details of those matters;
- (iii) the method of covering the expenses necessary for the measures stated in the preceding two items;

- (iv) the term of the agreement on examination and other measures;
 - (v) measures in case of a violation of the agreement on examination and other measures; and
 - (vi) other matters specified by Order of the Ministry of Health, Labour and Welfare as necessary matters concerning the implementation of the agreement on examination and other measures.
- (2) When a prefectural governor or relevant mayor has concluded an agreement on examination and other measures, that governor or mayor is to release the details of the agreement on examination and other measures pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (3) Beyond what is prescribed in the preceding two paragraphs, necessary matters concerning the conclusion of an agreement on examination and other measures are to be prescribed by Order of the Ministry of Health, Labour and Welfare.

(Instructions and Directives by a Prefectural Governor or Relevant Mayor)

- Article 36-7 (1) When a prefectural governor or relevant mayor finds that an administrator of an organization that examines pathogens and toxins with which an agreement on examination and other measures has been concluded has not taken any measures based on that agreement without reasonable grounds, that governor or mayor may recommend the administrator to take the necessary measures.
- (2) When the administrator of an organization that examines pathogens and toxins does not follow the recommendation as prescribed in the preceding paragraph without reasonable grounds, the prefectural governor or relevant mayor may give the necessary instructions to that administrator if that governor or mayor finds it necessary.
- (3) When the prefectural governor or relevant mayor has given instructions pursuant to the provisions of the preceding paragraph and if the administrator of an organization that examines pathogens and toxins who received the instructions does not follow the instructions without reasonable grounds, that governor or mayor may make that fact public.

(Reports on the Status of Implementation of Measures under Agreement on Examination and Other Measures)

- Article 36-8 (1) When a prefectural governor or relevant mayor finds it necessary, that governor or mayor may, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, request the manager of an organization that examines pathogens and toxins with which an agreement on examination and other measures has been concluded to report the status of implementation of the measures under that agreement, the status of its

operation, and other matters.

- (2) When a prefectural governor or relevant mayor requests a report pursuant to the provisions of the preceding paragraph, an administrator of an organization that examines pathogens and toxins must promptly report the matters listed in the items of that paragraph, except when there are reasonable grounds.
- (3) A prefectural governor who has received a report pursuant to the provisions of the preceding paragraph must report on the contents of the report to the Minister of Health, Labour and Welfare, and the mayor of a city or special ward with a public health center who has received a report pursuant to those provisions must report on the contents of the report to the prefectural governor, by electronic or magnetic means (meaning a method that utilizes an electronic data processing system or any other method that utilizes the information and communications technology specified by Order of the Ministry of Health, Labour and Welfare) and release it. In this case, the prefectural governor receiving the report must promptly report on the contents of the report to the Minister of Health, Labour and Welfare.
- (4) When the Minister of Health, Labour and Welfare or the prefectural governor finds it necessary, they may provide the necessary advice or assistance to the prefectural governor and to the mayor of a city or special ward with a public health center with regard to the matters prescribed in paragraph (1) for which the Minister or prefectural governor received a report pursuant to the provisions of the preceding paragraph.
- (5) When the Minister of Health, Labour and Welfare has received a report pursuant to the provisions of paragraph (3) or has given advice or assistance pursuant to the provisions of the preceding paragraph, the Minister is to, as necessary, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, release the contents of the report.

Section 2 Measures to Ensure Early Epidemic Medical Care

(Measures to Ensure Early Epidemic Medical Care)

Article 36-9 (1) During the period from the month during which the announcement of an outbreak or related event of a novel and reemerging influenza or coronavirus infection was made until the month during which the period specified by Cabinet Order has elapsed, when it is recognized that a medical institution in the area of the prefectural government has taken the measures (referred to below as "measures based on medical care and related agreements" in this paragraph and the following Article) listed in Article 36-2, paragraph (1), items (i) or (ii) that meet the standards specified by Order of the Ministry of Health, Labour and Welfare as measures to establish a system for the provision of medical care swiftly and adequately from an early stage of an

outbreak of a novel and reemerging influenza or coronavirus infection, designated infectious disease, or new infectious disease, and where the amount calculated pursuant to the provisions of a Cabinet Order as the amount of medical reimbursements to be paid to the medical institution (referred to below as the "target medical institution") for the month during which the medical institution is found to have taken the measures based on medical care and related agreements is less than the amount calculated pursuant to the provisions of a Cabinet Order before the announcement of an outbreak or related event of a novel and reemerging influenza or coronavirus infection, a prefectural governor is to take measures (referred to below as "measures to ensure early epidemic medical care") that include having the target medical institution pay the expenses necessary to ensure early epidemic medical care (referred to below as "expenses necessary to ensure early epidemic medical care").

- (2) A prefectural governor may entrust the affairs related to the measures to ensure early epidemic medical care pursuant to the provisions of the preceding paragraph to the Health Insurance Claims Review and Reimbursement Services (referred to below as "Reimbursement Services") or the Federation of National Health Insurance Associations (referred to below as "National Health Insurance Federation").

(Amount of Expenses Necessary to Ensure Early Epidemic Medical Care)

Article 36-10 The expenses necessary to ensure early epidemic medical care is the amount calculated pursuant to the provisions of Cabinet Order referred to in paragraph (1) of the preceding Article as the amount of the medical reimbursements to be paid to the target medical institution for the month during which the medical institution is found to have taken the measures based on medical care and related agreements; this applies during the period from the month during which the announcement of an outbreak or related event of a novel and reemerging influenza or coronavirus infection was made until the month during which the period specified by Cabinet Order referred to in paragraph (1) of the preceding Article has elapsed; the amount specified by Cabinet Order referred to in that paragraph is to be the amount calculated pursuant to the provisions of a Cabinet Order as the difference between the amount of the medical reimbursements to be paid to the target medical institution as calculated pursuant to the provisions of a Cabinet Order as stated in that paragraph in a month as prescribed in the Article.

(Payment of Expenses)

Article 36-11 A prefectural government is to pay the expenses necessary for the measures to ensure early epidemic medical care and expenses necessary for the

execution of affairs concerning measures to ensure early epidemic medical care.

(National Government Grants)

Article 36-12 Pursuant to the provisions of a Cabinet Order, the national government is to grant to prefectural governments an amount equivalent to three-eighths of the costs required for the measures to ensure early epidemic medical care.

(Subsidy to Ensure Early Epidemic Medical Care)

Article 36-13 (1) The amount equivalent to half of the cost required for the measures to ensure early epidemic medical care paid by a prefectural government pursuant to the provisions of Article 36-11 is to be appropriated by a subsidy to ensure early epidemic medical care delivered by the Reimbursement Services to the prefectural government, pursuant to the provisions of Cabinet Order.

(2) The subsidy to ensure early epidemic medical care stated in the preceding paragraph is to be allocated from the contributions to ensure early epidemic medical care collected by the Reimbursement Services pursuant to the provisions of paragraph (1) of the following Article.

(Obligation for the Collection and Payment of Contributions to Ensure Early Epidemic Medical Care)

Article 36-14 (1) In order to allocate funds for the expenses necessary for the services listed in the items of Article 36-25, paragraph (1) (excluding items (iii) and (iv)), during the period from the month during which the announcement of an outbreak or related event of a novel and reemerging influenza or coronavirus infection was made until the month during which the period specified by Cabinet Order referred to in Article 36-9, paragraph (1) has elapsed, for each month in which the measures to ensure early epidemic medical care were implemented, the Reimbursement Services is to collect contributions to ensure early epidemic medical care from the insurers (in the case of a national insurance program to be provided by a prefectural government together with municipalities within the prefecture pursuant to the provisions of the National Health Insurance Act (Act No. 192 of 1958), the prefectural government) stated in Article 7, paragraph (2) of the Act on Assurance of Medical Care for Elderly People (Act No. 80 of 1982) and the Associations of Medical Care Services for Older Senior Citizens stated in Article 48 of the Act on Assurance of Medical Care for Elderly People (referred to below as "insurers and other relevant organizations").

(2) The Reimbursement Services is to collect contributions for administrative expenses related to ensuring early epidemic medical care from insurers and

other relevant organizations every fiscal year in order to allocate them for the expenses necessary for the administration of affairs related to the services listed in the items of Article 36-25, paragraph (1) (excluding items (iii) and (iv)).

(3) Insurers and other relevant organizations have the duty to pay the contribution to ensure early epidemic medical care and the contribution for administrative expenses related to ensuring early epidemic medical care (referred to below as "contributions to ensure early epidemic medical care").

(Amount of Contribution to Ensure Early Epidemic Medical Care)

Article 36-15 The amount of the contributions to ensure early epidemic medical care to be collected from insurers and other relevant organizations pursuant to the provisions of paragraph (1) of the preceding Article is to be calculated pursuant to the provisions of Order of the Ministry of Health, Labor and Welfare, based on the amount equivalent to one-half of the expenses necessary for the measures to ensure early epidemic medical care in the month in which the measures to ensure early epidemic medical care were implemented, during the period from the month during which the announcement of an outbreak or related event of a novel and reemerging influenza or coronavirus infection was made until the month during which the period specified by Cabinet Order referred to in Article 36-9, paragraph (1) has elapsed, according to the ratio of the amount of medical reimbursements to be paid to a target medical institution by insurers and other relevant organizations pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Amount of Contributions for Administrative Expenses Related to Ensure Early Epidemic Medical Care)

Article 36-16 The amount of contributions for the administrative expenses related to ensuring early epidemic medical care to be paid by insurers and other relevant organizations pursuant to the provisions of Article 36-14, paragraph (2) is to be the amount calculated pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, based on the estimated amount of expenses necessary for the administrative processing related to the services listed in the items of Article 36-25, paragraph (1) (excluding items (iii) and (iv)) for each fiscal year, in accordance with the estimated number of policyholders that are prescribed in Article 7, paragraph (4) of the Act on Assurance of Medical Care for Elderly People concerning insurers and other relevant organizations and with the estimated number of insured persons of medical care for elderly people that are prescribed in Article 50 of that Act, calculated pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Special Provisions on the Amount of Contributions to Ensure Early Epidemic Medical Care in Case of a Merger or Split of Insurers)

Article 36-17 Special provisions for the calculation of the amount of the contributions to ensure early epidemic medical care for insurers established by a merger or split (meaning the insurers prescribed in Article 7, paragraph (2) of the Act on Assurance of Medical Care for Elderly People; the same applies below in this Article), insurers surviving after a merger or split, and insurers who succeeded the rights and obligations of the dissolved insurers are to be specified by Cabinet Order.

(Decisions, Notifications, and Other Actions Related to Contributions to Ensure Early Epidemic Medical Care)

Article 36-18 (1) For each month in which the measures to ensure early epidemic medical care are implemented during the period from the month during which the announcement of an outbreak or related event of a novel and reemerging influenza or coronavirus infection was made until the month during which the period specified by Cabinet Order referred to in Article 36-9, paragraph (1) has elapsed, the Reimbursement Services must determine the amount of contributions to ensure early epidemic medical care to be paid by insurers and other relevant organizations, and notify them of the amount of contributions to ensure early epidemic medical care to be paid by them, the method of payment, the deadline for payment, and other necessary matters.

(2) For each fiscal year, the Reimbursement Services must determine the amount of contribution for administrative expenses related to ensuring early epidemic medical care to be paid by insurers and other relevant organizations, and notify them of the amount of contribution for administrative expenses related to ensuring early epidemic medical care to be paid by them, the method of payment, the deadline for payment, and other necessary matters.

(3) When it becomes necessary to change the amount of contributions to ensure early epidemic medical care after the amount has been determined pursuant to the provisions of the preceding two paragraphs, the Reimbursement Services must adjust the contributions to be paid by the insurers and other relevant organizations and notify those organizations of the updated amount.

(4) When the amount of contributions to ensure early epidemic medical care paid by insurers and other relevant organizations (referred to below as "amount paid" in this paragraph) is less than the amount of contributions to ensure early epidemic medical care after the change (referred to below as "amount after change" in this paragraph) pursuant to the provisions of the preceding paragraph, the Reimbursement Services must share information on the method of payment, the deadline for payment, and other necessary matters concerning the shortfall amount with the notice pursuant to the provisions of the

preceding paragraph, and, if the amount paid exceeds the amount after change, must appropriate the amount in excess for unpaid contributions to ensure early epidemic medical care, and if there is any remaining amount, must refund the amount, or if there are no unpaid contributions to ensure early epidemic medical care, must refund the amount.

(Demand and Disposition to Collect Arrears)

- Article 36-19 (1) When an insurer or other relevant organization fails to pay the contributions to ensure early epidemic medical care by the deadline, the Reimbursement Services must demand payment by specifying a new deadline.
- (2) When the Reimbursement Services makes a demand pursuant to the provisions of the preceding paragraph, it is to send a written demand to the insurer or other relevant organization. In this case, the deadline to be specified in the written demand must be the day on which ten days or more have elapsed from the date on which the written demand is issued.
- (3) When an insurer or other relevant organization who has received a demand pursuant to the provisions of paragraph (1) fails to fully pay the contributions to ensure early epidemic medical care in response to the demand and the delinquency charge pursuant to the provisions of the following Article by the specified deadline, the Reimbursement Services is to request the Minister of Health, Labour and Welfare or the prefectural governor to collect the money pursuant to the provisions of Cabinet Order.
- (4) When the Minister of Health, Labour and Welfare or the prefectural governor has received a request for collection pursuant to the provisions of the preceding paragraph, they may dispose of the request pursuant to the provisions of the procedure for national tax delinquency.

(Delinquent Charges)

- Article 36-20 (1) If the Reimbursement Services has demanded payment of the contributions to ensure early epidemic medical care pursuant to the provisions of paragraph (1) of the preceding Article, the Reimbursement Services is to collect a delinquency charge calculated by the number of days from the day following the payment deadline to the day before the day of the full payment or the seizure of property at a rate of 14.5% per year of the demanded amount of the contributions; provided, however, that this does not apply when the demanded amount of the contributions is less than 1,000 yen.
- (2) In the case referred to in the preceding paragraph, if a part of the amount of the contributions to ensure early epidemic medical care has been paid, that amount, which is the basis for the calculation of the amount of the delinquency charge for the period after the date of the payment, is to be the amount after deducting that amount paid.

- (3) When the amount of the contributions to ensure early epidemic medical care stated in the preceding two paragraphs includes a fraction of less than one thousand yen in the calculation of the delinquency charge, the fraction is to be rounded down.
- (4) If the amount of the delinquency charge calculated pursuant to the provisions of the preceding three paragraphs includes a fraction of less than one hundred yen, the fraction is to be rounded down.
- (5) A delinquency charge is not to be collected in any of the following cases; provided, however, that in the case referred to in item (iii), that execution is suspended or limited to the amount corresponding to the period under suspension:
 - (i) when the person has fully paid the contributions to ensure early epidemic medical care by the deadline specified in the written demand;
 - (ii) when the amount of the delinquency charge is less than 100 yen;
 - (iii) when the execution of the disposition to collect arrears has been suspended or postponed with regard to the contributions to ensure early epidemic medical care; or
 - (iv) when it is found that there are unavoidable circumstances for not paying the contributions to ensure early epidemic medical care.

(Grace of Payment)

- Article 36-21 (1) If it is found to be extremely difficult for the insurer or other relevant organization to pay the contributions to ensure early epidemic medical care due to unavoidable circumstances, the Reimbursement Services may, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, receive the approval of the Minister of Health, Labour and Welfare based on an application by the organization, and postpone part of the payment for a period not exceeding one year from the deadline.
- (2) The Reimbursement Services must, when granting a suspension pursuant to the provisions of the preceding paragraph, notify the insurer or other relevant organization of the amount of contributions to ensure early epidemic medical care that is to be postponed, the length of the grace period, and other necessary matters.
 - (3) When the Reimbursement Services has granted a postponement pursuant to the provisions of paragraph (1), it may not make a new demand pursuant to the provisions of Article 36-19, paragraph (1) or a request for collection pursuant to the provisions of paragraph (3) of that Article with regard to the contributions to ensure early epidemic medical care that is to be postponed during the period of the postponement.

(Requests for Reports and Other Related Procedures)

Article 36-22 (1) When the Minister of Health, Labour and Welfare or the prefectural governor finds it necessary for calculating the amount of the contributions to ensure early epidemic medical care, they may request insurers and other relevant organizations to submit reports on their services or have employees inspect the situation on the spot.

(2) The provisions of Article 35, paragraphs (2) and (3) apply mutatis mutandis to the inspection under the provisions of the preceding paragraph.

(Return of the Expenses Necessary to Ensure Early Epidemic Medical Care)

Article 36-23 (1) Target medical institutions, during the period from the month during which the announcement of an outbreak or related event of a novel and reemerging influenza or coronavirus infection was made, until the month during which the period specified by Cabinet Order referred to in Article 36-9, paragraph (1) has elapsed, if the total amount of the medical reimbursements to be paid to the target medical institutions and the income related to the expenses necessary for ensuring early epidemic medical care implemented in the month of the outbreak, and other income specified by Cabinet Order, exceed the amount calculated as the amount of the medical reimbursements to be paid to the target medical institutions for the month specified by that Cabinet Order, must return the difference to the prefectural government as an amount specified by Cabinet Order (referred to below as "returned money" in this Article and Article 36-25, paragraph (1), item (iv)).

(2) When the returned money has been returned pursuant to the provisions of the preceding paragraph, the prefectural government must reimburse the national government the amount equivalent to three-eighths of the total returned money and refund the amount equivalent to one-half of the total returned money to the insurer or other relevant organization based on the amount of the contributions to ensure early epidemic medical care collected from the insurer or other relevant organization pursuant to the provisions of Article 36-14, paragraph (1).

(3) A prefectural government may entrust the affairs related to the return of money pursuant to the provisions of paragraph (1) and the affairs related to the return to the insurer or other relevant organization pursuant to the provisions of the preceding paragraph to the Reimbursement Services or the National Health Insurance Federation.

(4) The provisions of Article 36-19 to the preceding Article apply mutatis mutandis to the return of the expenses necessary to ensure early epidemic medical care prescribed in paragraph (1). In this case, any necessary technical replacement of terms is to be specified by Cabinet Order.

(Reimbursement of the Expenses Necessary to Ensure Early Epidemic Medical

Care)

Article 36-24 (1) When the prefectural governor has given instructions pursuant to the provisions of Article 36-4, paragraph (1) or paragraph (3), when the administrator of the target medical institution who received these instructions does not follow the instructions without reasonable grounds, the target medical institution may be ordered to reimburse all or part of the expenses necessary to ensure early epidemic medical care that have already been granted.

(2) The provisions of Articles 36-19 through 36-22 and paragraphs (2) and (3) of the preceding Article apply mutatis mutandis to the reimbursement of expenses necessary to ensure early epidemic medical care prescribed in the preceding paragraph. In this case, any necessary technical replacement of terms is to be specified by Cabinet Order.

(Business of the Reimbursement Services)

Article 36-25 (1) In addition to the services prescribed in Article 15 of the Health Insurance Claims Review and Reimbursement Services Act (Act No. 129 of 1948), the Reimbursement Services is to, in order to achieve the purpose prescribed in Article 1, carry out the following services (referred to below as "services related to measures to ensure early epidemic medical care"):

(i) collecting the contributions to ensure early epidemic medical care from insurers and other relevant organizations;

(ii) granting subsidies to ensure early epidemic medical care to prefectural governments;

(iii) conducting affairs related to measures to ensure early epidemic medical care entrusted by the prefectural governor pursuant to the provisions of Article 36-9, paragraph (2);

(iv) conducting affairs related to the return of the money entrusted by the prefectural government pursuant to the provisions of Article 36-23, paragraph (3) (including cases where it is applied mutatis mutandis pursuant to paragraph (2) of the preceding Article), affairs related to the return of money to insurers and other relevant organizations, and affairs related to the return of expenses necessary to ensure early epidemic medical care; and

(v) carrying out services incidental to the services listed in the preceding items.

(2) The Reimbursement Services may, by obtaining the approval of the Minister of Health, Labour and Welfare, entrust part of the services related to measures to ensure early epidemic medical care to the National Health Insurance Federation or other organizations prescribed by Order of the Ministry of Health, Labour and Welfare.

(Operational Method Statements)

Article 36-26 (1) The Reimbursement Services must prepare an operational method statement and obtain approval from the Minister of Health, Labour and Welfare before commencing the services related to measures to ensure early epidemic medical care. The same applies when any changes are made to that statement.

(2) The matters to be included in the operational method statement stated in the preceding paragraph are to be specified by Order of the Ministry of Health, Labour and Welfare.

(Reports)

Article 36-27 In addition to requesting insurers and other relevant organizations to report on the number of policyholders and other matters specified by Order of the Ministry of Health, Labour and Welfare every fiscal year, the Reimbursement Services may, when it finds it necessary for the services listed in Article 36-25, paragraph (1), item (i), request the submission of documents and other materials.

(Separate Accounting)

Article 36-28 The Reimbursement Services must establish a special account with regard to accounting for services related to measures to ensure early epidemic medical care, separate from accounting for other services.

(Approval of the Budget and Related Plans)

Article 36-29 The Reimbursement Services must prepare a budget, business plan, and financial plan for each fiscal year for the services related to measures to ensure early epidemic medical care, and before the start of the relevant fiscal year, obtain approval from the Minister of Health, Labour and Welfare. The same applies when any changes are made to those statements.

(Financial Statements and other related documents)

Article 36-30 (1) The Reimbursement Services must, for each fiscal year, prepare an inventory of assets, a balance sheet, and a profit and loss statement (referred to below as "financial statements") with regard to services related to measures to ensure early epidemic medical care, and submit them to the Minister of Health, Labour and Welfare for approval within three months after the end of the relevant fiscal year.

(2) When submitting a financial statement to the Minister of Health, Labour and Welfare pursuant to the provisions of the preceding paragraph, the Reimbursement Services must, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, attach the business report and the settlement of accounts to it, prepared in accordance with the budgetary

divisions for the fiscal year, as well as the auditor's written opinion on the financial statement and settlement of accounts.

- (3) When the Reimbursement Services has obtained approval from the Minister of Health, Labour and Welfare pursuant to the provisions of paragraph (1), the Reimbursement Services must make a public notice of the financial statements or a summary of those statements in the Official Gazette without delay, and the financial statements and annexed detailed statements as well as the business report, settlement of accounts, and the written opinion of the auditors stated in the preceding paragraph must be kept at the main office and made available for public inspection during the period specified by Order of the Ministry of Health, Labour and Welfare.

(Disposition of Profits and Losses)

Article 36-31 (1) In each fiscal year, with regard to the services related to measures to ensure early epidemic medical care, when profits have been confirmed in the calculation of profit and loss, the Reimbursement Services must compensate for the losses carried over from the previous fiscal year, and if there is any residual amount, the amount of the residual amount must be treated as a reserve fund.

- (2) In each fiscal year, when a loss is confirmed in the calculation of profit and loss for the services related to measures to ensure early epidemic medical care, the Reimbursement Services must adjust it by reducing the reserve under the provisions of the preceding paragraph, and if there is a shortage, the amount of the shortage must be treated as a loss to be carried forward.
- (3) The Reimbursement Services may allocate the reserve under paragraph (1) for the expenses necessary for the services listed in Article 36-25, paragraph (1), items (ii) through (iv), limited to the amount specified by the budget.

(Borrowings and Bonds)

Article 36-32 (1) The Reimbursement Services may, by getting the approval of the Minister of Health, Labour and Welfare, obtain a long-term or short-term borrowing or issue bonds for the services related to measures to ensure early epidemic medical care.

- (2) A long-term borrowings or bond pursuant to the provisions of the preceding paragraph must be redeemed within two years.
- (3) A short-term borrowing pursuant to the provisions of paragraph (1) must be redeemed within the relevant fiscal year. However, if it cannot be redeemed due to a lack of funds, it may be refinanced with the approval of the Minister of Health, Labour and Welfare, limited to the amount that cannot be redeemed.
- (4) A short-term borrowing refinanced pursuant to the provisions of the proviso to the preceding paragraph must be redeemed within one year.

- (5) When the Reimbursement Services issues a bond pursuant to the provisions of paragraph (1), the Reimbursement Services may issue that bond subject to a bond discount.
- (6) Creditors of bonds pursuant to the provisions of paragraph (1) are to have the right to receive performance of their own claims in preference to other creditors with respect to the property of the Reimbursement Services.
- (7) The order of the statutory lien stated in the preceding paragraph is to be next to the general statutory lien under the provisions of the Civil Code (Act No. 89 of 1896).
- (8) With the authorization of the Minister of Health, Labour and Welfare, the Reimbursement Services may entrust the whole or a part of the affairs concerning the issuance of bonds pursuant to the provisions of paragraph (1) to a bank or trust company.
- (9) The provisions of Article 705, paragraphs (1) and (2) and Article 709 of the Companies Act (Act No. 86 of 2005) apply mutatis mutandis to the bank or trust company entrusted pursuant to the provisions of the preceding paragraph.
- (10) Beyond what is prescribed in paragraph (1), paragraph (2), and paragraph (5) to the preceding paragraph, necessary matters concerning bond certificates stated in paragraph (1) are to be specified by Cabinet Order.

(Government Guarantees)

Article 36-33 Regardless of the provisions of Article 3 of the Act on Restrictions on Financial Assistance by the Government to Corporations (Act No. 24 of 1946), when the government finds it necessary for the smooth issuance of grants to ensure early epidemic medical care by the Reimbursement Services and for the implementation of the affairs stated in Article 36-25, paragraph (1), item (iii), within the scope decided by the Diet, the government may guarantee the Reimbursement Services' long-term borrowings, short-term borrowings, or debt obligations under the provisions of the preceding Article within the period found to be necessary.

(Investment of Surplus Funds)

Article 36-34 The Reimbursement Services must not invest surplus funds when carrying out services related to measures to ensure early epidemic medical care, except by the following methods:

- (i) holding national government bonds and other securities designated by the Minister of Health, Labour and Welfare;
- (ii) deposits in banks or other financial institutions designated by the Minister of Health, Labour and Welfare; or
- (iii) money trusts to financial institutions (meaning a financial institution that has obtained the authorization stated in Article 1, paragraph (1) of the Act

on Engagement in Trust Business Activities by Financial Institutions (Act No. 43 of 1943)) engaged in the trust business.

(Consultation)

Article 36-35 The Minister of Health, Labour and Welfare must consult with the Minister of Finance in advance in any of the following cases:

- (i) when the Minister intends to grant the authorization stated in Article 36-32, paragraph (1), the proviso to paragraph (3), or paragraph (8); and
- (ii) when the Minister intends to make a designation pursuant to the provisions of item (i) or item (ii) of the preceding Article.

(Delegation to Order of the Ministry of Health, Labour and Welfare)

Article 36-36 Beyond what is prescribed in this Section, necessary matters concerning the finance and accounting of the Reimbursement Services for the services related to measures to ensure early epidemic medical care are to be prescribed by Order of the Ministry of Health, Labour and Welfare.

(Requests for Reports and Other Related Procedures)

Article 36-37 (1) The Minister of Health, Labour and Welfare or the prefectural governor may collect reports on the status of the services or property of the Reimbursement Services or the person entrusted pursuant to the provisions of Article 36-25, paragraph (2) (referred to below as "trustee" in this paragraph and Article 77, paragraph (2)), or may have the relevant personnel inspect the status on the spot, when they find it necessary in relation to the services related to measures to ensure early epidemic medical care; provided, however, that with regard to the trustee, this is be limited to the scope of the entrusted business.

- (2) The provisions of Article 35, paragraphs (2) and (3) apply mutatis mutandis to the inspection carried out under the provisions of the preceding paragraph.
- (3) When a prefectural governor finds it necessary to carry out a disposition under the provisions of Article 29 of the Health Insurance Claims Review and Reimbursement Services Act with regard to services related to measures to ensure early epidemic medical care or finds it necessary to carry out a disposition under the provisions of Article 11, paragraph (2) or paragraph (3) of that Act with regard to services related to measures to ensure early epidemic medical care for the president, director, or auditor of the Reimbursement Services, the prefectural governor must notify the Minister of Health, Labour and Welfare of their decision, including the reasons for it.

(Special Provisions on the Application of the Health Insurance Claims Review and Reimbursement Services Act)

Article 36-38 With regard to the application of the provisions of Article 32, paragraph (2) of the Health Insurance Claims Review and Reimbursement Services Act, the services related to measures to ensure early epidemic medical care are deemed to be the services prescribed in Article 15 of that Act.

(Requests for Administrative Review)

Article 36-39 A person who is dissatisfied with the disposition of the Reimbursement Services under this Act or inaction of the Reimbursement Services may file an application for examination with the Minister of Health, Labour and Welfare. In this case, when the provisions of Article 25, paragraphs (2) and (3), Article 46, paragraphs (1) and (2), Article 47, and Article 49, paragraph (3) of the Administrative Complaint Review Act apply, the Minister of Health, Labour and Welfare is to be deemed the higher administrative authority of the Reimbursement Services.

(Matters Mandated by Order of the Ministry of Health, Labour and Welfare)

Article 36-40 Beyond what is prescribed in this section, necessary matters concerning measures to ensure early epidemic medical care are to be prescribed by Order of the Ministry of Health, Labour and Welfare.

Section 3 Medical and Other Services for Inpatients

(Medical Services for Inpatients)

Article 37 (1) If a prefectural governor has recommended hospitalization or implemented hospitalization measures pursuant to the provisions of Article 19 or 20 (including cases where these provisions are applied mutatis mutandis in Article 26) or the provisions of Article 46, the prefectural government will cover the following expenses for the medical services received by the patient (including a person with symptoms of a new infectious disease; the same applies below in this Article) who is subject to the hospitalization at a designated medical institution for infectious diseases if the patient or their custodian files an application for the payment of those expenses:

- (i) diagnosis;
- (ii) supply of medicines or therapeutic materials;
- (iii) medical procedures, surgery, and other therapy; and
- (iv) caring and other nursing following admission to a hospital and the medical treatment there.

(2) If the patient prescribed in the preceding paragraph or their spouse or the person obligated to support the patient as prescribed in Article 877, paragraph (1) of the Civil Code is found to be capable of covering the expenses referred to in paragraph (1) in whole or in part, the prefectural government is not required

to cover the expenses under the provisions of the that paragraph that the person is capable of covering, regardless of the provisions of that paragraph.

- (3) Beyond what is prescribed in the preceding paragraph, if the prefectural governor has recommended hospitalization or implemented hospitalization measures pursuant to the provisions of Article 19, Article 20, or Article 46 as applied mutatis mutandis pursuant to Article 26, paragraph (2) following the deemed replacement of terms, and the patient who is subject to the hospitalization does not respond to the request for cooperation pursuant to the provisions of Article 44-3, paragraph (2) or Article 50-2, paragraph (2), the prefectural governor is not required to cover all or part of the expenses pursuant to the provisions of that paragraph, regardless of the provisions of paragraph (1); provided, however, that this does not apply when it is found that the patient or their spouse, or the person obligated to support the patient as prescribed in Article 877, paragraph (1) of the Civil Code are unable to cover all or part of the expenses stated in paragraph (1).
- (4) An application referred to in paragraph (1) must be filed with the prefectural governor through the chief of the public health center having jurisdiction over the place of residence of the patient.

(Medical Services for Tuberculosis Patients)

Article 37-2 (1) To promote widespread development of proper medical care for tuberculosis, a prefectural government may, after receiving an application filed by a tuberculosis patient residing in any area under the prefecture's jurisdiction or their custodian, cover 95% of the expenses necessary for the tuberculosis patient to receive the medical services specified by Order of the Ministry of Health, Labour and Welfare at a designated medical institution for tuberculosis.

- (2) An application as referred to in the preceding paragraph must be filed with the prefectural governor through the chief of the public health center having jurisdiction over the place of residence of the tuberculosis patient.
- (3) When the prefectural governor makes a decision in relation to an application referred to in the preceding paragraph, the prefectural governor must hear opinions of the infectious disease examination committee prescribed in Article 24, paragraph (1) established in the public health center.
- (4) After six months have passed since an application referred to in paragraph (1) was filed, the coverage of the expenses by the prefectural government based on the application is to be terminated.

(Designated Medical Institutions for Infectious Diseases)

Article 38 (1) A designated medical institution for specified infectious diseases is to be designated by the Minister of Health, Labour and Welfare, upon

obtaining consent of the proprietor of that medical institution, and further subject to consultations with the prefectural governor having jurisdiction over the location of that medical institution.

- (2) A designated medical institution for class I infectious diseases, designated medical institution for class II infectious diseases, designated medical institution for class I agreement, designated medical institution for class II agreement, or designated medical institution for tuberculosis is to be designated by a prefectural governor, upon obtaining consent of the proprietor of that medical institution, which is to be selected from the hospitals (hospitals or clinics in the case of a designated medical institution for class I agreement, and hospitals, clinics or pharmacies in the case of a designated medical institution for class II agreement or a designated medical institution for tuberculosis) conforming to the standards specified by the Minister of Health, Labour and Welfare.
- (3) Pursuant to the provisions specified by the Minister of Health, Labour and Welfare, a designated medical institution for infectious diseases must take charge of the medical services for patients with infectious diseases and persons with symptoms of new infectious diseases for which the prefectural government covers expenses in accordance with the provisions of the preceding two Articles.
- (4) With regard to the medical services which are referred to in the respective items of Article 37, paragraph (1) and which are provided for persons with symptoms of a new infectious disease and patients with a class I or class II infectious disease or a novel and reemerging influenza or coronavirus infection, a designated medical institution for specified infectious diseases must follow any guidance offered by the Minister of Health, Labour and Welfare.
- (5) With regard to the medical services which are referred to in the respective items of Article 37, paragraph (1) and which are provided for patients with a class I or class II infectious disease or a novel and reemerging influenza or coronavirus infection, a designated medical institution for class I infectious diseases must follow any guidance offered by the prefectural governor pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (6) With regard to the medical services which are referred to in the respective items of Article 37, paragraph (1) and which are provided for patients with a class II infectious disease or a novel and reemerging influenza or coronavirus infection, a designated medical institution for class II infectious diseases must follow any guidance offered by the prefectural governor pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (7) With regard to the medical services which are referred to in the respective items of Article 37, paragraph (1) and which are provided for patients with a novel and reemerging influenza or coronavirus infection or a designated infectious disease and persons with symptoms of a new infectious disease, a

designated medical institution for class I agreement must follow any guidance offered by the prefectural governor pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

- (8) A designated medical institution for class II agreement must follow any guidance offered by the prefectural governor pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare with regard to medical services prescribed by Order of the Ministry of Health, Labour and Welfare stated in Article 44-3-2, paragraph (1) (including cases where it is applied mutatis mutandis by Cabinet Order pursuant to the provisions of Article 44-9, paragraph (1)) or Article 50-3, paragraph (1).
- (9) With regard to the medical services prescribed in paragraph (1) of the preceding Article, a designated medical institution for tuberculosis must follow any guidance offered by the prefectural governor pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (10) If a designated medical institution for infectious diseases intends to decline its designation, it must submit a notification stating that intention at least one year (or 30 days, in the case of a designated medical institution for tuberculosis) before the date of declination to the Minister of Health, Labour and Welfare in the case of a designated medical institution for specified infectious diseases or to the prefectural governor in the case of a designated medical institution for class I infectious diseases, designated medical institution for class II infectious diseases, designated medical institution for class I agreement, designated medical institution for class II agreement, or designated medical institution for tuberculosis.
- (11) If a designated medical institution for infectious diseases violates any of the provisions of paragraphs (3) through (9), or is otherwise found to be unsuitable to provide the medical services prescribed in the preceding two Articles, the Minister of Health, Labour and Welfare may revoke the designation of the institution if it is a designated medical institution for specified infectious diseases, or the prefectural governor may revoke the designation of the institution if it is a designated medical institution for class I infectious diseases, designated medical institution for class II infectious diseases, designated medical institution for class I agreement, designated medical institution for class II agreement, or designated medical institution for tuberculosis.

(Adjustment with Benefits for Medical Care under Other Laws)

- Article 39 (1) If a patient with an infectious disease (excluding a person with symptoms of a new infectious disease) eligible for the coverage of expenses pursuant to the provisions of Article 37, paragraph (1) or Article 37-2, paragraph (1) is concurrently eligible to receive benefits related to medical care

pursuant to the provisions of the Health Insurance Act (Act No. 70 of 1922), the National Health Insurance Act, the Mariners Insurance Act (Act No. 73 of 1939), the Industrial Accident Compensation Insurance Act (Act No. 50 of 1947), the National Public Servants Mutual Aid Association Act (Act No. 128 of 1958; including cases where it is applied mutatis mutandis in other laws or where the same rules govern), the Local Public Officers, etc. Mutual Aid Association Act (Act No. 152 of 1962), the Act on Assurance of Medical Care for Elderly People, or the Long-Term Care Insurance Act (Act No. 123 of 1997), the prefectural government is not required to cover the expenses under the provisions of Article 37, paragraph (1) or Article 37-2, paragraph (1) that are covered by the benefits granted under the laws listed above.

- (2) The provisions of Article 37, paragraph (1) or Article 37-2, paragraph (1) do not apply to tuberculosis patients eligible for the medical care pursuant to the provisions of the Act on Relief to Wounded and Sick Retired Soldiers (Act No. 168 of 1963).
- (3) If a tuberculosis patient eligible for the coverage of expenses pursuant to the provisions of Article 37, paragraph (1) or Article 37-2, paragraph (1) is concurrently eligible for the benefits of medical treatment and education under the provisions of the Child Welfare Act (Act No. 164 of 1947), the payment for the medical treatment and education under the provisions of that Act will not be made for the expenses covered by the prefectural government for that patient.

(Medical Fee Claims, Examination, and Payment)

Article 40 (1) A designated medical institution for infectious diseases is to claim the portion of medical reimbursements which is paid by the prefectural government pursuant to the provisions of Article 37, paragraph (1) or Article 37-2, paragraph (1) to the prefectural government.

- (2) The prefectural government must pay the expenses referred to in the preceding paragraph to the designated medical institution for infectious diseases.
- (3) A prefectural governor may from time to time examine the details of medical care provided and the medical reimbursements claimed by a designated medical institution for infectious diseases, and decide the amounts of medical reimbursements which that designated medical institution for infectious diseases is entitled to claim under the provisions of paragraph (1).
- (4) A designated medical institution for infectious diseases must follow the decisions made by the prefectural governor under the preceding paragraph.
- (5) When a prefectural governor decides the amounts of medical reimbursements pursuant to the provisions of paragraph (3), the prefectural governor must hear the opinion of the review committee provided for in the Health Insurance

Claims Review and Reimbursement Services Act, the national health insurance reimbursement review committee provided for in the National Health Insurance Act, and other reviewing bodies for medical care issues as specified by Cabinet Order.

- (6) A prefectural government may entrust the Reimbursement Services, the National Health Insurance Federation, or other persons specified by Order of the Ministry of Health, Labour and Welfare with affairs related to payments of medical reimbursements to a designated medical institution for infectious diseases.
- (7) A request for administrative review may not be filed with regard to any decision on the amounts of medical reimbursements under the provisions of paragraph (3).

(Standards for Medical Reimbursements)

Article 41 (1) The medical reimbursements payable for the medical services stated in the respective items of Article 37, paragraph (1) or the medical services specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 37-2, paragraph (1) performed by a designated medical institution for infectious diseases are governed by the rules applicable to the medical reimbursements through health insurance.

- (2) When it is impossible or unsuitable to apply the rules on the medical reimbursements prescribed in the preceding paragraph, the medical reimbursements will be governed by the provisions specified by the Minister of Health, Labour and Welfare.

(Special Provisions for Emergency and Other Medical Services)

Article 42 (1) If a patient (including a person with symptoms of a new infectious disease; the same applies below in this paragraph) hospitalized in a hospital or clinic which is not a designated medical institution for infectious diseases in any prefecture pursuant to the provisions of Article 19 or 20 (including cases where these provisions are applied mutatis mutandis in Article 26, paragraph (1); the same applies below in this paragraph) or pursuant to the provisions of Article 46 has received the medical services stated in the respective items of Article 37, paragraph (1) from the hospital or clinic, or if a tuberculosis patient (excluding patients hospitalized pursuant to the provisions of Article 19 or 20 as applied mutatis mutandis pursuant to Article 26 following the deemed replacement of terms; the same applies below in this paragraph) residing in any area of the prefecture has received the medical services specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 37-2, paragraph (1) from a hospital or clinic or pharmacy which is not a designated medical institution for tuberculosis in an emergency or under other

- unavoidable circumstances, the prefectural government may, upon request of the patient or their custodian, reimburse the expenses for that medical treatment in an amount calculated in the same way as applicable to the amount to be covered under the provisions of Article 37, paragraph (1) or Article 37-2, paragraph (1). The same applies when those medical services have been provided in an emergency or under other unavoidable circumstances without filing an application referred to in Article 37, paragraph (1) or Article 37-2, paragraph (1) if a patient hospitalized in a designated medical institution for infectious diseases pursuant to the provisions of Article 19, 20, or 46 has received the medical services stated in the respective items of Article 37, paragraph (1) from the medical institution, or if a tuberculosis patient residing in any area of the prefecture has received the medical services specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 37-2, paragraph (1) from a designated medical institution for tuberculosis.
- (2) The provisions of Article 37, paragraph (4) apply mutatis mutandis to the applications referred to in the preceding paragraph.
- (3) The expenses for medical treatment referred to in paragraph (1) are to be paid to the patient only if the medical services are found to have been truly necessary at the time the patient received them.

(Requests for Reports and Inspections)

- Article 43 (1) If it is found to be necessary to ensure that the expenses prescribed in Article 37, paragraph (1) and Article 37-2, paragraph (1) are properly covered, the prefectural governor (or either the Minister of Health, Labour and Welfare or the prefectural governor, with regard to designated medical institutions for specified infectious diseases; the same applies below in the following paragraph) may request that the administrator of a designated medical institution for infectious diseases make necessary reports or direct relevant officials to physically inspect the records of medical services and other books and documents (including electronic or magnetic records (meaning records produced by an electronic device, magnetic device, or any other device not recognizable to the human senses, which are made available for use in information processing by computers) when those records are prepared and retained in lieu of the books and documents) of a designated medical institution for infectious diseases, with the consent of its administrator.
- (2) If a designated medical institution for infectious diseases fails to respond to a request for a report as referred to in the preceding paragraph, makes a false report, or refuses to give its consent as referred to in that paragraph without reasonable grounds, the prefectural governor may instruct temporary suspension of or suspend the payment of medical reimbursements to the designated medical institution for infectious diseases.

(Matters Mandated by Order of the Ministry of Health, Labour and Welfare)

Article 44 Beyond what is provided for in this Act, necessary matters concerning the procedures for filing an application referred to in Article 37, paragraph (1) or Article 37-2, paragraph (1), the procedures for claiming and payment of medical reimbursements and for entrustment of affairs for processing those payments referred to in Article 40, and other necessary matters related to the coverage of expenses prescribed in this section are specified by Order of the Ministry of Health, Labour and Welfare.

Chapter VII Novel Influenza Infection

(Public Disclosure of Information on an Outbreak of a Novel Influenza Infection and Measures to Be Implemented)

Article 44-2 (1) When the Minister of Health, Labour and Welfare recognizes an outbreak of a novel and reemerging influenza or coronavirus infection, the Minister must promptly release the information on the outbreak and the area facing the outbreak, while releasing the information on that infectious disease pursuant to the provisions of Article 16, paragraph (1), and subsequently release information on the method of examining the pathogen, pathological conditions, method of diagnosis and medical treatment, and method of infection prevention, measures to be implemented pursuant to the provisions of this Act, and other information necessary to prevent the outbreak or spread of that infectious disease in newspapers, by broadcasting, via the Internet, or by any other suitable means.

(2) When the information under the provisions of the preceding paragraph is made public, due regard must be paid to protect personal information.

(3) If the infectious disease which is the subject of the information released pursuant to the provisions of paragraph (1) is no longer recognized as a novel and reemerging influenza or coronavirus infection because a large majority of the public has acquired immunity to that infectious disease or due to any other reason, the Minister of Health, Labour and Welfare must promptly make that fact public.

(Reporting or Cooperation in Order to Prevent Infections)

Article 44-3 (1) When a prefectural governor finds it necessary to prevent the spread of a novel and reemerging influenza or coronavirus infection, the prefectural governor may request a person who is justifiably suspected to be infected with that infectious disease to report their body temperature and other facts regarding their state of health, or request the person to refrain from leaving their residence or other equivalent places, or otherwise cooperate in

any way necessary to prevent transmission of that infectious disease during the period to be specified based on the incubation period of that infectious disease, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

- (2) When a prefectural governor finds it necessary to prevent the spread of a novel and reemerging influenza or coronavirus infection (limited to those specified by Order of the Ministry of Health, Labour and Welfare based on the severity of pathological conditions; the same applies in paragraph (1) of the following Article), the prefectural governor may request a patient with that infectious disease to report their body temperature and other facts regarding their state of health, until it is confirmed that they are not carrying the pathogens of the infectious disease, or request the patient to refrain from going out of an accommodation facility (limited to those that satisfy the criteria specified by Order of the Ministry of Health, Labour and Welfare as suitable for preventing the spread of the infectious disease; the same applies in paragraph (11) and paragraph (1) of that Article) or their residence or other equivalent places or otherwise cooperate in any way necessary to prevent the transmission of that infectious disease.
- (3) A person who has been requested to report pursuant to the provisions of the preceding two paragraphs must respond to the request, except when there are reasonable grounds, and a person who has been requested to cooperate pursuant to the provisions of the preceding two paragraphs must endeavor to respond to the request.
- (4) A prefectural governor may entrust a request to report pursuant to the provisions of paragraph (1) to a person found to be suitable by the prefectural governor.
- (5) A prefectural governor may entrust a request to report pursuant to the provisions of paragraph (2) to a designated medical institution for class II agreement (limited to a medical institution that takes measures based on the notice (limited to a notice that includes the measures stated in item (iii) of that paragraph) pursuant to the provisions of Article 36-2, paragraph (1), or a medical care agreement (limited to a medical care agreement that includes the measures stated in that item)) or any other person found to be suitable by the prefectural governor.
- (6) A person entrusted pursuant to the provisions of the preceding two paragraphs must report the contents of the report pursuant to the provisions of paragraph (1) or paragraph (2) to the prefectural governor who entrusted the person with the report.
- (7) When a prefectural governor makes a request for cooperation pursuant to the provisions of paragraph (1) or paragraph (2), the prefectural governor must, as necessary, endeavor to provide meals, supply daily necessities, and offer other

essential daily goods or services as necessary (referred to below as "meals or other support services" in the following paragraph).

- (8) If necessary meals or other support services are offered pursuant to the provisions of the preceding paragraph, the prefectural governor may collect the actual costs for the meal or other support services from the recipient or their custodian.
- (9) When the prefectural governor makes a request for a report or cooperation pursuant to the provisions of paragraph (1) or paragraph (2), the prefectural governor is to make a request for cooperation to the mayor of the municipality as necessary.
- (10) When the mayor of a municipality finds it necessary to respond to a request for cooperation pursuant to the provisions of the preceding paragraph, the mayor may request the prefectural governor to provide information on a person who is justifiably suspected to have a novel and reemerging influenza or coronavirus infection, information on a patient with that infection prescribed in paragraph (2), or other information.
- (11) When requesting cooperation pursuant to the provisions of paragraph (2), the prefectural governor must endeavor to secure necessary accommodation facilities by taking into consideration the medical condition and number of patients with a novel and reemerging influenza or coronavirus infection prescribed in that paragraph within the area under the jurisdiction of the prefectural governor and the circumstances of the outbreak and spread of the infectious disease.

(Medical Services for Persons Subject to Voluntary Restraint Due to a Novel and Reemerging Influenza or Coronavirus Infection)

Article 44-3-2 (1) Except in the cases specified by Order of the Ministry of Health, Labour and Welfare, if an application has been filed by a patient with a novel and reemerging influenza or coronavirus infection (referred to below as "person subject to voluntary restraint due to a novel and reemerging influenza or coronavirus infection") who is requested to cooperate in not leaving their accommodation facility, their residence, or other equivalent places pursuant to the provisions of paragraph (2) of the preceding Article, or their custodian, the prefectural government is to cover the expenses necessary for the medical services specified by Order of the Ministry of Health, Labour and Welfare that persons subject to voluntary restraint due to a novel and reemerging influenza or coronavirus infection receive from a designated medical institution for class II agreement.

- (2) The provisions of Article 37, paragraph (2) apply mutatis mutandis to the coverage stated in the preceding paragraph, the provisions of paragraph (4) of that Article apply mutatis mutandis to the application stated in the preceding

paragraph, and the provisions of Articles 39 through 41 and Article 43 apply mutatis mutandis to the case stated in that paragraph.

(Special Provisions for Emergency and Other Medical Services for Persons Subject to Voluntary Restraint Due to a Novel and Reemerging Influenza or Coronavirus Infection)

- Article 44-3-3 (1) Except for the cases specified by Order of the Ministry of Health, Labour and Welfare, if a person subject to voluntary restraint due to a novel and reemerging influenza or coronavirus infection who lives in the area receives medical services specified by Order of the Ministry of Health, Labour and Welfare referred to in paragraph (1) of the preceding Article from a hospital, clinic, or pharmacy other than a designated medical institution for class II agreement due to an emergency or for any other unavoidable circumstances, the prefectural government may pay the amount of medical treatment expenses calculated based on the amount to be covered pursuant to the provisions of that paragraph if the person subject to voluntary restraint due to that infection or their custodian files an application. The same applies when the person subject to voluntary restraint due to that infection receives the medical services prescribed by Order of the Ministry of Health, Labour and Welfare as referred to in that paragraph from a designated medical institution for class II agreement in that paragraph, and the medical services have been provided without filing the application stated in that paragraph due to an emergency or other unavoidable circumstances.
- (2) The provisions of Article 37, paragraph (4) apply mutatis mutandis to the applications referred to in the preceding paragraph.
- (3) The expenses for medical treatment referred to in paragraph (1) are to be paid to a person subject to voluntary restraint due to a novel and reemerging influenza or coronavirus infection only if the medical services are found to have been truly necessary at the time the patient received them.

(Matters Mandated by Order of the Ministry of Health, Labour and Welfare)

Article 44-3-4 Beyond what is provided for in the preceding two Articles, necessary matters concerning the procedures for filing an application referred to in Article 44-3-2, paragraph (1) and the coverage of expenses prescribed in this Chapter are to be specified by Order of the Ministry of Health, Labour and Welfare.

(Requests and Inquiries for Submission of Specimens of Novel and Reemerging Influenza or Coronavirus Infections)

Article 44-3-5 (1) If the Minister of Health, Labour and Welfare finds it necessary for collecting information on the nature of a novel and reemerging

influenza or coronavirus infection and the severity of pathological conditions following infection with the infectious disease and other necessary information during the period from the time when an announcement pursuant to the provisions of Article 44-2, paragraph (1) is made to the time when an announcement pursuant to the provisions of paragraph (3) of that Article is made, the Minister may request the administrator of a designated medical institution for infectious diseases or other persons specified by Order of the Ministry of Health, Labour and Welfare to submit all or part of the specimens or pathogens sampled from the patient with the infectious disease.

- (2) When the Minister of Health, Labour and Welfare has made a request pursuant to the provisions of the preceding paragraph, they must notify the prefectural governor (if the location is within a city or special ward with a public health center, the mayor of that city or ward having jurisdiction over the location; the same applies in the following paragraph and paragraph (5)) having jurisdiction over the location of the person who received that request.
- (3) When a person who has received a request pursuant to the provisions of paragraph (1) possesses or comes to possess all or part of the specimens or pathogens stated in that paragraph, the person must immediately submit those specimens or pathogens to the prefectural governor.
- (4) When the prefectural governor prescribed in paragraph (2) has received specimens or pathogens pursuant to the provisions of the preceding paragraph, they must immediately examine them pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, and the results must be reported by electronic or magnetic means to the Minister of Health, Labour and Welfare (in the case of the mayor of a city or special ward with a public health center, the Minister and the prefectural governor having jurisdiction over that city or ward).
- (5) When the Minister of Health, Labour and Welfare finds it necessary to personally conduct an examination, the Minister may ask the prefectural governor to submit all or a part of the specimens or the pathogens of the infectious disease which had been submitted to the prefectural governor pursuant to the provisions of paragraph (3).
- (6) The provisions of Article 26-3, paragraphs (1) and (3) apply *mutatis mutandis* to a person who does not comply with the provisions of paragraph (1). In this case, the term "a class I infectious disease, a class II infectious disease, or a novel and reemerging influenza or coronavirus infection" in paragraph (1) of that Article is deemed to be replaced with "a novel and reemerging influenza or coronavirus infection," and the term "the specimens related to or pathogens of the infectious disease prescribed in the relevant item" in that paragraph and paragraph (3) of that Article is deemed to be replaced with "the specimens or pathogens sampled from the patient of a novel and reemerging influenza or

coronavirus infection"

(Notification of Discharge and Other Actions of Patients with a Novel and Reemerging Influenza or Coronavirus Infection)

Article 44-3-6 If a patient with a novel and reemerging influenza or coronavirus infection who has been hospitalized pursuant to the provisions of Article 19 or Article 20 as applied mutatis mutandis pursuant to Article 26, paragraph (2) following the deemed replacement of terms has been discharged or has died, the physician of a designated medical institution for infectious diseases specified by Order of the Ministry of Health, Labour and Welfare must notify the prefectural governor having jurisdiction over the location of the designated medical institution for infectious diseases and the Minister of Health (or, if the location is within a city or special ward with a public health center, the mayor of that city or ward, prefectural governor, and the Minister) by electronic or magnetic means regarding the matters specified by Order of the Ministry of Health, Labour and Welfare in relation to the patient.

(Application of Provisions for Measures Taken for Buildings)

Article 44-4 (1) If it is found to be particularly necessary to prevent an outbreak or the spread of a novel and reemerging influenza or coronavirus infection, the national government may apply all or part of the provisions of Articles 28 and 31 through 36 and Chapters XIII and XIV (limited to the part related to the measures implemented pursuant to the provisions of Article 28 or Articles 31 through 33) for a period not longer than two years specified by Cabinet Order, pursuant to the provisions of Cabinet Order, by deeming that infectious disease as a class I infectious disease.

(2) The period specified by Cabinet Order as referred to in the preceding paragraph may be extended for a period of no longer than one year specified by Cabinet Order if it is found to be particularly necessary to continue applying the provisions which apply to the infectious disease under the Cabinet Order referred to in that paragraph even after the end of the specified period. The same applies when the period specified by Cabinet Order which has been previously extended is to be further extended after the end of that period.

(3) When the Minister of Health, Labour and Welfare intends to propose to establish, revise, or repeal a Cabinet Order referred to in the preceding two paragraphs, the Minister must hear the opinion of the Health Science Council in advance; provided, however, that this does not apply when there is no time to seek opinions of the Health Science Council in advance when a Cabinet Order referred to in paragraph (1) needs to be urgently established, revised, or repealed.

(4) In the case referred to in the proviso of the preceding paragraph, the Minister

of Health, Labour and Welfare must promptly report the contents of its proposed draft of the Cabinet Order to the Health Science Council.

(Assistance and Support from Other Prefectural Governors and Relevant Mayors)

Article 44-4-2 (1) A prefectural governor may, during the period from the time when an announcement pursuant to the provisions of Article 44-2, paragraph (1) is made to the time when an announcement pursuant to the provisions of paragraph (3) of that Article is made, request other prefectural governors for support in securing physicians, nurses, and other medical personnel responsible for treating patients with novel and reemerging influenza or coronavirus infections (referred to below as "medical care personnel for novel and reemerging influenza or coronavirus infections" in this Article and the following Article), or physicians, nurses, and other medical personnel engaged in work related to building a system to provide medical care to prevent outbreaks and the spreading of novel and reemerging influenza or coronavirus infections (excluding medical care personnel for novel and reemerging influenza or coronavirus infections; referred to below as "relevant persons to the prevention of novel and reemerging influenza or coronavirus infections" in this Article and the following Article) conducted by the prefectural governor.

(2) A prefectural governor may request the Minister of Health, Labour and Welfare to coordinate support provided by other prefectural governors for securing medical care personnel for novel and reemerging influenza or coronavirus infections during the period from the time an announcement pursuant to the provisions of Article 44-2, paragraph (1) is made to the time an announcement pursuant to the provisions of paragraph (3) of that Article is made, when all of the following items apply:

(i) it is found that it is difficult to secure medical care personnel for novel and reemerging influenza or coronavirus infections even if measures based on a notice (limited to a notice that includes the measures stated in item (v) of that paragraph) pursuant to the provisions of Article 36-2, paragraph (1) and measures based on a medical care agreement taken by a medical institution that has concluded that agreement (limited to a medical care agreement that includes the measures stated in that item) are properly taken in the prefecture, and that the provision of medical care in the prefecture is hindered or likely to become hindered;

(ii) it is found that the supply and demand of medical care in the prefecture is strained or likely to become strained, compared with the supply and demand of medical care in other prefectures, due to the situation, trends, and other circumstances of the outbreak of a novel and reemerging influenza or coronavirus infection;

- (iii) it is found that support by other prefectural governors for securing medical care personnel for novel and reemerging influenza or coronavirus infections cannot be smoothly provided only by issuing a request pursuant to the provisions of the preceding paragraph; and
 - (iv) other criteria specified by Order of the Ministry of Health, Labour and Welfare are satisfied.
- (3) Beyond what is provided for in the preceding paragraph, if the prefectural governor finds it particularly necessary to prevent an outbreak or the spread of a novel and reemerging influenza or coronavirus infection during the period from the time an announcement pursuant to the provisions of Article 44-2, paragraph (1) is made to the time an announcement pursuant to the provisions of paragraph (3) of that Article is made, and if the prefectural governor finds that support by other prefectural governors in securing relevant persons for preventing novel and reemerging influenza or coronavirus infections cannot not be smoothly provided only by issuing a request under paragraph (1), the prefectural governor may request the Minister of Health, Labour and Welfare to coordinate support provided by other prefectural governors for securing relevant persons for preventing novel and reemerging influenza or coronavirus infections.
- (4) When the Minister of Health, Labour and Welfare receives a request for the coordination of support from a prefectural governor pursuant to the provisions of the preceding two paragraphs, when the Minister finds it particularly necessary by comprehensively considering the situation, trends, and other circumstances of the nationwide outbreak of a novel and reemerging influenza or coronavirus infection, the contents of the report under the provisions of Article 36-5, paragraph (4), and other matters, the Minister may request prefectural governors other than the relevant prefectural governor to support the prefectural governor in securing medical care personnel for novel and reemerging influenza or coronavirus infections or relevant persons for preventing these infections.
- (5) Beyond what is provided for in the preceding paragraph, even when the Minister of Health, Labour and Welfare does not request the coordination of support under paragraph (2) or paragraph (3) but the Minister finds it urgently necessary to coordinate support for securing human resources over a wide area in order to prevent the spread of a novel and reemerging influenza or coronavirus infection, after comprehensively considering the situation and trends of the nationwide outbreak of that infection, during the period from the time when an announcement pursuant to the provisions of Article 44-2, paragraph (1) is made to the time when an announcement pursuant to the provisions of paragraph (3) of that Article is made, the Minister may request the prefectural governor for support in securing medical care personnel for

novel and reemerging influenza or coronavirus infections or relevant persons for preventing these infections.

(6) During the period from the time when an announcement pursuant to the provisions of Article 44-2, paragraph (1) is made to the time when an announcement pursuant to the provisions of paragraph (3) of that Article is made, when the Minister of Health, Labour and Welfare finds it urgently necessary for the support in securing human resources over a wide area in light of the circumstances of the spread of a novel and reemerging influenza or coronavirus infection, after comprehensively considering the situation, trends, and other circumstances of the nationwide outbreak of that infection, the Minister may request public or other relevant medical institutions and other medical institutions specified by Order of the Ministry of Health, Labour and Welfare for support in securing medical care personnel for novel and reemerging influenza or coronavirus infections or relevant persons for preventing these infections pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare. In this regard, the medical institution requested for assistance must not refuse assistance unless there are reasonable grounds.

(Coverage of Expenses for Support Provided from Other Prefectural Governors and Relevant Mayors)

Article 44-4-3 A prefectural government that has received support for securing medical care personnel for novel and reemerging influenza or coronavirus infections or relevant persons for preventing these infections from other prefectural governors, public or other relevant medical institutions, or other medical institutions specified by Order of the Ministry of Health, Labor and Welfare referred to in paragraph (6) of the preceding Article pursuant to the provisions of the preceding Article must cover the expenses necessary for that support.

(Comprehensive Coordination by the Minister of Health, Labour and Welfare)

Article 44-5 (1) During the period from the time when the announcement pursuant to the provisions of Article 44-2, paragraph (1) is made to the time when the announcement pursuant to the provisions of paragraph (3) of that Article is made, when the Minister of Health, Labour and Welfare finds it necessary to prevent novel and reemerging influenza or coronavirus infections from spreading beyond prefectural boundaries by securing human resources for preventing these infections or transferring patients pursuant to the provisions of Article 21 as applied mutatis mutandis by replacing the terms pursuant to Article 26, paragraph (2), the Minister is to conduct comprehensive coordination with prefectural governors, medical institutions, or other relevant

persons on necessary measures the prefectural governors, medical institutions, or other relevant persons are to implement in order to prevent the spread of the infectious diseases.

- (2) When a prefectural governor finds it necessary, they may request the Minister of Health, Labour and Welfare to carry out comprehensive coordination pursuant to the provisions of the preceding paragraph with regard to the prefectural governor and other prefectural governors, medical institutions, and other relevant persons. In this case, the Minister of Health, Labour and Welfare must carry out comprehensive coordination pursuant to the provisions of that paragraph when it is found to be necessary.
- (3) In the case referred to in paragraph (1), the prefectural governor, medical institutions, and other relevant persons may offer their opinions to the Minister of Health, Labour and Welfare concerning comprehensive coordination pursuant to the provisions of that paragraph.
- (4) When the Minister of Health, Labour and Welfare finds it necessary to carry out comprehensive coordination pursuant to the provisions of paragraph (1), they may request prefectural governors, medical institutions, and other relevant persons to submit reports or materials on the implementation status of measures necessary to prevent the spread of a novel and reemerging influenza or coronavirus infection implemented by the prefectural governors, medical institutions, and other relevant persons.
- (5) When carrying out comprehensive coordination pursuant to the provisions of paragraph (1), the Minister of Health, Labour and Welfare must endeavor to ensure consistency with the basic response policy prescribed in Article 18, paragraph (1) of the Act on Special Measures against Novel Influenza, etc.

(Reports on the Status of Novel and Reemerging Influenza or Coronavirus Infections)

Article 44-6 (1) When a prefectural governor has conducted any affairs concerning a novel and reemerging influenza or coronavirus infection under the provisions of this Act or any Cabinet Order based on this Act, the prefectural governor must report the information on those affairs to the Minister of Health, Labour and Welfare pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

- (2) The provisions of the preceding paragraph apply *mutatis mutandis* when a mayor of a municipality has had relevant officials implement a measure prescribed in Article 35, paragraph (1) as applied *mutatis mutandis* in paragraph (5) of that Article in connection with a novel and reemerging influenza or coronavirus infection.

Chapter VII-2 Designated Infectious Diseases

(Public Disclosure of Information on Measures, etc. to be Implemented
Regarding Designated Infectious Diseases)

- Article 44-7 (1) When the Minister of Health, Labour and Welfare finds that the severity of pathological conditions following infection with a designated infectious disease is serious and there is a risk of a nationwide rapid spread, the Minister must promptly release that information, while releasing the information on that designated infectious disease pursuant to the provisions of Article 16, paragraph (1), and subsequently release information on the methods of examining the pathogen, pathological conditions, methods of diagnosis and medical treatment, and methods of infection prevention, measures to be implemented pursuant to the provisions of this Act, and other information necessary for the prevention or spread of the designated infectious disease in newspapers, by broadcasting, via the Internet, or by any other suitable means.
- (2) When the information under the provisions of the preceding paragraph is made public, due regard must be paid to protect personal information.
- (3) If the designated infectious disease which is the subject of the information released pursuant to the provisions of paragraph (1) is no longer recognized as having the risk of nationwide and rapid spread because a large majority of the public has acquired immunity to that designated infectious disease or due to any other reason, the Minister of Health, Labour and Welfare must promptly make that fact public.

(Mutatis Mutandis Application of this Act to Designated Infectious Diseases)

Article 44-8 The provisions of Articles 44-4-2 through 44-5 apply mutatis mutandis to designated infectious diseases (limited to those for which the announcement pursuant to the provisions of paragraph (1) of the preceding Article has been made). In this case, "Article 44-2, paragraph (1)" in Article 44-4-2, paragraphs (1) through (3), (5), and (6), and Article 44-5, paragraph (1) is deemed to be replaced with "Article 44-7, paragraph (1)," the term "medical care personnel for novel and reemerging influenza or coronavirus infections" in Article 44-4-2 and Article 44-4-3 is deemed to be replaced with "medical care personnel for designated infectious diseases," the term "relevant persons for preventing novel and reemerging influenza or coronavirus infections" in that Article is deemed to be replaced with "relevant persons for preventing designated infectious diseases," the term "secure human resources for preventing novel and reemerging influenza or coronavirus infections or to transfer patients pursuant to the provisions of Article 21 as applied mutatis mutandis by replacing the terms pursuant to Article 26, paragraph (2)" in Article 44-5, paragraph (1) is deemed to be replaced with "secure human resources for preventing novel and reemerging influenza or coronavirus

infections," and any other necessary technical replacement of terms is to be specified by Cabinet Order.

Article 44-9 (1) With regard to the designated infectious diseases, all or part of the provisions of Article 8, Chapters III through the preceding Chapter (excluding Articles 44-2 and 44-4-2 through 44-5), X, XIII, and XIV apply mutatis mutandis, pursuant to the provisions of Cabinet Order, during a period of no longer than one year as specified by Cabinet Order.

(2) The period specified by Cabinet Order as referred to in the preceding paragraph may be extended for a period of no longer than one year as specified by Cabinet Order if it is found to be particularly necessary to continue applying mutatis mutandis the provisions which are required to apply mutatis mutandis to the disease specified by the Cabinet Order, pursuant to the Cabinet Order referred to in that paragraph, even after the end of the specified period.

(3) When the Minister of Health, Labour and Welfare intends to propose to establish, revise, or repeal a Cabinet Order referred to in the preceding two paragraphs, the Minister must hear the opinion of the Health Science Council in advance.

Chapter VIII New Infectious Diseases

(Public Disclosure of Information on the Outbreak of New Infectious Diseases and Measures to Be Implemented)

Article 44-10 (1) When the Minister of Health, Labour and Welfare recognizes an outbreak of a new infectious disease, the Minister must promptly release the information on that outbreak and the area facing the outbreak, while releasing the information on that new infectious disease pursuant to the provisions of Article 16, paragraph (1), and subsequently release the information on the methods of examining the pathogen, pathological conditions, methods of diagnosis and medical treatment, and methods of infection prevention, measures to be implemented pursuant to the provisions of this Act, and other information necessary to prevent the outbreak or spread of the new infectious disease in newspapers, by broadcasting, via the Internet, or by any other suitable means.

(2) When the information under the provisions of the preceding paragraph is made public, due regard must be paid to protect personal information.

(Collection of Specimens of New Infectious Diseases)

Article 44-11 (1) When a prefectural governor finds it necessary to prevent the spread of a new infectious disease, the prefectural governor may recommend that the person stated in Article 15, paragraph (3), item (iii) submit the

- specimens prescribed in that item or accept the specimens collected by the relevant officials, or recommend that the person's custodian submit the specimens or have the person accept the specimens collected by the relevant officials; provided, however, that this does not apply when the prefectural governor is considered to be able to obtain the specimens which are the subject of the intended recommendation (including pathogens of the new infectious disease separated from the specimens which are the subject of the intended recommendation; the same applies below in this paragraph) from a person who possesses the specimens which are the subject of the intended recommendation.
- (2) When the Minister of Health, Labour and Welfare finds it urgently necessary to prevent the spread of a new infectious disease, the Minister may recommend that the person stated in Article 15, paragraph (3), item (iii) submit the specimens prescribed in that item or accept the specimens collected by relevant officials, or recommend that the person's custodian submit the specimens or have the person accept the specimens collected by relevant officials; provided, however, that this does not apply when the Minister of Health, Labour and Welfare is considered to be able to obtain the specimens which are the subject of the intended recommendation (including pathogens of the new infectious disease separated from the specimens which are the subject of the intended recommendation) from a person who possesses the specimens which are the subject of the intended recommendation.
- (3) If the person receiving a recommendation made under the provisions of paragraph (1) does not follow the recommendation, the prefectural governor may, to the minimum extent necessary for examination, direct the officials to collect the specimens prescribed in Article 15, paragraph (3), item (iii) from the person stated in that item who is the subject of the recommendation.
- (4) If the person receiving a recommendation made under the provisions of paragraph (2) does not follow the recommendation, the Minister of Health, Labour and Welfare may, to the minimum extent necessary for examination, direct the officials to collect the specimens prescribed in Article 15, paragraph (3), item (iii) from the person stated in that item who is the subject of the recommendation.
- (5) Prefectural governors must examine the specimens which were submitted in accordance with the provisions of paragraph (1) or which the officials collected in accordance with those provisions, or the specimens collected by the officials based on the prefectural governor's direction in accordance with the provisions of paragraph (3), pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (6) Prefectural governors must report the results of the examinations referred to in the preceding paragraph and other matters specified by Order of the Ministry of Health, Labour and Welfare to the Minister of Health, Labour and

Welfare, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

- (7) When the Minister of Health, Labour and Welfare finds it necessary to personally conduct an examination, the Minister may ask the prefectural governor to submit a part of the specimens which were submitted under the provisions of paragraph (1) or which the officials collected under those provisions, or a part of the specimens collected by the officials based on the prefectural governor's direction under the provisions of paragraph (3).
- (8) When a prefectural governor finds it particularly necessary to recommend the submission or collection of the specimens under the provisions of paragraph (1), direct relevant officials to implement a measure that involves collecting the specimens under the provisions of paragraph (3), or examine the specimens under the provisions of paragraph (5), the prefectural governor may ask another prefectural governor or the Minister of Health, Labour and Welfare to dispatch an employee of an infectious disease research institute and to provide other necessary assistance.
- (9) The provisions of Article 16-3, paragraphs (5) and (6) apply *mutatis mutandis* when a prefectural governor recommends the submission or collection of specimens under the provisions of paragraph (1) or directs relevant officials to implement a measure that involves collecting specimens under the provisions of paragraph (3).
- (10) The provisions of Article 16-3, paragraphs (5) and (6) apply *mutatis mutandis* when the Minister of Health, Labour and Welfare recommends the submission or collection of specimens under the provisions of paragraph (2) or directs relevant officials to implement a measure of collecting specimens under the provisions of paragraph (4).

(Medical Examinations of New Infectious Diseases)

- Article 45 (1) When a prefectural governor finds it necessary to prevent the spread of a new infectious disease, the prefectural governor may recommend that a person who is justifiably suspected to be infected with the new infectious disease take a medical examination by a physician to ascertain whether the person is infected with that new infectious disease or not, or recommend to their custodian that the person take a medical examination.
- (2) If the person receiving a recommendation made under the provisions of the preceding paragraph does not follow the recommendation, the prefectural governor may direct relevant officials to conduct a medical examination of the person who is justifiably suspected to be infected with the new infectious disease and who is the subject of the recommendation.
 - (3) The provisions of Article 16-3, paragraphs (5) and (6) apply *mutatis mutandis* when a prefectural governor recommends a medical examination prescribed in

paragraph (1) or implements a measure that involves conducting the medical examination prescribed in the preceding paragraph.

(Hospitalization of Persons with Symptoms of a New Infectious Disease)

Article 46 (1) When a prefectural governor finds it necessary to prevent the spread of a new infectious disease, the prefectural governor may recommend that a person with symptoms of a new infectious disease (in the case of a person with symptoms of a new infectious disease (limited to those specified by Order of the Ministry of Health, Labour and Welfare based on the severity of pathological conditions), limited to those specified by Order of the Ministry of Health, Labour and Welfare, after taking into consideration the pathological conditions of the new infectious disease or the risk of the pathological conditions following infection with the new infectious disease becoming severe, and those other than the relevant persons who have not responded to the request for cooperation pursuant to the provisions of Article 50-2, paragraph (2)) be hospitalized or recommend to their custodian that the person with symptoms of the new infectious disease be hospitalized in a designated medical institution for specified infectious diseases or a designated medical institution for class I agreement for a specified period of not more than 10 days; provided, however, that in an emergency or under other unavoidable circumstances, the prefectural governor may recommend that the person with symptoms of a new infectious disease be hospitalized or recommend to their custodian that the person with symptoms of a new infectious disease be hospitalized in a hospital or clinic found suitable by the prefectural governor other than a designated medical institution for specified infectious diseases or a designated medical institution for class I agreement.

- (2) If the person receiving a recommendation made under the provisions of the preceding paragraph does not follow the recommendation, the prefectural governor may hospitalize the person with symptoms of a new infectious disease who is subject to the recommendation in a designated medical institution for specified infectious diseases or a designated medical institution for class I agreement (or if the person does not follow a recommendation made under the proviso of that paragraph, in a hospital or clinic found suitable by the prefectural governor other than a designated medical institution for specified infectious diseases or a designated medical institution for class I agreement) for a specified period of not more than 10 days.
- (3) In an emergency or under other unavoidable circumstances, a prefectural governor may hospitalize a person with symptoms of a new infectious disease who has been hospitalized pursuant to the provisions of the preceding two paragraphs in another hospital or clinic deemed suitable by the prefectural governor other than the one where the person is currently hospitalized for a

specified period of not more than 10 days from the date on which the person was hospitalized under the provisions of the preceding two paragraphs.

- (4) If a prefectural governor finds it necessary to continue the hospitalization of a person with symptoms of a new infectious disease who is hospitalized under the provisions of the preceding three paragraphs after the end of the period of hospitalization, the prefectural governor may extend the period of hospitalization for a specified period of not more than 10 days. The same applies when the period of hospitalization is to be further extended after the end of the period previously extended.
- (5) If a prefectural governor intends to make a recommendation under the provisions of paragraph (1), the prefectural governor must give adequate explanations to the person with symptoms of the new infectious disease or their custodian and endeavor to help them understand the situation, and must afford them an opportunity to express their opinions to the official designated by the prefectural governor. In this case, the prefectural governor must give advance notice to the person with symptoms of the new infectious disease or their custodian of the date and time and the place set for that opportunity to express their opinions, as well as the facts underlying the recommendation.
- (6) The person with symptoms of the new infectious disease or their custodian receiving a notice given under the provisions of the preceding paragraph may have an agent appear and submit evidence in their favor.
- (7) The official hearing the opinions under the provisions of paragraph (5) must prepare a hearing report and submit it to the prefectural governor.

(Transferring Persons with Symptoms of a New Infectious Disease)

Article 47 Prefectural governors must transfer the person with symptoms of a new infectious disease who is to be hospitalized pursuant to the provisions of the preceding Article to the hospital where that person is to be hospitalized.

(Discharging Persons with Symptoms of a New Infectious Disease)

Article 48 (1) If it is confirmed that the person hospitalized pursuant to the provisions of Article 46 is unlikely to spread to the public the new infectious disease for which they were hospitalized, the prefectural governor must discharge the hospitalized person.

- (2) With regard to a person who is hospitalized pursuant to the provisions of Article 46, the administrator of the hospital may express their opinion to the prefectural governor, stating that the person is unlikely to spread to the public the new infectious disease for which they were hospitalized.
- (3) A person hospitalized pursuant to the provisions of Article 46 or their custodian may request the prefectural governor to approve the discharge of the hospitalized person.

(4) After receiving a request for discharge under the provisions of the preceding paragraph, a prefectural governor must confirm whether or not the hospitalized person is likely to spread to the public the new infectious disease for which they were hospitalized.

(Minimum Necessary Measures)

Article 48-2 The measures implemented pursuant to the provisions of Articles 44-11 through 47 must be the minimum necessary measures to prevent an outbreak or the spread of a new infectious disease based on the risks of spreading the new infectious disease to the public, the severity of pathological conditions following infection with the new infectious disease, and other circumstances.

(Notice in Writing for Hospitalization of Persons with Symptoms of a New Infectious Disease)

Article 49 The provisions of Article 16-3, paragraphs (5) and (6) apply *mutatis mutandis* when a prefectural governor recommends the hospitalization prescribed in Article 46, paragraph (1), implements the hospitalization measures prescribed in paragraph (2) or (3) of that Article, or extends the period of hospitalization prescribed in paragraph (4) of that Article.

(Filing a Complaint with a Prefectural Governor)

Article 49-2 The provisions of Article 24-2 apply *mutatis mutandis* to a person with symptoms of a new infectious disease hospitalized pursuant to the provisions of Article 46.

(Disinfection and Other Measures for New Infectious Diseases)

Article 50 (1) When a prefectural governor finds it necessary to prevent the outbreak or spread of a new infectious disease, the prefectural governor may implement or direct relevant officials to implement all or part of the measures prescribed in Article 26-3, paragraphs (1) and (3), Article 26-4, paragraphs (1) and (3), Articles 27 through 33, and Article 35, paragraph (1), by deeming that new infectious disease as a class I infectious disease.

(2) The provisions of Article 26-3, paragraphs (5) through (8) apply *mutatis mutandis* when a prefectural governor implements or directs relevant officials to implement a measure prescribed in paragraph (1) or (3) of that Article pursuant to the provisions of the preceding paragraph.

(3) The provisions of Article 26-4, paragraphs (5) through (8) apply *mutatis mutandis* when a prefectural governor implements or directs relevant officials to implement a measure prescribed in paragraph (1) or (3) of that Article pursuant to the provisions of paragraph (1).

- (4) The provisions of Article 35, paragraphs (2) and (3) apply mutatis mutandis when a prefectural governor directs relevant officials to implement a measure prescribed in paragraph (1) of that Article pursuant to the provisions of paragraph (1).
- (5) The provisions of Article 36, paragraphs (1) and (2) apply mutatis mutandis when a prefectural governor implements or directs relevant officials to implement a measure prescribed in Article 26-3, paragraph (1) or (3), Article 26-4, paragraph (1) or (3), Article 27, paragraph (1) or (2), Article 28, paragraph (1) or (2), Article 29, paragraph (1) or (2), Article 30, paragraph (1), or Article 31, paragraph (1), pursuant to the provisions of paragraph (1).
- (6) The provisions of Article 36, paragraph (4) apply mutatis mutandis when a prefectural governor implements or directs relevant officials to implement a measure prescribed in Article 32 or 33, pursuant to the provisions of paragraph (1).
- (7) When the Minister of Health, Labour and Welfare finds it urgently necessary to prevent an outbreak or the spread of a new infectious disease, the Minister may implement or direct relevant officials to implement all or part of the measures prescribed in Article 26-3, paragraphs (2) and (4), Article 26-4, paragraphs (2) and (4), and Article 35, paragraph (1) as applied mutatis mutandis in paragraph (4) of that Article, by deeming that new infectious disease as a class I infectious disease.
- (8) The provisions of Article 35, paragraphs (2) and (3) as applied mutatis mutandis in paragraph (4) of that Article apply mutatis mutandis when the Minister of Health, Labour and Welfare directs relevant officials to implement a measure prescribed in paragraph (1) of that Article as applied mutatis mutandis in paragraph (4) of that Article, pursuant to the provisions of the preceding paragraph.
- (9) The provisions of Article 36, paragraphs (1) and (2) as applied mutatis mutandis in paragraph (3) of that Article apply mutatis mutandis when the Minister of Health, Labour and Welfare implements or directs relevant officials to implement a measure prescribed in Article 26-3, paragraph (2) or (4) or Article 26-4, paragraph (2) or (4), pursuant to the provisions of paragraph (7).
- (10) When a mayor of a municipality finds it necessary to prevent an outbreak or the spread of a new infectious disease, the mayor of a municipality may direct relevant officials to implement a measure prescribed in Article 35, paragraph (1) as applied mutatis mutandis in paragraph (5) of that Article, by deeming that new infectious disease as a class I infectious disease.
- (11) The provisions of Article 35, paragraphs (2) and (3) as applied mutatis mutandis in paragraph (5) of that Article apply mutatis mutandis when a mayor of a municipality directs relevant officials to implement a measure prescribed in paragraph (1) of that Article as applied mutatis mutandis in

paragraph (5) of that Article, pursuant to the provisions of the preceding paragraph.

- (12) The provisions of Article 36, paragraphs (1) and (2) as applied *mutatis mutandis* in paragraph (5) of that Article apply *mutatis mutandis* when a mayor of a municipality directs relevant officials to implement a measure prescribed in Article 27, paragraph (2), Article 28, paragraph (2), or Article 29, paragraph (2), in accordance with the prefectural governor's instructions under the provisions of Article 27, paragraph (2), Article 28, paragraph (2), or Article 29, paragraph (2), which is implemented pursuant to the provisions of paragraph (1).
- (13) The measures implemented pursuant to the provisions of paragraph (1), (7), or (10) must be the minimum necessary measures to prevent an outbreak or the spread of a new infectious disease.

(Reporting or Cooperation in Order to Prevent Infections)

- Article 50-2 (1) When a prefectural governor finds it necessary to prevent the spread of a new infectious disease, the prefectural governor may request a person who is justifiably suspected to be infected with that new infectious disease to report their body temperature and other facts regarding their state of health, or request the person to refrain from leaving their residence or other equivalent places or otherwise cooperate in any way necessary to prevent transmission of that new infectious disease during the period to be specified based on the estimated length of the incubation period of that new infectious disease, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (2) When a prefectural governor finds it necessary to prevent the spread of a new infectious disease (limited to those specified by Order of the Ministry of Health, Labour and Welfare based on the severity of pathological conditions; the same applies in paragraph (1) of the following Article), the prefectural governor may request a person with symptoms of the new infectious disease to report their body temperature and other facts regarding their state of health, or request the person to refrain from going out of an accommodation facility (limited to those that satisfy the criteria specified by Order of the Ministry of Health, Labour and Welfare as suitable for preventing the spread of a new infectious disease) or their residence or other equivalent places or otherwise cooperate in any way necessary to prevent the transmission of the new infectious disease, until it is confirmed that there is no risk of the new infectious disease spreading to the public, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (3) A person who has been requested to report pursuant to the provisions of the preceding two paragraphs must comply with the request, except when there

are reasonable grounds, and a person who has been requested to cooperate pursuant to the provisions of the preceding two paragraphs must endeavor to comply with the request.

- (4) The provisions of Article 44-3, paragraph (4) apply mutatis mutandis when the prefectural governor requests a report under the provisions of paragraph (1), the provisions of paragraph (5) apply mutatis mutandis when the prefectural governor requests a report under the provisions of paragraph (2), the provisions of paragraph (6) apply mutatis mutandis when the prefectural governor requests a report under the provisions of paragraphs (1) or (2), the provisions of paragraphs (7) through (10) apply mutatis mutandis when the prefectural governor requests cooperation under the provisions of paragraphs (1) or (2), and the provisions of paragraph (11) apply mutatis mutandis when the prefectural governor requests cooperation under the provisions of paragraph (2). In this case, the term "a novel and reemerging influenza or coronavirus infection" in paragraph (10) of that Article is deemed to be replaced with "a new infectious disease," the term "paragraph (2)" in that paragraph is deemed to be replaced with "Article 50-2, paragraph (2)," the term "patients with a novel and reemerging influenza or coronavirus infection" in that paragraph and paragraph (11) of that Article is deemed to be replaced with "persons with symptoms of a new infectious disease," the term "that paragraph" in the latter paragraph is deemed to be replaced with "Article 50-2, paragraph (2)," the term "infectious disease" in that paragraph is deemed to be replaced with "new infectious disease," and the term "accommodation facilities" in that paragraph is deemed to be replaced with "accommodation facilities prescribed in that paragraph."

(Medical Services for Persons Subject to Voluntary Restraint Due to New Infectious Diseases)

Article 50-3 (1) Except in cases specified by Order of the Ministry of Health, Labour and Welfare, if an application has been filed by a person with symptoms of a new infectious disease (referred to below as "person subject to voluntary restraint due to new infectious diseases") who is requested to cooperate in not going out of their accommodation facility, residence, or other equivalent places pursuant to the provisions of paragraph (2) of the preceding Article, or their custodian, the prefectural government is to cover the expenses necessary for the medical services specified by Order of the Ministry of Health, Labour and Welfare that persons subject to voluntary restraint due to new infectious diseases receive from a designated medical institution for class II agreement.

- (2) The provisions of Article 37, paragraph (2) apply mutatis mutandis to the coverage stated in the preceding paragraph, the provisions of paragraph (4) of

that Article apply mutatis mutandis to the application stated in the preceding paragraph, and the provisions of Articles 40, Article 41, and Article 43 apply mutatis mutandis to the case stated in that paragraph.

(Special Provisions for Emergency and Other Medical Services for Persons Subject to Voluntary Restraint Due to New Infectious Diseases)

- Article 50-4 (1) Except for the cases specified by Order of the Ministry of Health, Labour and Welfare, if a person subject to voluntary restraint due to new infectious diseases who lives in the area receives medical services specified by Order of the Ministry of Health, Labour and Welfare referred to in paragraph (1) of the preceding Article from a hospital, clinic, or pharmacy other than a designated medical institution for class II agreement due to an emergency or any other unavoidable circumstances, the prefectural government may pay the amount of medical treatment expenses calculated based on the amount to be covered pursuant to the provisions of that paragraph if the person subject to voluntary restraint due to new infectious diseases or their custodian files an application. The same applies when a person subject to voluntary restraint due to a new infectious disease receives the medical services prescribed by Order of the Ministry of Health, Labour and Welfare from a designated medical institution for class II agreement, and the medical services have been provided without filing the application stated in that paragraph due to an emergency or other unavoidable circumstances.
- (2) The provisions of Article 37, paragraph (4) apply mutatis mutandis to the applications referred to in the preceding paragraph.
- (3) The expenses for medical treatment referred to in paragraph (1) are to be paid to a person subject to voluntary restraint due to new infectious diseases only if the medical services are found to have been truly necessary at the time that patient received them.

(Matters Mandated by Order of the Ministry of Health, Labour and Welfare)

Article 50-5 Beyond what is provided for in the preceding two Articles, necessary matters concerning the procedures for filing an application referred to in Article 50-3, paragraph (1) and the coverage of expenses prescribed in this Chapter are to be specified by Order of the Ministry of Health, Labour and Welfare.

(Requests and Inquiries for Submission of Specimens of New Infectious Diseases)

Article 50-6 (1) If the Minister of Health, Labour and Welfare finds it necessary for collecting information on the nature of a new infectious disease and the severity of pathological conditions following infection with the new infectious

disease and other necessary information during the period from the time when the announcement pursuant to the provisions of Article 44-10, paragraph (1) is made to the time when Cabinet Order in Article 53, paragraph (1) is repealed, the Minister may request the administrator of a designated medical institution for infectious diseases or other persons specified by Order of the Ministry of Health, Labour and Welfare to submit all or part of the specimens or the pathogens sampled from persons with symptoms of the new infectious disease.

- (2) When the Minister has made a request pursuant to the provisions of the preceding paragraph, they are to notify the prefectural governor (if the location is within a city or special ward with a public health center, the mayor of that city or ward having jurisdiction over the location; the same applies in the following paragraph and paragraph (5)) having jurisdiction over the location of the person who received that request.
- (3) When a person who has received a request pursuant to the provisions of paragraph (1) possesses or comes to possess all or part of the specimens or pathogens stated in that paragraph, the person must immediately submit the specimens or pathogens to the prefectural governor.
- (4) When the prefectural governor prescribed in paragraph (2) has received specimens or pathogens pursuant to the provisions of the preceding paragraph, they must immediately conduct tests on the specimens or pathogens pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, and the results must be reported by electronic or magnetic means to the Minister of Health, Labour and Welfare (in the case of the mayor of a city or special ward with a public health center, the Minister and the prefectural governor having jurisdiction over that city or ward).
- (5) When the Minister of Health, Labour and Welfare finds it necessary to personally conduct an examination, the Minister may ask the prefectural governor to submit all or a part of the specimens or pathogens of the infectious disease which had been submitted to the prefectural governor pursuant to the provisions of paragraph (3).
- (6) The provisions of Article 26-3, paragraphs (1) and (3) apply mutatis mutandis to a person who does not comply with the provisions of paragraph (1). In this case, the term "a class I infectious disease, a class II infectious disease, or a novel and reemerging influenza or coronavirus infection" in paragraph (1) of that Article is deemed to be replaced with "a new infectious disease," and the term "the specimens or pathogens of the infectious disease prescribed in the relevant item" in that paragraph and paragraph (3) of that Article is deemed to be replaced with "the specimens sampled from persons with symptoms of a new infectious disease, or from those with pathogens of a new infectious disease."

(Notification of Discharge and Other Actions of Persons with Symptoms of a

New Infectious Disease)

Article 50-7 If a person with symptoms of a new infectious disease who has been hospitalized pursuant to the provisions of Article 46 has been discharged or has died, the physician of a designated medical institution for infectious diseases specified by Order of the Ministry of Health, Labour and Welfare must notify the prefectural governor having jurisdiction over the location of the designated medical institution for infectious diseases and the Minister of Health (or, if the location is within a city or special ward with a public health center, the mayor of that city or ward, prefectural governor, and the Minister) by electronic or magnetic means regarding the matters specified by Order of the Ministry of Health, Labour and Welfare in relation to that person.

(Technical Guidance and Advice of the Minister of Health, Labour and Welfare)

Article 51 (1) If a prefectural governor intends to implement or direct relevant officials to implement a measure prescribed in Article 44-11, paragraph (1), Article 45, paragraph (1), Article 46, paragraph (1), (3) or (4), Article 47, or Article 48, paragraph (1) or (4), or intends to implement or direct relevant officials to implement a measure prescribed in Article 26-3, paragraph (1), Article 26-4, paragraph (1), Articles 27 through 33, or Article 35, paragraph (1) pursuant to the provisions of Article 50, paragraph (1), the prefectural governor must, in advance, inform the Minister of Health, Labour and Welfare of the details of the measure, the time for implementing the measure, and other matters specified by Order of the Ministry of Health, Labour and Welfare, and the prefectural governor must implement the measure in close coordination with the Minister of Health, Labour and Welfare.

(2) After receiving information provided under the provisions of the preceding paragraph, the Minister of Health, Labour and Welfare must offer technical guidance and advice to the prefectural governor to ensure proper implementation of the measures prescribed in Articles 44-11 through 48 and Article 50, paragraph (1).

(3) When the Minister of Health, Labour and Welfare intends to offer technical guidance and advice to a prefectural governor pursuant to the provisions of the preceding paragraph, the Minister must hear the opinion of the Health Science Council in advance.

(4) The provisions of the preceding three paragraphs apply *mutatis mutandis* when a mayor of a municipality directs relevant officials to implement a measure prescribed in Article 35, paragraph (1) as applied *mutatis mutandis* in paragraph (5) of that Article, pursuant to the provisions of Article 50, paragraph (10).

(Assistance and Support from Other Prefectural Governors and Relevant

Mayors)

Article 51-2 (1) A prefectural governor may, during the period from the time an announcement pursuant to the provisions of Article 44-10, paragraph (1) is made until the time the Cabinet Order in Article 53, paragraph (1) is repealed, request other prefectural governors for support in securing physicians, nurses, and other medical personnel responsible for treating persons with symptoms of new infectious diseases (referred to below as "medical care personnel for new infectious diseases" in this Article and the following Article), or physicians, nurses, and other medical personnel engaged in work related to building a system to provide medical care to prevent an outbreak and the spreading of the new infectious disease (excluding medical care personnel for new infectious diseases; referred to below as "relevant persons for preventing new infectious diseases" in this Article and the following Article) conducted by the prefectural governor.

(2) A prefectural governor may request the Minister of Health, Labour and Welfare to coordinate support provided by other prefectural governors for securing medical care personnel for new infectious diseases during the period from the time an announcement pursuant to the provisions of Article 44-10, paragraph (1) is made until the time Cabinet Order in Article 53, paragraph (1) is repealed, when all of the following items apply:

(i) it is found that it is difficult to secure medical care personnel for new infectious diseases even if measures based on a notice (limited to a notice that includes the measures stated in item (v) of that paragraph) pursuant to the provisions of Article 36-2, paragraph (1) and measures based on a medical care agreement taken by a medical institution that has concluded that agreement (limited to a medical care agreement that includes the measures stated in that item) are properly taken in the prefecture, and that the provision of medical care in the prefecture is hindered or likely to become hindered;

(ii) it is found that the supply and demand of medical care in the prefecture is strained or likely to become strained, compared with the supply and demand of medical care in other prefectures due to the situation, trends, and other circumstances of the outbreak of a new infectious disease;

(iii) it is found that support by other prefectural governors for securing medical care personnel for new infectious diseases cannot be smoothly provided only by issuing a request pursuant to the provisions of the preceding paragraph; and

(iv) satisfaction of other criteria specified by Order of the Ministry of Health, Labour and Welfare.

(3) Beyond what is provided for in the preceding paragraph, if the prefectural governor finds it particularly necessary to prevent an outbreak or the spread of

a new infectious disease during the period from the time an announcement pursuant to the provisions of Article 44-10, paragraph (1) is made until the time the Cabinet Order in Article 53, paragraph (1) is repealed, and if the prefectural governor finds that support by other prefectural governors in securing relevant persons for preventing new infectious diseases cannot be smoothly provided only by issuing a request under paragraph (1), the prefectural governor may request the Minister of Health, Labour and Welfare to coordinate support provided by other prefectural governors for securing relevant persons for preventing new infectious diseases.

- (4) When the Minister of Health, Labour and Welfare receives a request for coordination of support from a prefectural governor pursuant to the provisions of the preceding two paragraphs and if the Minister finds it particularly necessary by comprehensively considering the situation, trends, and other circumstances of the outbreak of a new infectious disease throughout the country, the contents of the report under the provisions of Article 36-5, paragraph (4), and other matters, the Minister may request prefectural governors other than the relevant prefectural governor to support the prefectural governor in securing medical care personnel for new infectious diseases or persons engaged in medical services for a new infectious disease or relevant persons for preventing new infectious diseases.
- (5) Beyond what is provided for in the preceding paragraph, even when the Minister of Health, Labour and Welfare does not request the coordination of support under paragraph (2) or paragraph (3) but the Minister finds it urgently necessary to coordinate support for securing human resources over a wide area in order to prevent the spread of a new infectious disease, after comprehensively considering the situation and trends of the outbreak of a new infectious disease on a nationwide scale, during the period from the time when an announcement pursuant to the provisions of Article 44-10, paragraph (1) is made to the time when the Cabinet Order in Article 53, paragraph (1) is repealed, the Minister may request the prefectural governor for support in securing medical care personnel for new infectious diseases or relevant persons for preventing new infectious diseases.
- (6) During the period from the time when an announcement pursuant to the provisions of Article 44-10, paragraph (1) is made to the time when the Cabinet Order in Article 53, paragraph (1) is repealed, if the Minister of Health, Labour and Welfare finds it urgently necessary for the support in securing human resources over a wide area in light of the circumstances of the spread of a new infectious disease, after comprehensively considering the situation, trends, and other circumstances of the outbreak of a new infectious disease on a nationwide scale, the Minister may request public or other relevant medical institutions and other medical institutions specified by Order of the Ministry of

Health, Labour and Welfare for support in securing medical care personnel for new infectious diseases or relevant persons for preventing new infectious diseases pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare. In this regard, the medical institution requested to provide assistance must not refuse assistance unless there are reasonable grounds.

(Coverage of Expenses for Support Provided from Other Prefectural Governors and Relevant Mayors)

Article 51-3 A prefectural government that has received support for securing medical care personnel for new infectious diseases or relevant persons for preventing new infectious diseases from other prefectural governors, public or other relevant medical institutions, or other medical institutions specified by Order of the Ministry of Health, Labor and Welfare referred to in paragraph (6) of the preceding Article pursuant to the provisions of the preceding Article must cover the expenses necessary for that support.

(Comprehensive Coordination by the Minister of Health, Labour and Welfare)

Article 51-4 (1) During the period from the time when an announcement pursuant to the provisions of Article 44-10, paragraph (1) is made to the time when the Cabinet Order in Article 53, paragraph (1) is repealed, if the Minister of Health, Labour and Welfare finds it necessary to prevent a new infectious disease from spreading beyond prefectural boundaries by securing human resources for preventing new infectious diseases or to transfer patients pursuant to the provisions of Article 47, the Minister is to conduct comprehensive coordination with prefectural governors, medical institutions, or other relevant persons on necessary measures the prefectural governors, medical institutions, or other relevant persons are to implement in order to prevent the spread of the new infectious disease.

(2) When a prefectural governor finds it necessary, the prefectural governor may request the Minister of Health, Labour and Welfare to carry out comprehensive coordination pursuant to the provisions of the preceding paragraph with regard to the prefectural governor and other prefectural governors, medical institutions, and other relevant persons. In this case, the Minister of Health, Labour and Welfare must carry out comprehensive coordination pursuant to the provisions of that paragraph when it is found to be necessary.

(3) The provisions of Article 44-5, paragraphs (3) through (5) apply mutatis mutandis to comprehensive coordination under the provisions of paragraph (1).

(4) When the Minister of Health, Labour and Welfare intends to carry out comprehensive coordination pursuant to the provisions of paragraph (1), the Minister must hear the opinions of the Health Science Council in advance; provided, however, that this does not apply when there is no time to seek

opinions of the Health Science Council in advance in an emergency.

- (5) In the case referred to in the proviso of the preceding paragraph, the Minister of Health, Labour and Welfare must promptly report the details of the implemented comprehensive coordination to the Health Science Council.

(Instructions of the Minister of Health, Labour and Welfare)

Article 51-5 (1) When the Minister of Health, Labour and Welfare finds it urgently necessary to prevent an outbreak or the spread of a new infectious disease, or when a prefectural governor violates the provisions of this Chapter or has failed to manage or execute the affairs pursuant to the provisions of this Chapter, or the Minister finds it particularly necessary to prevent its outbreak or its rapid spread across the country, the Minister may give necessary instructions to a prefectural governor in connection with the affairs conducted by the prefectural governor pursuant to the provisions of Article 44-11, paragraph (1), Article 45, paragraph (1), Article 46, paragraph (1), (3) or (4), Article 47, Article 48, paragraph (1) or (4), Article 50, paragraph (1), or Article 50-2, paragraph (1) or (2).

- (2) When the Minister of Health, Labour and Welfare intends to give instructions to a prefectural governor pursuant to the provisions of the preceding paragraph, the Minister must hear the opinion of the Health Science Council in advance; provided, however, that this does not apply when there is no time to seek opinions of the Health Science Council in advance in an emergency.
- (3) In the case referred to in the proviso of the preceding paragraph, the Minister of Health, Labour and Welfare must promptly report the details of the instructed measures to the Health Science Council.

(Reports on the Progress of Affairs Related to a New Infectious Disease)

Article 52 (1) If a prefectural governor has implemented or has directed relevant officials to implement a measure prescribed in Article 44-11, paragraph (1) or (3) or Articles 45 through 48 or has implemented or has directed relevant officials to implement a measure prescribed in Article 26-3, paragraph (1) or (3), Article 26-4, paragraph (1) or (3), Articles 27 through 33, or Article 35, paragraph (1) pursuant to the provisions of Article 50, paragraph (1), or if a prefectural governor has conducted the affairs under the provisions of Article 50-2, paragraph (1) or (2), the prefectural governor must subsequently report the details of the measure or affairs and their subsequent progress to the Minister of Health, Labour and Welfare.

- (2) The provisions of the preceding paragraph apply *mutatis mutandis* when a mayor of a municipality has had relevant officials implement a measure prescribed in Article 50, paragraph (10).

(Designation of a New Infectious Disease by Cabinet Order)

Article 53 (1) When the national government is ready to outline the measures to be implemented for the pathological conditions specific to a new infectious disease to prevent its spread by gathering and analyzing the information on that disease, the national government must promptly implement the measures of applying all or part of the provisions of Chapters III through VI (excluding Sections 1 and 2), X, XIII and XIV, by deeming the new infectious disease and a person with symptoms of the new infectious disease as a class I infectious disease and a patient with a class I infectious disease respectively for a period of no longer than one year specified by Cabinet Order, pursuant to the provisions of Cabinet Order.

(2) The period specified by Cabinet Order as referred to in the preceding paragraph may be extended for a period of no longer than one year specified by Cabinet Order if it is found to be particularly necessary to continue applying the provisions which apply to the new infectious disease specified by Cabinet Order pursuant to the Cabinet Order referred to in that paragraph, even after the end of the specified period. The same applies when the period specified by Cabinet Order which has been previously extended is to be further extended after the end of that period.

(3) When the Minister of Health, Labour and Welfare intends to propose to establish, revise, or repeal a Cabinet Order referred to in the preceding two paragraphs, the Minister must hear the opinion of the Health Science Council in advance.

Chapter IX Tuberculosis

(Periodical Medical Examinations)

Article 53-2 (1) The employers prescribed in Article 2, item (iii) of the Industrial Safety and Health Act (Act No. 57 of 1972) (referred to below as "employer" in this Chapter and Chapter XIII), the heads of schools (including specialized training colleges and schools for specialized education, and excluding schools where the school term is shorter than one year; the same applies below), or the heads of correctional institutions or other institutions specified by Cabinet Order (each referred to below as "specified institution" in this Chapter and Chapter XIII) must provide the persons engaged in the business or services operated by those employers, the students, pupils or children of those schools, or the persons detained in those specified institutions (excluding persons who have not started elementary school yet) who are specified by Cabinet Order with periodical medical examinations for tuberculosis at the periodic intervals specified by Cabinet Order, by designating the dates or the period in each instance.

- (2) The chief of a public health center may give instructions to employers (excluding the national government, prefectural governments, and cities and special wards with a public health center) or the heads of schools or specified institutions (excluding the schools or specified institutions established by the national government, a prefectural government, or a city or special ward with a public health center) in connection with the designation of the dates or periods for periodical medical examinations provided under the provisions of the preceding paragraph.
- (3) A mayor of a municipality must provide the persons residing in the region under the municipal jurisdiction (excluding persons who have not started elementary school yet) who are not eligible for medical examinations referred to in paragraph (1) and who are specified by Cabinet Order with periodical medical examinations for tuberculosis at the periodic intervals specified by Cabinet Order, by designating the dates or period in each instance based on instructions given by the chief of the public health center (or by the prefectural governor, in the case of a city or special ward with a public health center).
- (4) If a medical examination has been provided for persons eligible for medical examinations referred to in paragraph (1) pursuant to the provisions of the Industrial Safety and Health Act, the School Health and Safety Act (Act No. 56 of 1958), or other applicable laws, or any order or regulations based on those acts and laws, and that medical examination conforms to the technical standards referred to in Article 53-9, the employer or the head of the school or specified institution, as applicable, is deemed to have provided a periodical medical examination under the provisions of that paragraph for the eligible persons.
- (5) The number of medical examinations to be provided under the provisions of paragraph (1) or (3) is specified by Cabinet Order.

(Duty to Undergo a Medical Examination)

Article 53-3 (1) The persons eligible for a medical examination referred to in paragraph (1) or (3) of the preceding Article must undergo the medical examination provided by their employer, the head of the school or specified institution, or the mayor of a municipality on the designated date or within the designated period.

- (2) If a person required to undergo a medical examination pursuant to the provisions of the preceding paragraph is under the age of 16 or an adult ward, their custodian must implement necessary measures to have the person take the medical examination.

(Medical Examinations Undergone on Other Occasions)

Article 53-4 If a person who is supposed to take a periodical medical

examination has undergone another medical examination conforming to the technical standards referred to in Article 53-9 within three months before the date specified for the periodical medical examination or the date of the end of the period designated for that examination, and the person submits a medical certificate or another document confirming the details of that medical examination to the entity responsible for the periodical medical examination on or before the date of the periodical medical examination or the date of the end of the period designated for that examination, the person is deemed to have undergone the periodical medical examination.

(Persons Failing to Undergo a Periodical Medical Examination)

Article 53-5 If a person is unable to undergo a periodical medical examination because of an illness or any other unavoidable situations and those situations are eliminated within two months, the person must undergo a medical examination within one month after the elimination of those situations and submit a medical certificate or another document certifying the details of the medical examination to the entity responsible for the periodical medical examination.

(Records of Periodical Medical Examinations)

Article 53-6 (1) When an entity responsible for providing periodical medical examinations (referred to below as "medical examination provider" in this Chapter) has provided a periodical medical examination or received a medical certificate or another document submitted pursuant to the provisions of the preceding two Articles, the medical examination provider must prepare a record of the medical examination without delay and retain the record.

(2) If a person who has undergone a periodical medical examination requests disclosure of the record prepared pursuant to the provisions of the preceding paragraph, the medical examination provider must not refuse this request without reasonable grounds.

(Provision of Information or Reports)

Article 53-7 (1) After providing a periodical medical examination, the medical examination provider must report or provide information on the number of medical examinees and other matters specified by Order of the Ministry of Health, Labour and Welfare with regard to the medical examination (including other medical examinations for which a certificate or another document has been submitted pursuant to the provisions of Article 53-4 or 53-5) to the prefectural governor through the chief of the public health center having jurisdiction over the location where the periodical medical examination has been provided (or through the chief of the public health center and the mayor

of the city or special ward with a public health center when the location is within that city or ward).

- (2) The provisions of the preceding paragraph apply mutatis mutandis when a medical examination provider governed by the provisions of any other law or any order or regulation based on those laws provides a medical examination which is deemed to constitute a medical examination conducted under the provisions of Article 53-2, paragraph (1) pursuant to the provisions of paragraph (4) of that Article.

(Consultations with Other Administrative Organs)

Article 53-8 (1) If the chief of a public health center gives instructions to an employer pursuant to the provisions of Article 53-2, paragraph (2) in connection with the persons who are engaged in the employer's business or services and to whom the provisions of the Industrial Safety and Health Act are applied, the chief of the public health center must consult with the chief of the Labour Standards Inspection Office having jurisdiction over the location for the business or services.

- (2) With regard to the schools under the administrative jurisdiction of the board of education, the chief of the public health center is to give notice to the board of education stating the matters to be instructed under Article 53-2, paragraph (2) in lieu of giving the instructions under that paragraph.
- (3) After receiving a notice referred to in the preceding paragraph, the board of education is to give necessary instructions to those schools.

(Matters Mandated by Order of the Ministry of Health, Labour and Welfare)

Article 53-9 The methods and technical standards for periodical medical examinations, the matters to be stated in medical certificates and other documents prescribed in Article 53-4 or 53-5, and the forms and the retention period of records for medical examinations are specified by Order of the Ministry of Health, Labour and Welfare.

(Notice of Notification on Tuberculosis Patients)

Article 53-10 If a prefectural governor receives a notification of a tuberculosis patient under the provisions of Article 12, paragraph (1), and the notification was made through the chief of a public health center which is not the public health center that has jurisdiction over the place of residence of the patient, the prefectural governor must immediately give notice to the chief of the public health center having jurisdiction over the place of residence of the patient, stating the contents of the notification.

(Notification by Administrators of Medical Institutions)

Article 53-11 (1) When a tuberculosis patient is hospitalized or a tuberculosis patient who has been hospitalized is discharged, the administrator of the hospital must notify the chief of the nearest public health center of the matters specified by Order of the Ministry of Health, Labour and Welfare in relation to the patient within seven days.

(2) If the chief of a public health center receives a notification referred to in the preceding paragraph with regard to a person who does not reside in the area under the jurisdiction of the public health center, the chief of the public health center must give notice to the chief of the public health center having jurisdiction over the place of residence of the patient stating the contents of the notification.

(Tuberculosis Registration Cards)

Article 53-12 (1) The chief of a public health center must keep tuberculosis registration cards and record information concerning tuberculosis patients and persons who have recovered from tuberculosis as specified by Order of the Ministry of Health, Labour and Welfare, residing in the area under its jurisdiction.

(2) The records referred to in the preceding paragraph are to be made for the persons in relation to whom a notification has been filed under the provisions of Article 12, paragraph (1) or in relation to whom a notice has been given under the provisions of Article 53-10.

(3) The matters required to be stated on tuberculosis registration cards, their transfer, the retention period, and other necessary matters concerning tuberculosis registration cards are specified by Order of the Ministry of Health, Labour and Welfare.

(Detailed Examinations)

Article 53-13 When the chief of a public health center finds it necessary to prevent tuberculosis or based on medical needs, the chief of the public health center is to conduct X-ray examinations or other detailed examinations by the methods specified by Order of the Ministry of Health, Labour and Welfare for the persons registered on tuberculosis registration cards.

(Home Guidance)

Article 53-14 (1) When the chief of a public health center finds it necessary to prevent tuberculosis or based on medical needs, the chief of the public health center is to direct public health nurses or other officials to visit the residence of a person whose information is on a tuberculosis registration card and to offer guidance for ensuring proper administration of prescribed drugs and other necessary guidance.

(2) When the chief of a public health center finds it necessary to prevent tuberculosis or ensuring effective medical care, the chief of the public health center may ask a hospital, clinic, pharmacy, or another person specified by Order of the Ministry of Health, Labour and Welfare to offer guidance for ensuring proper administration of prescribed drugs and other necessary guidance to a person whose information is on a tuberculosis registration card pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Instructions of Physicians)

Article 53-15 If a physician has diagnosed a tuberculosis patient, the physician must give instructions to the patient or their custodian or any other person actually taking care of the patient regarding proper medication of prescribed drugs and other matters necessary for medical care of the patient specified by Order of the Ministry of Health, Labour and Welfare, and for disinfection and other matters necessary to prevent infection as specified by Order of the Ministry of Health, Labour and Welfare.

Chapter IX-2 Materials and Supplies Required for Infectious Disease Countermeasures

(Requests Concerning Production and Other Matters)

Article 53-16 (1) Under the following circumstances, the Minister of Health, Labour and Welfare may request persons engaged in the production of materials and supplies required for infectious disease countermeasures (referred to below as "producers") to promote the production of those materials and supplies: when it is likely, based on a reasonable judgement, that an outbreak of an infectious disease or its spread is likely to seriously affect the lives of the people and public health due to the fact that an outbreak or the spread of the infectious disease would be difficult to prevent, and there is a high probability that the supply of medicines (meaning medicines prescribed in Article 2, paragraph (1) of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, excluding those intended to be used exclusively for animals), medical devices (meaning medical devices prescribed in paragraph (4) of that Article, excluding those intended to be used exclusively for animals), personal protective equipment (meaning wearable personal equipment to prevent exposure to pathogens and toxins) and other supplies to prevent infectious diseases and medical care for patients with infectious diseases, and supplies and materials (referred to below as "materials and supplies required for infectious disease countermeasures") which have been found to be indispensable for the production of these supplies, will be

insufficient due to increased demand, decreased imports, or for other reasons or that their supply may become unstable due to the current supply and demand situation or other circumstances, and it is consequently found to be necessary to promote the production of those materials and supplies in order to deal with the situation.

- (2) When making a request pursuant to the provisions of the preceding paragraph, the Minister of Health, Labour and Welfare is to consult the competent minister for the business (meaning the minister having jurisdiction over the business producing the materials and supplies required for infectious disease countermeasures; the same applies below in this Article and paragraph (2) of the following Article) in advance.
- (3) A producer who has received a request pursuant to the provisions of paragraph (1) must, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, prepare a plan for the production of the materials and supplies required for infectious disease countermeasures in response to the request (referred to below as "production plan" in this Article) and notify the Minister of Health, Labour and Welfare and the competent minister for the business. The same applies when this is changed.
- (4) When the competent minister for the business finds it particularly necessary to deal with the situation prescribed in paragraph (1) with regard to materials and supplies required for infectious disease countermeasures produced by the business over which the minister has jurisdiction, the minister may give instructions to the producer who submitted a notification pursuant to the provisions of the preceding paragraph to change the production plan to which the notification refers.
- (5) The Minister of Health, Labour and Welfare may request the competent minister for the business to give instructions pursuant to the provisions of the preceding paragraph.
- (6) A producer who has submitted a notification pursuant to the provisions of paragraph (3) must, in accordance with the production plan related to the notification (in the case of a notification of change in accordance with the provisions of the second sentence of that Article, the plan after the change; the same applies in the following paragraph.) produce the materials and supplies required for infectious disease countermeasures that are part of the production plan.
- (7) When a producer who has received instructions pursuant to the provisions of paragraph (4) fails to follow the instructions without reasonable grounds or when it is found that the producer prescribed in the preceding paragraph is not producing the materials and supplies required for infectious disease countermeasures that are part of the production plan to which the notification refers without reasonable grounds, the Minister of Health, Labour and Welfare

or the competent minister for the business may make that fact public.

- Article 53-17 (1) When the Minister of Health, Labour and Welfare finds it particularly necessary to deal with the situation prescribed in paragraph (1) of the preceding Article, they may request the minister with jurisdiction over a capable producer (this refers to the minister with jurisdiction over a business that is not engaged in the production of materials and supplies required for infectious disease countermeasures and is found to be capable of producing those materials and supplies (referred to below as "capable producer" in this paragraph and paragraph (3)); the same applies in that paragraph) to request a capable producer to cooperate in the production of those materials and supplies.
- (2) When the Minister of Health, Labour and Welfare intends to make a request pursuant to the provisions of the preceding paragraph, the Minister is to consult with the competent minister for the business in advance.
- (3) The minister with jurisdiction over a capable producer who receives a request pursuant to the provisions of paragraph (1) is to request cooperation in the production of materials and supplies required for infectious disease countermeasures from a capable producer who engages in the business under the jurisdiction of the minister.

(Requests Concerning Imports and Other Related Matters)

- Article 53-18 (1) When the Minister of Health, Labour and Welfare finds it necessary to promote the import of materials and supplies required for infectious disease countermeasures in order to deal with the situation prescribed in Article 53-16, paragraph (1), the Minister may request a person engaged in the business of importing those materials and supplies (referred to below as "importer") to promote their import.
- (2) The provisions of paragraphs (2) through (7) of Article 53-16 apply mutatis mutandis when a request is made to an importer pursuant to the provisions of the preceding paragraph. In this case, the term "production" in paragraph (2) of that Article is deemed to be replaced with "import," the term "this Article and paragraph (2) of the following Article" in that paragraph is deemed to be replaced with "this Article," the term "the production of" in paragraph (3) of that Article is deemed to be replaced with "the import of," the term "production plan" in that paragraph is deemed to be replaced with "import plan," the term "producing" in paragraph (4) of that Article is deemed to be replaced with "importing," the term "the producer" in that paragraph is deemed to be replaced with "the producer who is deemed to be able to import the materials and supplies required for infectious disease countermeasures in consideration of the import situation of those materials and supplies," the term "production plan" in that paragraph is deemed to be replaced with "import plan," the term

"production plan" in paragraphs (6) and (7) of that Article is deemed to be replaced with "import plan," and the term "production" in those paragraphs is deemed to be replaced with "importation."

(Requests Concerning Shipment, etc.)

Article 53-19 (1) When the Minister of Health, Labour and Welfare finds it necessary to coordinate the shipment or delivery of materials and supplies required for infectious disease countermeasures in order to deal with the situation prescribed in Article 53-16, paragraph (1), the Minister may request a person engaged in the business of producing, importing, selling, or loaning those materials and supplies to coordinate the shipment or delivery of those materials and supplies.

(2) When the Minister of Health, Labour and Welfare intends to make a request pursuant to the provisions of the preceding paragraph, the Minister is to consult with the minister having jurisdiction over the business producing, importing, selling, or loaning the materials and supplies required for infectious disease countermeasures in advance.

(Instructions and Directives on Sale, Loan, Transport, or Storage)

Article 53-20 (1) Under the following circumstances, the Minister of Health, Labour and Welfare may instruct persons engaged in the production, import, and sale of the materials and supplies required for infectious disease countermeasures to sell those materials and supplies by specifying the deadline by which those materials must be sold, the quantity to be sold, and the person to whom those materials must be sold: when it is likely, based on a reasonable judgement, that an outbreak of an infectious disease or its spread in a specific region may have a serious impact on the lives of the people and public health due to the fact that an outbreak or the spread of the infectious disease would be difficult to prevent, and it is found to be necessary to urgently increase the supply of the materials and supplies required for infectious disease countermeasures in that specific region because it is found that there is a high probability that the supply of those materials and supplies will be insufficient or their supply may become unstable due to the current supply and demand situation or other circumstances.

(2) When the Minister of Health, Labour and Welfare finds it necessary in order to deal with the situation prescribed in the preceding paragraph, they may instruct those engaged in the business of loaning the materials and supplies required for infectious disease countermeasures to loan those materials and supplies by specifying the deadline by which those materials must be loaned, quantity of the materials to be loaned, loan period, and borrower.

(3) When the Minister of Health, Labour and Welfare finds it particularly

necessary to deal with the situation prescribed in paragraph (1), the Minister may instruct those engaged in the business of loaning the materials and supplies required for infectious disease countermeasures to transport those materials and supplies by specifying the deadline by which those materials must be transported, quantity of the materials to be transported, transportation route, and conditions for transportation.

- (4) When the Minister of Health, Labour and Welfare finds it particularly necessary to deal with the situation prescribed in paragraph (1), the Minister may instruct those engaged in the business of storing the materials and supplies required for infectious disease countermeasures to store those materials and supplies by specifying the quantity of the materials to be stored, storage period, and conditions for storage.
- (5) When the Minister of Health, Labour and Welfare intends to give instructions pursuant to the provisions of each of the preceding paragraphs, the Minister is to consult with the minister having jurisdiction over the business producing, importing, selling, loaning, transporting, or storing materials and supplies required for infectious disease countermeasures in advance.
- (6) When a person who has received instructions pursuant to the provisions of paragraphs (1) to (4) fails to follow the instructions without reasonable grounds, the Minister of Health, Labour and Welfare may make that fact public.

(Financial Measures, etc.)

Article 53-21 The national government may take necessary financial and other measures for producers who have produced materials and supplies required for infectious disease countermeasures in accordance with a request under the provisions of Article 53-16, paragraph (1) or an instruction under the provisions of paragraph (4) of that Article, importers who have imported those materials and supplies in accordance with a request under the provisions of Article 53-18, paragraph (1) or an instruction under the provisions of Article 53-16, paragraph (4), which is applied mutatis mutandis in paragraph (2) of that Article, and persons who have sold, loaned, transported, or stored those materials and supplies in accordance with the instructions under the provisions of the preceding Article, paragraphs (1) through (4).

(Collection of Reports)

Article 53-22 (1) The Minister of Health, Labour and Welfare or the minister having jurisdiction over the business producing, importing, selling, or loaning materials and supplies required for infectious disease countermeasures may request a person engaged in the business of producing, importing, selling, or loaning those materials and supplies to report on the status of the production, import, selling, or loaning of those materials and supplies in order to ascertain

the domestic supply and demand of those materials and supplies.

(2) A person who has received a request for a report pursuant to the provisions of the preceding paragraph must endeavor to comply with the request.

(Entry and Inspections, etc.)

Article 53-23 (1) The Minister of Health, Labor and Welfare or the minister having jurisdiction over the business producing, importing, selling, loaning, transporting, or storing materials and supplies required for infectious disease countermeasures may, to the extent necessary for the enforcement of the provisions of Article 53-16, paragraphs (1) and (2) through (7) (including cases where these provisions are applied mutatis mutandis pursuant to Article 53-18, paragraph (2)), Article 53-18, paragraph (1), and Article 53-20, have persons engaged in the business of producing, importing, selling, loaning, transporting, or storing those materials and supplies make a report on the status of business or accounting, or have personnel from the Ministry enter their office, place of business, or other workplace to inspect their books, documents, and other items.

(2) The provisions of Article 35, paragraphs (2) and (3) apply mutatis mutandis to the entry and inspection carried out under the provisions of the preceding paragraph.

Chapter X Measures on Importing Animals Likely to Transmit Pathogens Causing Infectious Diseases

(Prohibition of Imports)

Article 54 No person may import the following animals, specified by Cabinet Order as being highly likely to transmit an infectious disease to humans (referred to below as "designated animals"); provided, however, that this does not apply if designated animals must be imported from an area specified by Order of the Ministry of Health, Labour and Welfare or Order of the Ministry of Agriculture, Forestry and Fisheries as referred to in item (i) under special circumstances and the permission of the Minister of Health, Labour and Welfare and the Minister of Agriculture, Forestry and Fisheries is obtained:

(i) an animal shipped from any of the areas specified by Order of the Ministry of Health, Labour and Welfare or Order of the Ministry of Agriculture, Forestry and Fisheries for respective designated animals by taking into consideration the status of the outbreak of an infectious disease and other circumstances; or

(ii) an animal transported via any of the areas specified by Order of the Ministry of Health, Labour and Welfare or Order of the Ministry of Agriculture, Forestry and Fisheries as referred to in the preceding item.

(Import Quarantines)

- Article 55 (1) A person intending to import a designated animal (referred to below as an "importer") must attach the certificate issued by the competent governmental organization of the exporting country or its photocopy including the result of the inspection in the exporting country which states that the animal is not infected with any of the infectious diseases specified by Cabinet Order for that designated animal or that the animal is not suspected to be infected with those infectious diseases and stating other matters specified by Order of the Ministry of Health, Labour and Welfare or Order of the Ministry of Agriculture, Forestry and Fisheries.
- (2) No designated animal may be imported through any place other than the seaports or airports specified by Order of the Ministry of Agriculture, Forestry and Fisheries.
- (3) Importers must notify the Animal Quarantine Service of the types and quantities of the designated animals to be imported, the time and place of import, and other information specified by Order of the Ministry of Agriculture, Forestry and Fisheries, pursuant to the provisions of Order of the Ministry of Agriculture, Forestry and Fisheries. In this case, the Director General of the Animal Quarantine Service may instruct the person who submitted a notification to change the time or place of the import for which the notification was submitted when it is found to be particularly necessary for efficiently carrying out the inspection referred to in the following paragraph.
- (4) Importers must have the designated animals inspected by an animal quarantine officer at an office of the Animal Quarantine Service or at a place designated by the animal quarantine officer inside a seaport or airport specified pursuant to the provisions of paragraph (2), in order to ascertain whether or not those designated animals are infected or suspected of being infected with any of the infectious diseases specified by Cabinet Order as referred to in paragraph (1); provided, however, that that inspection may be carried out at any other place designated by the Minister of Agriculture, Forestry and Fisheries under special circumstances.
- (5) The animal quarantine officer may give necessary instructions to the person undergoing the inspection referred to in the preceding paragraph when it is found to be necessary for carrying out the inspection referred to in that paragraph.
- (6) Beyond what is prescribed in the preceding paragraphs, necessary matters concerning quarantine of designated animals are specified by Order of the Ministry of Agriculture, Forestry and Fisheries.

(Measures Based on Inspections)

- Article 56 (1) If an animal quarantine officer discovers a designated animal

infected or suspected of being infected with any of the infectious diseases specified by Cabinet Order as referred to in paragraph (1) of the preceding Article during the inspection referred to in paragraph (4) of that Article, the provisions of Article 13 do not apply. In this case, the Director General of the Animal Quarantine Service is to immediately inform the prefectural governor of the name of the importer of the designated animal and other matters specified by the Order of the Ministry of Health, Labour and Welfare as referred to in paragraph (1) of that Article through the chief of the nearest public health center.

- (2) The prefectural governor who receives a notice under the provisions of the preceding paragraph must immediately report the contents of the notice to the Minister of Health, Labour and Welfare.
- (3) The Director General of the Animal Quarantine Service may direct animal quarantine officers to isolate, disinfect, slaughter, or subject the designated animal prescribed in paragraph (1) to other measures pursuant to the provisions of Order of the Ministry of Agriculture, Forestry and Fisheries.

(Import Notifications)

Article 56-2 (1) A person intending to import animals (excluding designated animals) specified by Order of the Ministry of Health, Labour and Welfare as being likely to transmit an infectious disease to humans or the corpses of animals specified by Order of the Ministry of Health, Labour and Welfare as being likely to transmit an infectious disease to humans (referred to below as "notifiable animals or the like" in this Article and Article 77, paragraph (1), item (xii)) must submit a notification stating the types and quantities of the notifiable animals or the like and other matters specified by Order of the Ministry of Health, Labour and Welfare with the Minister of Health, Labour and Welfare, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare. In this case, the notification must be accompanied by a certificate issued by the competent governmental organization of the exporting country or a photocopy of the certificate including the result of the inspection in the exporting country, stating that the animals are not infected with any of the infectious diseases specified by Cabinet Order for each of the notifiable animals or the like, or that the animals are not suspected to be infected with that infectious diseases, and stating other matters specified by Order of the Ministry of Health, Labour and Welfare or Order of the Ministry of Agriculture, Forestry and Fisheries.

- (2) Beyond what is prescribed in the preceding paragraph, necessary matters concerning the notification of import of notifiable animals or the like are specified by Order of the Ministry of Health, Labour and Welfare.

Chapter XI Specified Pathogens

Section 1 Class I Pathogens

(Prohibition of Possession of Class I Pathogens and Toxins)

Article 56-3 (1) No person may possess class I pathogens and toxins; provided, however, that this does not apply in the following cases:

- (i) when a holder of specified class I pathogens and toxins possesses such pathogens and toxins that require testing or research specified by Cabinet Order (referred to below as "specified class I pathogens and toxins"), or testing or research to be conducted at a laboratory designated by the Minister of Health, Labour and Welfare;
 - (ii) when a person required to perform sterilization or detoxification (referred to below as "sterilization or detoxification") of class I pathogens and toxins or to transfer such pathogens and toxins pursuant to the provisions of Article 56-22, paragraph (1) (referred to below as the "person obligated to sterilize and transfer class I pathogens") possesses class I pathogens and toxins pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare until the person completes the sterilization or detoxification or transfer (referred to below as "sterilization and transfer") of those pathogens and toxins;
 - (iii) when a person undertaking the transportation entrusted by a person prescribed in the preceding two items possesses the entrusted class I pathogens and toxins to be transported; or
 - (iv) when an employee of any of the persons prescribed in the preceding three items possesses class I pathogens and toxins as part of their duties.
- (2) A holder of a specified class I pathogens and toxins referred to in item (i) of the preceding paragraph means the national government or an incorporated administrative agency (meaning an incorporated administrative agency prescribed in Article 2, paragraph (1) of the Act on General Rules for Independent Administrative Agencies (Act No. 103 of 1999)) or another juridical person specified by Cabinet Order which is designated by the Minister of Health, Labour and Welfare as being capable of properly possessing each type of pathogen and toxin.

(Prohibition of Import of Class I Pathogens and Toxins)

Article 56-4 No person may import class I pathogens and toxins; provided, however, that this does not apply when a holder of specified class I pathogens and toxins (meaning a holder of specified class I pathogens and toxin prescribed in paragraph (2) of the preceding Article; the same applies below) imports such pathogens and toxins designated by the Minister of Health, Labour and Welfare as being required to be procured from foreign countries.

(Prohibition of Transfer and Receipt of Class I Pathogens and Toxins)

Article 56-5 No person may transfer or receive class I pathogens and toxins; provided, however, that this does not apply in the following cases:

- (i) when a holder of specified class I pathogens and toxins transfers those pathogens and toxins to another holder of specified class I pathogens and toxins or receives those pathogens and toxins from another holder of class I pathogens and toxins or from a person obligated to sterilize and transfer class I pathogens and toxins, after obtaining the approval of the Minister of Health, Labour and Welfare; or
- (ii) when a person obligated to sterilize and transfer class I pathogens and toxins transfers specified class I pathogens and toxins to a holder of such pathogens and toxins pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

Section 2 Class II Pathogens

(Permission to Possess Class II Pathogens and toxins)

Article 56-6 (1) A person intending to possess class II pathogens and toxins must obtain the permission of the Minister of Health, Labour and Welfare pursuant to the provisions of Cabinet Order; provided, however, that this does not apply in the following cases:

- (i) when a person required to perform the sterilization and transfer of class II pathogens and toxins pursuant to the provisions of Article 56-22, paragraph (1) (referred to below as "person obligated to sterilize and transfer class II pathogens and toxins") possesses class II pathogens and toxins pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare until the person completes the sterilization and transfer of those pathogens and toxins;
 - (ii) when a person undertaking the transportation entrusted by a person who obtained the permission referred to in the main clause of this paragraph (referred to below as "permitted holder of a class II pathogen and toxin") or by a person obligated to sterilize and transfer a class II pathogen possesses the entrusted class II pathogen to be transported; or
 - (iii) when an employee of a permitted holder of a class II pathogen and toxin or a person prescribed in the preceding two items possesses a class II pathogen or toxin as part of their duties.
- (2) A person intending to obtain permission as referred to in the main clause of the preceding paragraph must file an application stating the following information with the Minister of Health, Labour and Welfare pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare:

- (i) the applicant's personal name or entity name and address, and the name of the representative if the applicant is a corporation;
- (ii) the type of the class II pathogen (or the type and quantity if it is a toxin);
- (iii) the purpose and method of possession; and
- (iv) the location, structure, and facilities of the laboratory for the storage, use, and sterilization or detoxification of the class II pathogens and toxins (referred to below as "laboratory for handling class II pathogens and toxins").

(Ineligibility)

Article 56-7 A person falling under any of the following items will not be granted the permission referred to in the main clause of paragraph (1) of the preceding Article:

- (i) a person specified by Order of the Ministry of Health, Labour and Welfare as being unable to properly possess class II pathogens and toxins due to a mental or physical disorder;
- (ii) a person who has become subject to an order commencing bankruptcy proceedings and has not been released from bankruptcy restrictions;
- (iii) a person who has been sentenced to imprisonment without work or a heavier punishment and for whom five years have yet to elapse since the day on which the execution of the sentence was completed or the sentence ceased to be applicable;
- (iv) a person who has been punished by a fine due to a violation of any provisions of this Act, the Rabies Prevention Act (Act No. 247 of 1950), or the Quarantine Act or any order based on those acts and for whom five years have yet to elapse since the day on which the execution of the sentence was completed or the sentence ceased to be applicable;
- (v) a person whose permission has been revoked under the provisions of Article 56-35, paragraph (2) and for whom five years have yet to elapse since the date of the revocation (or, if the permission is revoked for a corporation, a person who used to be an officer of the corporation (meaning a member executing business, a director, an executive officer, or other equivalent persons, including any person who is found to have the same or a higher control over the corporation than the members executing business, directors, executive officers, or other equivalent persons whether or not they are an adviser, consultant, or person with any other designation; the same applies below in this Article) at any time during the period of sixty days before the date on which the notice of disposition of the revocation under the provisions of Article 15 of the Administrative Procedure Act (Act No. 88 of 1993) is given and for whom five years have yet to elapse since the date of the revocation);
- (vi) a person who submitted a notification pursuant to the provisions of Article

56-22, paragraph (2) during the period commencing on the date the notice under Article 15 of the Administrative Procedure Act stating the disposition of revocation of permission under the provisions of Article 56-35, paragraph (2) is issued and ending on the date of revocation or the date on which the cancellation of revocation is determined (excluding those whose submission of the notification is on reasonable grounds) and for whom five years have yet to elapse since the date of the notification;

- (vii) when a notification is filed under the provisions of Article 56-22, paragraph (2) during the period prescribed in the preceding item, a person who used to be an officer or an employee specified by Cabinet Order of the corporation which submitted the notification (excluding corporations whose submission of the notification is on reasonable grounds), or an employee specified by Cabinet Order of the individual who submitted the notification (excluding those whose submission of the notification is on reasonable grounds) at any time during the period of 60 days before the date of the notice referred to in the preceding item and for whom five years have yet to elapse since the date of the notification;
- (viii) a minor who does not have business ability equivalent to adults and whose statutory agent (or an officer of the corporation, when the statutory agent is a corporation) falls under any of the preceding items;
- (ix) a corporation retaining an officer or an employee specified by Cabinet Order who falls under any of items (i) through (vii); or
- (x) an individual retaining an employee specified by Cabinet Order who falls under any of items (i) through (vii).

(Criteria for Permission)

Article 56-8 The Minister of Health, Labour and Welfare may not grant the permission referred to in the main clause of Article 56-6, paragraph (1) unless the application for the permission is found to conform with both of the following items:

- (i) the purpose of possession is examination, medical treatment, or manufacture or test and research of pharmaceutical products or other products specified by Order of the Ministry of Health, Labour and Welfare; and
- (ii) the location, structure, and facilities of the laboratory for handling class II pathogens and toxins conform with the technical standards specified by Order of the Ministry of Health, Labour and Welfare and there is no risk of an outbreak or spread of any infectious disease caused by class II pathogens.

(Conditions for Permission)

Article 56-9 (1) Conditions may be attached to the permission referred to in the

main clause of Article 56-6, paragraph (1).

- (2) The conditions referred to in the preceding paragraph are limited to the minimum extent necessary to prevent an outbreak or the spread of an infectious disease caused by a class II pathogen or toxin, and must not impose unreasonable obligations on the person obtaining the permission.

(Certificate of Permission)

Article 56-10 (1) When the Minister of Health, Labour and Welfare has granted the permission referred to in the main clause of Article 56-6, paragraph (1), the Minister must issue a certificate of permission stating the types of class II pathogens and toxins which are the subject of the permission (or the types and quantities if they are toxins) and other matters specified by Order of the Ministry of Health, Labour and Welfare.

- (2) Reissuance or return of a certificate of permission or other procedural matters concerning the certificate of permission are specified by Order of the Ministry of Health, Labour and Welfare.

(Change in Permitted Matters)

Article 56-11 (1) When a permitted holder of class II pathogens and toxins intends to change any of the matters stated in Article 56-6, paragraph (2), items (ii) through (iv), they must obtain the permission of the Minister of Health, Labour and Welfare pursuant to the provisions of Cabinet Order; provided, however, that this does not apply when the intended change is a minor change as specified by Order of the Ministry of Health, Labour and Welfare.

- (2) When a permitted holder of class II pathogens and toxins intends to make a minor change prescribed in the proviso of the preceding paragraph, they must notify the Minister of Health, Labour and Welfare of their intention in advance pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (3) If a permitted holder of class II pathogens and toxins has changed any of the matters stated in Article 56-6, paragraph (2), item (i), they must notify the Minister of Health, Labour and Welfare within 30 days from the date of that change pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (4) The provisions of Articles 56-8 and 56-9 apply *mutatis mutandis* to the permission referred to in the main clause of paragraph (1).

(Permission to Import Class II Pathogens and Toxins)

Article 56-12 (1) A person intending to import class II pathogens and toxins must obtain the permission of the Minister of Health, Labour and Welfare

pursuant to the provisions of Cabinet Order.

(2) A person intending to obtain the permission referred to in the preceding paragraph must file an application stating the following information with the Minister of Health, Labour and Welfare pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare:

- (i) the applicant's personal name or entity name and address, and the name of the representative if the applicant is a corporation;
- (ii) the type of class II pathogen to be imported (or the type and quantity if it is a toxin);
- (iii) the purpose of import;
- (iv) the exporter's personal name or entity name and address;
- (v) the period of import;
- (vi) the means of transportation; and
- (vii) the name of the port of import.

(Criteria for Permission)

Article 56-13 When an application for permission referred to in paragraph (1) of the preceding Article is filed, the Minister of Health, Labour and Welfare may not grant the permission unless the application is found to conform with all of the following items:

- (i) the applicant is a permitted holder of class II pathogens and toxins;
- (ii) the purpose of import is examination, medical treatment, or manufacture or test and research of pharmaceutical products or other products specified by Order of the Ministry of Health, Labour and Welfare; and
- (iii) there is no risk of an outbreak or spread of any infectious disease caused by class II pathogens.

(Mutatis Mutandis Application)

Article 56-14 The provisions of Article 56-9 apply mutatis mutandis to the permissions referred to in Article 56-12, paragraph (1), the provisions of Article 56-10 apply mutatis mutandis to the certificates of permission for the permission referred to in Article 56-12, paragraph (1), and the provisions of Article 56-11 apply mutatis mutandis to the persons obtaining the permission referred to in Article 56-12, paragraph (1). In this case, the phrase "Article 56-6, paragraph (2), items (ii) through (iv)" in Article 56-11, paragraph (1) is deemed to be replaced with "Article 56-12, paragraph (2), items (ii) through (vii)," the phrase "Article 56-6, paragraph (2), item (i)" in paragraph (3) of that Article is deemed to be replaced with "Article 56-12, paragraph (2), item (i)," the phrase "Articles 56-8 and 56-9" in paragraph (4) of that Article is deemed to be replaced with "Articles 56-9 and 56-13."

(Restriction on the Transfer and Receipt of Class II Pathogens and Toxins)

Article 56-15 No person may transfer or receive class II pathogens and toxins, except in any of the following cases:

- (i) when a permitted holder of class II pathogens and toxins transfers or receives those pathogens and toxins to or from another permitted holder, or from a person obligated to sterilize and transfer them; or
- (ii) when a person obligated to sterilize and transfer class II pathogens and toxins transfers them to a permitted holder, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

Section 3 Class III Pathogens

(Notification of Possession of Class III Pathogens Toxins)

Article 56-16 (1) A person possessing class III pathogens and toxins must notify the Minister of Health, Labour and Welfare of the types of pathogens and toxins they possess, as well as any other matters specified by Order of the Ministry of Health, Labour and Welfare, within seven days of acquiring them, pursuant to the provisions of Cabinet Order; provided, however, that this does not apply in the following cases:

- (i) when a hospital, clinic, or organization that examines pathogens and toxins possesses class III pathogens and toxins, until they are sterilized and transferred, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, and acquires them while performing its services;
 - (ii) when a person entrusted with transportation by a person possessing class III pathogens and toxins possesses the entrusted class III pathogens and toxins to be transported; or
 - (iii) when an employee of a person possessing class III pathogens and toxins possesses class III pathogens and toxins as part of their duties.
- (2) If a person possessing class III pathogens and toxins has submitted a notification under the main clause of the preceding paragraph changes any of the matters stated in the notification, the person must notify the Minister of Health, Labour and Welfare of that change within seven days from the date of the change pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare. The same applies when the holder ceases to possess the class III pathogens and toxins related to the notification.

(Notification of Importing Class III Pathogens and Toxins)

Article 56-17 A person who has imported class III pathogens and toxins must notify the Minister of Health, Labour and Welfare of the following matters within seven days of the importation of those pathogens and toxins, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare:

- (i) the importer's personal name or entity name and address, and the name of the representative if the importer is a corporation;
- (ii) the type of class III pathogen imported (or the type and quantity if it is a toxin);
- (iii) the purpose of import;
- (iv) the exporter's personal name or entity name and address;
- (v) the date of import;
- (vi) the means of transportation; and
- (vii) the name of the port of import.

Section 4 Duties of Holders

(Establishment of Rules for Preventing an Outbreak of an Infectious Disease)

- Article 56-18 (1) A holder of specified class I pathogens and toxins or a permitted holder of class II pathogens and toxins must establish their own rules to prevent an outbreak of an infectious disease and file the established rules with the Minister of Health, Labour and Welfare before they acquire the relevant pathogens and toxins, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, to prevent an outbreak or the spread of an infectious disease caused by the relevant pathogens.
- (2) If a holder of specified class I pathogens and toxins or a permitted holder of class II pathogens and toxins revises the rules to prevent an outbreak of an infectious disease, they must notify the Minister of Health, Labour and Welfare of the revision within 30 days of the revision.

(Appointment of Chief Supervisors for Handling Pathogens)

- Article 56-19 (1) A holder of specified class I pathogens and toxins or a permitted holder of class II pathogens and toxins must appoint a chief supervisor for handling pathogens and toxins to assign them the duty of supervising the prevention of an outbreak or the spread of any infectious disease caused by the relevant pathogens, who must be selected from those who satisfy the requirements specified by Order of the Ministry of Health, Labour and Welfare for the knowledge and experience related to handling the relevant pathogens and toxins.
- (2) When a holder of specified class I pathogens and toxins or a permitted holder of class II pathogens and toxins has appointed a chief supervisor for handling pathogens and toxins, they must notify the Minister of Health, Labour and Welfare of that fact within 30 days of the appointment, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare. The same applies when the chief supervisor is dismissed.

(Responsibilities of Chief Supervisors for Handling Pathogens)

Article 56-20 (1) The chief supervisor for handling pathogens and toxins must execute the assigned duties in good faith.

(2) Any person who enters a laboratory for the storage, use, and sterilization or detoxification of specified class I pathogens and toxins (referred to as "laboratory for handling class I pathogens and toxins") or a laboratory for handling class II pathogens and toxins must follow the instructions given by the chief supervisor for handling pathogens and toxins, to ensure the enforcement of this Act or any order or the rules for preventing an outbreak of an infectious disease based on this Act.

(3) In connection with the prevention of an outbreak or spread of an infectious disease caused by a pathogen, a holder of specified class I pathogens and toxins or a permitted holder of class II pathogens and toxins must respect the opinions of their chief supervisor for handling pathogens and toxins.

(Education and Training)

Article 56-21 A holder of specified class I pathogens and toxins or a permitted holder of class II pathogens and toxins must ensure that individuals entering laboratories and handling these pathogens and toxins are familiar with the rules for preventing infectious disease outbreaks, and provide necessary education and training to those persons to prevent an outbreak or the spread of an infectious disease caused by the relevant pathogens, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Sterilization)

Article 56-22 (1) When a person stated in either of the following items falls under the case prescribed in that item, the person must sterilize, detoxify, or transfer the class I pathogens and toxins or class II pathogens and toxins in their possession:

(i) a holder of specified class I pathogens and toxins or a permitted holder of class II pathogens and toxins: when they no longer need to possess those pathogens and toxins, or when the designation referred to in Article 56-3, paragraph (2) or the permission referred to in the main clause of Article 56-6, paragraph (1) is revoked or suspended;

(ii) a hospital, clinic, or an organization that examines pathogens and toxins: when it has come into possession of class I pathogens and toxins or class II pathogens and toxins while performing its services.

(2) When a person required to perform the sterilization and transfer of class I pathogens and toxins or class II pathogens and toxins pursuant to the provisions of the preceding paragraph intends to perform the sterilization and transfer of the relevant pathogens and toxins, the person must notify the

Minister of Health, Labour and Welfare of the type of the relevant pathogen and toxin, the methods of sterilization and transfer, and other matters specified by Order of the Ministry of Health, Labour and Welfare, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(3) When a holder of specified class I pathogens and toxins or a permitted holder of class II pathogens and toxins submits a notification under the provisions of the preceding paragraph, and they no longer need to possess those pathogens and toxins, the designation referred to in Article 56-3, paragraph (2) or the permission referred to in the main clause of Article 56-6, paragraph (1) ceases to be effective.

(Duty of Keeping Records)

Article 56-23 (1) A holder of specified class I pathogens and toxins, a permitted holder of class II pathogens and toxins, or a person possessing class III pathogens and toxins (excluding employees prescribed in Article 56-16, paragraph (1), item (iii); referred to below as "holder of class III pathogens and toxins") must keep books and record the matters concerning the storage, use, and sterilization or detoxification of the relevant pathogens and toxins and other necessary matters concerning the prevention of an outbreak or the spread of an infectious disease caused by the relevant pathogens, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(2) The books referred to in the preceding paragraph must be retained pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Standards for Laboratories)

Article 56-24 A holder of a specified class I pathogens and toxins, permitted holder of class II pathogens and toxins, a holder of a class III pathogens and toxins, or a person possessing class IV pathogens and toxins (excluding individuals who are employees of a person possessing class IV pathogens and toxins and possess them as part of their duties; referred to below as "holder of class IV pathogens and toxins") must maintain the laboratories for the storage, use, or sterilization or detoxification of those specified pathogens and toxins in such a way that their location, structure, and facilities conform with the technical standards specified by Order of the Ministry of Health, Labour and Welfare.

(Standards for Storage)

Article 56-25 When storing, using, transporting (excluding transportation by vessels or aircraft; the same applies below except in paragraph (4) of the following Article), or sterilizing specified pathogens and toxins, a holder of specified class I pathogens and toxins, a permitted holder of class II pathogens

and toxins, a person entrusted with transportation by any of those holders, a holder of class III pathogens and toxins, or a holder of class IV pathogens and toxins (referred to below as "holder of specified pathogens and toxins") must implement necessary measures to prevent an outbreak or the spread of an infectious disease caused by specified pathogens in conformity with the technical standards specified by Order of the Ministry of Health, Labour and Welfare.

(Exclusion from Application)

- Article 56-26 (1) The provisions of the preceding three Articles and Article 56-32 do not apply in the case stated in Article 56-16, paragraph (1), item (i).
- (2) The provisions of Article 56-23, Article 56-24, and Article 56-32, paragraph (1) do not apply in the case stated in Article 56-16, paragraph (1), item (ii).
- (3) The provisions of the preceding two Articles and Article 56-32 do not apply when a hospital, clinic, or organization that examines pathogens and toxins possesses class IV pathogens and toxins until it completes the sterilization and transfer of those pathogens and toxins pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, if that institution came into possession of that pathogen while performing its services.
- (4) The provisions of Article 56-24 and Article 56-32, paragraph (1) do not apply when a person entrusted with transportation by a holder of class IV pathogens and toxins possesses the entrusted class IV pathogens and toxins to be transported.

(Notification of Transportation)

- Article 56-27 (1) When a holder of specified class I pathogens and toxins, a person obligated to sterilize and transfer class I pathogens and toxins, a permitted holder of class II pathogens and toxins, a person obligated to sterilize and transfer class II pathogens and toxins, a person entrusted with transportation by any of those holders or persons, or a holder of class III pathogens and toxins transports class I pathogens and toxins, class II pathogens and toxins, or class III pathogens and toxins outside its place of business (excluding transportation by vessels or aircraft), they must notify the Prefectural Public Safety Commission of that fact and obtain a document certifying the notification issued by the commission (referred to below as "transportation certificate"), pursuant to the provisions of the Rules of the National Public Safety Commission.
- (2) After receiving a notification filed under the preceding paragraph, the Prefectural Public Safety Commission may give necessary instructions in connection with the dates and times for transportation, transportation routes, or other matters specified in the Rules of the National Public Safety

- Commission, pursuant to the provisions of the Rules of the National Public Safety Commission, when it is found to be necessary to prevent class I pathogens and toxins, class II pathogens and toxins, or class III pathogens and toxins to be transported from being stolen, lost, or involved in other accidents.
- (3) When the Prefectural Public Safety Commission gives instructions referred to in the preceding paragraph, the commission must set out the details of those instructions in the transportation certificate.
- (4) After obtaining a transportation certificate issued in the case prescribed in paragraph (1), a holder of specified class I pathogens and toxins, a person obligated to sterilize and transfer class I pathogens and toxins, a permitted holder of class II pathogens and toxins, a person obligated to sterilize and transfer class II pathogens and toxins, a person entrusted with transportation by any of those holders or persons, and a holder of class III pathogens and toxins must carry their transportation certificate with them and perform the transportation in accordance with the conditions set out in the transportation certificate.
- (5) When a police officer finds it particularly necessary to prevent class I pathogens and toxins, class II pathogens and toxins, or class III pathogens and toxins being transported in an automobile or light vehicle from being stolen, lost, or involved in other accidents, the police officer may stop the automobile or light vehicle, ask the person transporting those pathogens and toxins to present the transportation certificate, or verify whether or not the transportation is performed in accordance with the conditions set out in the transportation certificate pursuant to the provisions of the Rules of the National Public Safety Commission, or may order a change of the transportation route or take other suitable measures to the extent necessary for the enforcement of the provisions of paragraph (1), paragraph (2), and the preceding paragraph to prevent the relevant pathogens and toxins from being stolen, lost, or involved in other accidents.
- (6) The authority prescribed in the preceding paragraph must not be construed as being granted for criminal investigation purposes.
- (7) The renewal or reissuance of a transportation certificate, or return of that transportation certificate when it is no longer necessary, and the necessary liaison between or among the Prefectural Public Safety Commissions in connection with the notifications referred to in paragraph (1), the instructions referred to in paragraph (2), and the issuance, renewal, reissuance, and return of a transportation certificate when the transportation involves two or more prefectures, are specified by Cabinet Order.

(Notification of Accidents)

Article 56-28 A holder of specified pathogens and toxins, a person obligated to

sterilize and transfer class I pathogens and toxins, or a person obligated to sterilize and transfer class II pathogens and toxins must make a report to a police officer or a coast guard officer without delay if specified pathogens and toxins in their possession are stolen, lost, or involved in other accidents.

(Emergency Measures in Times of Disaster)

- Article 56-29 (1) A holder of specified pathogens and toxins, a person obligated to sterilize and transfer class I pathogens and toxins, or a person obligated to sterilize and transfer class II pathogens and toxins must immediately implement emergency measures pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare if an infectious disease caused by specified pathogens in their possession have broken out or spread, or are likely to break out or spread, as a result of an earthquake, fire, or another disaster.
- (2) A person who has discovered a situation referred to in the preceding paragraph must immediately inform a police officer or a coast guard officer of that situation.
- (3) If a situation referred to in paragraph (1) occurs, a holder of specified pathogens and toxins, a person obligated to sterilize and transfer class I pathogens and toxins, or a person obligated to sterilize and transfer class II pathogens and toxins must notify the Minister of Health, Labour and Welfare of that situation without delay, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

Section 5 Supervision

(Collection of Reports)

Article 56-30 The Minister of Health, Labour and Welfare or a prefectural public safety commission may direct a holder of specified pathogens and toxins, a person who has imported class III pathogens and toxins, a person who has imported class IV pathogens and toxins, a person obligated to sterilize and transfer class I pathogens and toxins, or a person obligated to sterilize and transfer class II pathogens and toxins (referred to below as "holder, etc. of specified pathogens and toxins") to make a report to the extent necessary for the enforcement of the provisions of this Chapter (or the provisions of Article 56-27, paragraph (2), in the case of the Prefectural Public Safety Commission).

(Entry and Inspections)

Article 56-31 (1) The Minister of Health, Labour and Welfare or a prefectural public safety commission may, to the extent necessary for the enforcement of the provisions of this Chapter (or the provisions of Article 56-27, paragraph (2), in the case of the Prefectural Public Safety Commission), direct relevant

officials (or police officials, in the case of the Prefectural Public Safety Commission) to enter the offices or places of business of a holders, etc. of specified pathogens and toxins, to inspect their books, documents and other necessary objects, to interview the relevant persons, or to forcibly collect specified pathogens and toxins or objects contaminated by those pathogens, without compensation, to the minimum extent necessary for inspection.

(2) The provisions of Article 35, paragraphs (2) and (3) apply *mutatis mutandis* to the entry and inspection carried out under the provisions of the preceding paragraph.

(Order for Improvement)

Article 56-32 (1) When the Minister of Health, Labour and Welfare finds that the location, structure, or facilities of a laboratory for the storage, use, or sterilization or detoxification of specified pathogens and toxins does not conform with the technical standards referred to in Article 56-24, the Minister may order a holder of specified class I pathogens and toxins, a permitted holder of class II pathogens and toxins, a holder of class III pathogens and toxins, or a holder of class IV pathogens and toxins to repair or alter the laboratory or to implement other necessary measures for preventing an outbreak or the spread of an infectious disease caused by specified pathogens.

(2) When the Minister of Health, Labour and Welfare finds that the measures for the storage, use, transportation, or sterilization or detoxification of specified pathogens and toxins does not conform with the technical standards referred to in Article 56-25, the Minister may order a holder of specified pathogens and toxins to change the methods for the storage, use, transportation, or sterilization or detoxification, or to implement other necessary measures to prevent an outbreak or the spread of an infectious disease caused by those specified pathogens.

(Order to Change the Rules for Preventing an Outbreak of an Infectious Disease)

Article 56-33 When the Minister of Health, Labour and Welfare finds it necessary to prevent an outbreak or the spread of an infectious disease caused by specified class I pathogens or class II pathogens, the Minister may order a holder of specified class I pathogens and toxins or a permitted holder of class II pathogens and toxins to change its rules for prevention of an outbreak of an infectious disease.

(Order of Dismissal)

Article 56-34 When a chief supervisor for handling pathogens and toxins violates any provisions of this Act or any order based on this Act, the Minister of

Health, Labour and Welfare may order a holder of specified class I pathogens and toxins or a permitted holder of class II pathogens and toxins to dismiss the chief supervisor for handling pathogens and toxins.

(Revocation of a Designation)

Article 56-35 (1) If a holder of specified class I pathogens and toxins falls under any of the following items, the Minister of Health, Labour and Welfare may revoke its designation under the provisions of Article 56-3, paragraph (2) or suspend the designation for a specified period of not more than one year:

(i) if the holder has violated this Act or any order or disposition based on this Act;

(ii) if the location, structure, or facilities of a laboratory for handling class I pathogens and toxins do not conform to the technical standards specified by Order of the Ministry of Health, Labour and Welfare; or

(iii) if the holder is found to be incapable of possessing specified class I pathogen and toxins properly.

(2) If a permitted holder of class II pathogens and toxins falls under any of the following items, the Minister of Health, Labour and Welfare may revoke the permission referred to in the main clause of Article 56-6, paragraph (1) or suspend the permission for a specified period of not more than one year:

(i) if the holder falls under any item of Article 56-7;

(ii) if the holder has violated this Act or any order or disposition based on this Act;

(iii) if the location, structure, or facilities of a laboratory for handling class II pathogens and toxins do not conform with the technical standards referred to in Article 56-8, item (ii); or

(iv) if the holder has violated any of the conditions referred to in Article 56-9, paragraph (1) (including cases where it is applied mutatis mutandis in Article 56-11, paragraph (4)).

(Administrative Order for Sterilization)

Article 56-36 When the Minister of Health, Labour and Welfare finds it necessary, the Minister may order a person required to perform the sterilization and transfer of class I or II pathogens and toxins pursuant to the provisions of Article 56-22, paragraph (1) to change the methods of the sterilization and transfer of the relevant pathogens and toxins or to implement other necessary measures to prevent an outbreak or the spread of an infectious disease caused by the relevant pathogen, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Administrative Order in Times of Disaster)

Article 56-37 When the Minister of Health, Labour and Welfare finds it urgently necessary to prevent an outbreak or the spread of an infectious disease caused by specified pathogens in the case referred to in Article 56-29, paragraph (1), the Minister may order a holder of specified pathogens and toxins, a person obligated to sterilize and transfer class I pathogens and toxins, or a person obligated to sterilize and transfer class II pathogens and toxins to change the location for storage of specified pathogens and toxins, to perform the sterilization or detoxification of specified pathogens, or to implement other necessary measures for preventing an outbreak or the spread of an infectious disease caused by a specified pathogen.

(Relations between the Minister of Health, Labour and Welfare and the Commissioner General of the National Police Agency or Other Organs)

Article 56-38 (1) When it is found to be particularly necessary to maintain public safety or maritime safety, the Commissioner General of the National Police Agency or the Commandant of the Japan Coast Guard may express their opinions to the Minister of Health, Labour and Welfare in connection with the operation of the provisions of Article 56-18, paragraph (1), Article 56-19, paragraph (1), Article 56-20, Article 56-21, Article 56-22, paragraph (1), Articles 56-23 through 56-25, Article 56-28, Article 56-29, paragraph (1), or Article 56-32 through the preceding Article.

(2) The Commissioner General of the National Police Agency or the Commandant of the Japan Coast Guard may direct relevant officials to enter the offices or places of business of a holder of specified pathogens and toxins, a person obligated to sterilize and transfer class I pathogens and toxins, or a person obligated to sterilize and transfer class II pathogens and toxins, to inspect their books, documents, and other necessary items, or to interview the relevant persons, to the extent necessary for the enforcement of the provisions of the preceding paragraph.

(3) The provisions of Article 35, paragraphs (2) and (3) apply *mutatis mutandis* to the entry and inspection carried out under the provisions of the preceding paragraph.

(4) When the Minister of Health, Labour and Welfare has designated a laboratory referred to in Article 56-3, paragraph (1), item (i) or a corporation referred to in paragraph (2) of that Article, granted the permission referred to in the main clause of Article 56-6, paragraph (1), the main clause of Article 56-11, paragraph (1) (including cases where it is applied *mutatis mutandis* in Article 56-14), or Article 56-12, paragraph (1), given the approval referred to in Article 56-5, item (i), executed any disposition pursuant to the provisions of Article 56-35, or received a notification submitted under the provisions of Article 56-11, paragraph (2) or (3) (including cases where they are applied *mutatis mutandis*

in Article 56-14), Articles 56-16 through 56-18, Article 56-19, paragraph (2), Article 56-22, paragraph (2), or Article 56-29, paragraph (3), the Minister must communicate this to the Commissioner General of the National Police Agency, the Commandant of the Japan Coast Guard, or the Commissioner of the Fire and Disaster Management Agency without delay.

- (5) After receiving a notification filed under the provisions of Article 56-28, the police officer or the coast guard officer must inform the Minister of Health, Labour and Welfare of that fact without delay.
- (6) When it is found to be necessary to prevent an outbreak or the spread of an infectious disease caused by specified pathogens, the Minister of Health, Labour and Welfare may ask the minister having jurisdiction over the services provided by the enterprises handling those specified pathogens to implement necessary measures to ensure that those enterprises will properly handle the specified pathogens.
- (7) When the Minister of Health, Labour and Welfare finds it urgently necessary to protect the life and person of each member of the public, the Minister may request prefectural governors to dispatch an employee of an infectious disease research institute or to provide other necessary assistance to prevent an outbreak or the spread of an infectious disease caused by specified pathogens.

Chapter XII Surveys and Research on Infectious Diseases and Pathogens and Toxins and Research and Development of Medicines

(Promotion of Surveys and Research on Infectious Diseases and Pathogens and Toxins, and Research and Development of Medicines)

Article 56-39 (1) The national government is to promote surveys and research on the mechanisms of the onset of infectious diseases, their infectious nature, the pathologies in the case of contracting infectious diseases, methods of diagnosis and treatment of infectious diseases, and pathogens and toxins, which form the basis for ensuring high-quality and adequate medical care for patients with infectious diseases by seeking cooperation, such as the provisions of information and samples obtained during the treatment of patients with infectious diseases, and by ensuring close cooperation with other relevant medical institutions while utilizing the results of investigations pursuant to the provisions of Article 15 and other information obtained through investigations, notifications, or other acts pursuant to this Act, and promote research and development of pharmaceuticals that will serve as the basis for that research by seeking cooperation in conducting clinical trials of pharmaceuticals and by ensuring close cooperation with other relevant medical institutions.

- (2) The Minister of Health, Labour and Welfare is to use a suitable method to

actively provide the results of the surveys and research prescribed in the preceding paragraph to persons who conduct surveys and research on the mechanisms of the onset of infectious diseases, their infectious nature, the pathologies in the case of contracting infectious diseases, methods of diagnosis and treatment of infectious diseases, and pathogens and toxins, physicians, and other relevant persons.

- (3) The Minister of Health, Labour and Welfare may entrust the affairs related to the surveys and research prescribed in paragraph (1), the research and development of medicines, and the provisions of the results of the surveys and research prescribed in the preceding paragraph to the National Center for Global Health and Medicine and other institutions.
- (4) When providing the results of the surveys and research prescribed in paragraph (1) pursuant to the provisions of paragraph (2), the Minister of Health, Labour and Welfare must pay due regard to the protection of personal information.

(Surveys and Research to Ensure High Quality and Adequate Medical Care for Patients)

Article 56-40 In order to contribute to ensuring high-quality and adequate medical care for patients, the Minister of Health, Labour and Welfare is to investigate and conduct research on information that is to be retained pursuant to the provisions of Articles 44-3-6 and 50-7 and other information related to infectious diseases specified by Order of the Ministry of Health, Labor and Welfare (referred to below as "information related to infectious diseases").

(Use or Provisions of Anonymous Information on Infectious Diseases for the Improvement of Public Health)

Article 56-41 (1) In order to contribute to the improvement of public health, the Minister of Health, Labour and Welfare may use anonymous information on infectious diseases (this refers to information on infectious diseases processed in accordance with the standards specified by Order of the Ministry of Health, Labour and Welfare to make it impossible to identify a patient or any other person specified by Order of the Ministry of Health, Labour and Welfare (referred to as a "the persons in question" in the following Article) related to infectious diseases or to restore the information on infectious diseases used in the preparation of that anonymous information on infectious diseases; the same applies below), or, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, provide it to the persons who are stated in the following items and who carry out the operations specified in each of the items as operations that are found to have a considerable public interest if those

- persons carry them out upon receiving that information on infectious diseases:
- (i) other national administrative organs and local governments: surveys concerning the planning and drafting of policies that contribute to the provisions of adequate health and medical services;
 - (ii) universities and other research institutions: research on the causes of diseases, methods for prevention, diagnosis, and treatment of diseases, and other studies on the improvement and promotion of public hygiene; and
 - (iii) private business operators and other persons specified by Order of the Ministry of Health, Labour and Welfare: analyses contributing to research and development in the medical field and other services specified by Order of the Ministry of Health, Labour and Welfare (excluding those conducted for the purpose of advertising or advertising specific goods or services);
- (2) When using or providing anonymous information on infectious diseases pursuant to the provisions of the preceding paragraph, the Minister of Health, Labour and Welfare may use the anonymous information on infectious diseases in conjunction with information related to anonymous medical insurance, etc. prescribed in Article 16-2, paragraph (1) of the Act on Assurance of Medical Care for Elderly People and other information specified by Order of the Ministry of Health, Labour and Welfare, or provide it so that it can be used in a consolidated manner.
- (3) When the Minister of Health, Labour and Welfare intends to provide anonymous information on infectious diseases pursuant to the provisions of paragraph (1), the Minister must hear the opinions of the Health Science Council in advance.

(Prohibition of Collation, etc.)

Article 56-42 When handling anonymous information on infectious diseases and after receiving information on infectious diseases pursuant to the provisions of paragraph (1) of the preceding Article, the person who uses the information (referred to below as "user of anonymous information on infectious diseases") must not, in order to identify the persons in question to whom the information on infectious diseases used in the preparation of the anonymous information on infectious diseases refers, obtain information on the processing methods used to create the anonymous information on infectious diseases, such as descriptions (meaning any matter described or recorded in a document, drawing, or electronic or magnetic record (meaning records created in electronic or magnetic form (means an electronic or magnetic form, magnetic form, or any other form that cannot be recognized by human perception)), or expressed by sound, movement, or other means) deleted from the information on infectious diseases, or collate the anonymous information on infectious diseases with other information.

(Deleted)

Article 56-43 A user of anonymous information on infectious diseases must delete the anonymous information on infectious diseases without delay when it is no longer necessary to use the provided anonymous information on infectious diseases.

(Safety Management Measures)

Article 56-44 A user of anonymous information on infectious diseases must take the necessary and suitable measures specified by Order of the Ministry of Health, Labour and Welfare to prevent leakage of, loss of, or damage to anonymous information on infectious diseases and for the safe management of that information.

(Obligations of Users)

Article 56-45 A user of anonymous information on infectious diseases or a person who has been a user of anonymous information on infectious diseases must not inform others of the anonymous information on infectious diseases that they have learned through the use of the anonymous information on infectious diseases or use it for unjust purposes.

(Entry and Inspections, etc.)

Article 56-46 (1) The Minister of Health, Labour and Welfare may, to the extent necessary for the enforcement of the provisions of this Chapter (excluding Article 56-39 and Article 56-40), order a user of anonymous information on infectious diseases (excluding other administrative organs of the national government; the same applies below in this paragraph and the following Article) to report, submit or present books and documents, have the officials interview the person concerned, enter the office or other place of business of a user of anonymous information on infectious diseases, and inspect books, documents and other items of a user of anonymous information on infectious diseases.

(2) The provisions of Article 35, paragraphs (2) and (3) apply mutatis mutandis to the entry and inspection carried out under the provisions of the preceding paragraph.

(Correction Orders)

Article 56-47 When the Minister of Health, Labour and Welfare finds that a user of anonymous information on infectious diseases is in violation of the provisions of Articles 56-42 through 56-45, the Minister may order the user to take necessary measures to rectify the violation.

(Entrustment to Reimbursement and Other Similar Services)

Article 56-48 The Minister of Health, Labour and Welfare may entrust the whole or part of the affairs related to the survey and research prescribed in Article 56-40 and the use or provision of anonymous information on infectious diseases pursuant to the provisions of Article 56-41, paragraph (1), to the Reimbursement Services, the National Health Insurance Federation, or any other person (referred to as "reimbursement and other similar services" in paragraphs (1) and (3) of the following Article) specified by Order of the Ministry of Health, Labour and Welfare.

(Fees)

Article 56-49 (1) A user of anonymous information on infectious diseases must pay a fee specified by a Cabinet Order in consideration of actual costs to the national government (when reimbursement and other similar services perform all of the affairs related to the provision of anonymous information on infectious diseases pursuant to the provisions of Article 56-41, paragraph (1), upon entrustment from the Minister of Health, Labour and Welfare pursuant to the provisions of the preceding Article, reimbursement and other similar services).

(2) When the person who intends to pay the fees in the preceding paragraph is a prefectural government or another person specified by a Cabinet Order as a person who plays a particularly important role for the improvement of public health, the Minister of Health, Labour and Welfare may reduce or exempt the fees pursuant to the provisions of a Cabinet Order.

(3) Fees paid to reimbursement and other similar services pursuant to the provisions of paragraph (1) are deemed their income.

Chapter XIII Coverage of Expenses

(Expenses to Be Paid by Municipal Governments)

Article 57 Municipal governments must pay the following expenses:

(i) expenses necessary for disinfection performed by the municipal government pursuant to the provisions of Article 27, paragraph (2) (including cases where it is performed pursuant to the provisions of Article 50, paragraph (1));

(ii) expenses necessary for extermination of rodents, insects, or the like performed by the municipal government pursuant to the provisions of Article 28, paragraph (2) (including cases where it is performed pursuant to the provisions of Article 50, paragraph (1));

(iii) expenses necessary for disinfection performed by the municipal government pursuant to the provisions of Article 29, paragraph (2) (including

- cases where it is performed pursuant to the provisions of Article 50, paragraph (1));
- (iv) expenses necessary for supplying water for daily use performed by the municipal government pursuant to the provisions of Article 31, paragraph (2) (including cases where it is performed pursuant to the provisions of Article 50, paragraph (1));
- (v) expenses necessary for periodical medical examinations provided by the municipal government in the capacity of an employer or provided by the heads of schools or specified institutions established by the municipal government, pursuant to the provisions of Article 53-2, paragraph (1); or
- (vi) expenses necessary for periodical medical examinations provided by the mayor of a municipality pursuant to the provisions of Article 53-2, paragraph (3).

(Expenses Paid by Prefectural Governments)

Article 58 Prefectural governments must pay the following expenses:

- (i) expenses necessary for the affairs (excluding affairs conducted pursuant to the provisions of Article 15-3, paragraph (1) that are performed by the Minister of Health, Labour and Welfare pursuant to the provisions of paragraph (5) of that Article) conducted pursuant to the provisions of Article 14, Article 14-2, Article 15 (excluding paragraphs (2) and (6)), Article 15-2, Article 15-3, Article 16, paragraph (1), Article 16-3, paragraphs (1), (3) or (7) through (10), Article 44-3-5, paragraphs (3) through (5), Article 44-11, paragraphs (1), (3) or (5) through (8) or Article 50-6, paragraphs (3) through (5).
- (ii) expenses necessary for medical examinations conducted under the provisions of Article 17 or 45;
- (iii) expenses necessary for the confirmation under the provisions of Article 18, paragraph (4), Article 22, paragraph (4) (including cases where it is applied mutatis mutandis in Article 26), or Article 48, paragraph (4);
- (iv) expenses necessary for the transportation under the provisions of Article 21 (including cases where it is applied mutatis mutandis in Article 26) or Article 47;
- (iv)-2 expenses necessary for receipt or forcible collection of the specimens or pathogens of an infectious disease under the provisions of Article 26-3, paragraph (1) or (3) (including cases where they are applied mutatis mutandis in Article 44-3-5, paragraph (6) and Article 50-6, paragraph (6)) (including cases where they are performed pursuant to the provisions of Article 50, paragraph (1)) or required for the affairs conducted pursuant to the provisions of Article 26-3, paragraphs (5) through (8) (including cases where they are applied mutatis mutandis in Article 50, paragraph (2));

- (iv)-3 expenses necessary for receipt or collection of specimens under the provisions of Article 26-4, paragraph (1) or (3) (including cases where it is performed pursuant to the provisions of Article 50, paragraph (1)) or required for the affairs conducted pursuant to the provisions of Article 26-4, paragraphs (5) through (8) (including cases where they are applied mutatis mutandis in Article 50, paragraph (3));
- (v) expenses necessary for disinfection under the provisions of Article 27, paragraph (2) (including cases where it is performed pursuant to the provisions of Article 50, paragraph (1));
- (vi) expenses necessary for extermination of rodents, insects, or the like under the provisions of Article 28, paragraph (2) (including cases where it is performed pursuant to the provisions of Article 50, paragraph (1));
- (vii) expenses necessary for measures implemented under the provisions of Article 29, paragraph (2) (including cases where they are implemented pursuant to the provisions of Article 50, paragraph (1));
- (viii) expenses necessary for measures implemented for the buildings under the provisions of Article 32, paragraph (2) (including cases where they are implemented pursuant to the provisions of Article 50, paragraph (1));
- (ix) expenses necessary for restricting or blocking traffic under the provisions of Article 33 (including cases where it is performed pursuant to the provisions of Article 50, paragraph (1));
- (x) expenses necessary for the measures listed in the items of Article 36-2, paragraph (1), Article 36-3, paragraph (1), item (i), and Article 36-6, paragraph (1), item (i) (limited to the portion covered by the prefectural government pursuant to the provisions of Article 36-2, paragraph (1), Article 36-3, paragraph (1), item (iii), and Article 36-6, paragraph (1), item (iii));
- (xi) expenses covered pursuant to the provisions of Article 37, paragraph (1);
- (xii) expenses covered pursuant to the provisions of Article 37-2, paragraph (1);
- (xiii) expenses necessary for the payment of medical treatment expenses under the provisions of Article 42, paragraph (1);
- (xiv) expenses covered pursuant to the provisions of Article 44-3-2, paragraph (1) and Article 50-3, paragraph (1);
- (xv) expenses necessary for payment of medical treatment expenses pursuant to the provisions of Article 44-3-3, paragraph (1) and Article 50-4, paragraph (1);
- (xvi) expenses covered pursuant to the provisions of Article 44-4-3 (including when applied mutatis mutandis pursuant to Article 44-8) and Article 51-3;
- (xvii) expenses necessary for periodical medical examinations provided by the prefectural government in the capacity of an employer or provided by the heads of schools or specified institutions established by the prefectural government, pursuant to the provisions of Article 53-2, paragraph (1); and

(xviii) expenses necessary for detailed examinations provided by the chief of a public health center pursuant to the provisions of Article 53-13.

(Expenses Paid by Employers)

Article 58-2 Employers (excluding the national government, prefectural governments, and municipal governments) must pay the expenses necessary for periodical medical examinations conducted under the provisions of Article 53-2, paragraph (1).

(Expenses Paid by Establishers of Schools or Specified Institutions)

Article 58-3 Establishers of schools or specified institutions (excluding those established by the national government, a prefectural government, or a municipal government) must pay the expenses necessary for periodical medical examinations provided by the heads of schools or specified institutions pursuant to the provisions of Article 53-2, paragraph (1).

(Expenses Covered by Prefectural Governments)

Article 59 Prefectural governments will cover two-thirds of the expenses referred to in Article 57, items (i) through (ix) pursuant to the provisions of Cabinet Order.

(Prefectural Government Subsidies)

Article 60 (1) Prefectural governments are to grant a subsidy to cover two-thirds of the expenses referred to in Article 58-3 pursuant to the provisions of Cabinet Order.

(2) Prefectural governments may grant a subsidy to the establisher of a designated medical institution for class I infectious diseases or a designated medical institution for class II infectious diseases, pursuant to the provisions of Cabinet Order, to cover all or part of the expenses necessary for the establishment and operation of the designated medical institution for class I infectious diseases or the designated medical institution for class II infectious diseases.

(3) Prefectural governments may grant a subsidy, pursuant to the provisions of Cabinet Order, to cover all or part of the expenses necessary for the establisher of a public or other relevant medical institution that has taken the measures stated in the items of Article 36-2, paragraph (1), regional medical care support hospital or advanced treatment hospital, and a medical institution that has concluded a medical care agreement or an organization that examines pathogens and toxins and has concluded an agreement on examination and other measures for the establishment of these medical institutions or organizations.

(Expenses Covered by the National Government)

- Article 61 (1) The national government must cover the expenses necessary for the support pursuant to the provisions of Article 44-4-2, paragraphs (5) and (6) (including cases where these provisions are applied mutatis mutandis in Article 44-8) and Article 51-2, paragraphs (5) and (6) (excluding the expenses in item (xvi) of that Article, which are to be paid by the prefectural government pursuant to the provisions of Article 58), and the expenses necessary for the import quarantine pursuant to the provisions of Article 55 (excluding the expenses for raising and management of designated animals during import quarantine).
- (2) The national government will cover three-fourths of the expenses referred to in Article 58, item (xi), the expenses referred to in item (xiii) of that Article (excluding expenses for medical services specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 37-2, paragraph (1)), and the expenses referred to in Article 58, items (xiv) and (xv) pursuant to the provisions of Cabinet Order.
- (3) The national government will cover one-half of the expenses referred to in Article 58, items (i) through (ix) and (xviii) and Article 59 pursuant to the provisions of Cabinet Order.

(National Government Subsidies)

- Article 62 (1) The national government is to grant a subsidy to cover three-fourths of the expenses referred to in items (x) and (xvi) of Article 58 pursuant to the provisions of Cabinet Order.
- (2) The national government is to grant a subsidy to cover one-half of the expenses referred to in Article 58, item (xii) and the expenses referred to in item (xiii) of that Article (limited to the expenses for the medical services specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 37-2, paragraph (1)) pursuant to the provisions of Cabinet Order.
- (3) The national government may grant a subsidy to cover up to one-half of the expenses referred to in paragraphs (2) and (3) of Article 60 pursuant to the provisions of Cabinet Order.
- (4) The national government may grant a subsidy to the establisher of a designated medical institution for specified infectious diseases within the limits of the budget, pursuant to the provisions of Cabinet Order, to cover part of the expenses necessary for the establishment and operation of the designated medical institution for specified infectious diseases.

(Collection of Expenses)

- Article 63 (1) If a mayor of a municipality has directed relevant officials to

- disinfect the places where patients with a class I, class II, class III, or class IV infectious disease or a novel and reemerging influenza or coronavirus infection stay or previously stayed, or where there are or were the corpses of persons who had died of any of those infectious diseases, and other places contaminated or suspected to have been contaminated with the pathogens of any of those infectious diseases pursuant to the provisions of Article 27, paragraph (2) (including cases where that disinfection is performed pursuant to the provisions of Article 50, paragraph (1)), the mayor may collect the amounts of actual costs required for the disinfection from the patients or their custodians or the persons responsible for the administration of those places or their agents.
- (2) If a mayor of a municipality has directed relevant officials to exterminate rodents, insects, or the like contaminated or suspected to have been contaminated with the pathogens of a class I infectious disease, a class II infectious disease, a class III infectious disease, or a class IV infectious disease pursuant to the provisions of Article 28, paragraph (2) (including cases where that extermination is performed pursuant to the provisions of Article 50, paragraph (1)), the mayor of a municipality, or their agents may collect the amounts of actual costs required for the extermination from the persons responsible for the administration of the areas where the rodents, insects or the like exist.
- (3) If a mayor of a municipality has directed relevant officials to disinfect food or drinks, clothing, bedding, or other items contaminated or suspected to have been contaminated with the pathogens of a class I, class, class III, or class IV infectious disease or a novel and reemerging influenza or coronavirus infection pursuant to the provisions of Article 29, paragraph (2) (including cases where that disinfection is performed pursuant to the provisions of Article 50, paragraph (1)), the mayor may collect the amounts of actual costs required for the disinfection from the holder of the food or drinks, clothing, bedding, or other items.
- (4) The provisions of the preceding three paragraphs apply *mutatis mutandis* when a prefectural governor has relevant officials implement disinfection measures prescribed in Article 27, paragraph (2), carry out extermination of rodents, insects, or the like prescribed in Article 28, paragraph (2), or perform disinfection prescribed in Article 29, paragraph (2).

Chapter XIV Miscellaneous Provisions

(Instructions of the Minister of Health, Labour and Welfare)

Article 63-2 (1) When the Minister of Health, Labour and Welfare finds it urgently necessary to prevent an outbreak or the spread of an infectious disease, the Minister may give necessary instructions to prefectural governors

in connection with the affairs which they conduct pursuant to the provisions of this Act (excluding Chapter VIII; the same applies below in the following paragraph) or pursuant to the provisions of any Cabinet Order based on this Act.

- (2) In addition to the provisions stated in the preceding paragraph, when a prefectural governor violates the provisions of this Act or Cabinet Order based on this Act, or has failed to manage or execute the affairs pursuant to these provisions and if the Minister of Health, Labour and Welfare finds it particularly necessary to prevent an outbreak or the rapid nationwide spread of a novel and reemerging influenza or coronavirus infection or a designated infectious disease (limited to those for which an announcement has been made pursuant to the provisions of Article 44-7, paragraph (1)), the Minister may provide necessary instructions to the prefectural governor concerning the Type I statutory entrusted functions (referred to as "Type I statutory entrusted functions" in Articles 65 and 65-2) prescribed in Article 2, paragraph (9), item (i) of the Local Autonomy Act (Act No. 67 of 1947) conducted by the prefectural governor pursuant to the provisions of this Act or Cabinet Order based on this Act.

(Comprehensive Coordination by Prefectural Governors)

- Article 63-3 (1) When a prefectural governor finds it necessary to prevent an outbreak of an infectious disease or to prevent the spread of an infectious disease in the whole or in parts of the area under the jurisdiction of the prefectural governor, the mayor of a municipality, medical institution, infectious disease research institute, or other relevant persons (referred to below as "relevant organizations and associated parties" in this Article) are to conduct comprehensive coordination with recommendations for hospitalization pursuant to the provisions of Article 19, Article 20 (including cases where these provisions are applied *mutatis mutandis* pursuant to Article 26), or Article 46, measures for hospitalization, and other measures necessary to prevent an outbreak or the spread of an infectious disease in the whole or parts of the area implemented by the relevant organizations and associated parties.
- (2) When the mayor of a city or special ward with a public health center finds it necessary, that mayor may request the prefectural governor to carry out comprehensive coordination pursuant to the provisions of the preceding paragraph with regard to that mayor and other relevant organizations and associated parties. In this case, the prefectural governor must carry out comprehensive coordination pursuant to the provisions of that paragraph if deemed necessary.
- (3) In the case referred to in paragraph (1), the relevant organizations and associated parties may offer their opinions to the prefectural governor

concerning comprehensive coordination pursuant to the provisions of that paragraph.

- (4) When a prefectural governor finds it necessary to carry out comprehensive coordination pursuant to the provisions of paragraph (1), they may request the relevant organizations and associated parties to submit reports or materials on the implementation status of measures necessary to prevent an outbreak or the spread of an infectious disease affecting all or part of the area under the jurisdiction of the prefectural governor implemented by those organizations and parties.

(Instructions of a Prefectural Governor)

Article 63-4 When a prefectural governor finds it urgently necessary to prevent an outbreak or the spread of a novel and reemerging influenza or coronavirus infection, designated infectious disease, or new infectious disease during the period from the announcement of an outbreak or related event of that infection until the announcement or other official communication that it is no longer recognized as a novel and reemerging influenza or coronavirus infection, they may provide the mayor of a city or special ward with a public health center necessary instructions concerning the recommendation or measures for hospitalization pursuant to the provisions of Article 19, Article 20 (including cases where these provisions are applied *mutatis mutandis* pursuant to Article 26), or Article 46.

(Cities and Special Wards with a Public Health Center)

Article 64 (1) In the case of a city or special ward with a public health center, "prefectural governor" in the provisions of Chapter IV through Chapter VI (excluding Sections 1 and 2), Chapter VII through Chapter IX and Chapter X through the preceding Chapter (excluding Article 38, paragraphs (1), (2), (5) through (8), paragraphs (10) and (11) (excluding the part related to designated medical institutions for tuberculosis in the provisions of paragraphs (2), (10) and (11) of that Article), Article 40, paragraphs (3) through (5), Article 43 (excluding the part related to designated medical institutions for tuberculosis), Article 44-3, paragraph (11) (including cases where it is applied *mutatis mutandis* pursuant to Article 50-2, paragraph (4)), Article 44-3-5, Article 44-3-6, Article 44-4-2 and Article 44-4-3 (including cases where these provisions are applied *mutatis mutandis* pursuant to Article 44-8), Article 50-6, Article 50-7, Article 51-2, Article 51-3, Article 53-2, paragraph (3), Article 53-7, paragraph (1), Article 56-27, paragraph (7), and Article 60, paragraphs (1) through (3) (excluding the part related to agreements on examination and other measures)) and Article 63-2 is deemed to be "the mayor of a city or special ward with a public health center," and "prefectural government" is deemed to be "city or

special ward with a public health center."

- (2) In the cases of special wards, the term "municipal government(s)" in Article 31, paragraph (2) and Article 57 (limited to the part related to the provisions of item (iv)) is deemed to be replaced with "Tokyo Metropolis."

(Special Provisions for Large Cities)

Article 64-2 Beyond what is prescribed in Chapter III (excluding Article 12, paragraphs (2) and (3), Article 13, paragraphs (3) and (4), Article 14, paragraphs (1) and (6), Article 14-2, paragraphs (1) and (7), Article 15, paragraphs (13), and Article 16, paragraphs (2) and (3); the same applies in Article 65, paragraph (2)) and the preceding Article, in cases of the designated cities referred to in Article 252-19, paragraph (1) of the Local Autonomy Act (referred to below as "designated cities") and the core cities referred to in Article 252-22, paragraph (1) of that Act (referred to below as "core cities"), the affairs which prefectural governments are supposed to conduct under this Act (limited to those related to the prevention of tuberculosis) which are specified by Cabinet Order are to be conducted by the designated cities or core cities (referred to below as "designated and core cities") pursuant to the provisions of Cabinet Order. In this case, the provisions concerning prefectural governments in this Act are deemed the provisions concerning the designated and core cities, by which these cities are governed.

(Order of Statutory Liens)

Article 64-3 The statutory liens for the contributions to ensure early epidemic medical care and other money collected pursuant to the provisions of this Act are to be ranked next in priority to national taxes and local taxes.

(Statute of Limitations)

Article 64-4 (1) The right to collect or receive a refund of the contributions to ensure early epidemic medical care pursuant to the provisions of this Act and the right to receive expenses necessary for ensuring early epidemic medical care is to expire by statute of limitations when two years have elapsed from the time when they may be exercised.

- (2) A notification or demand for the collection of money collected pursuant to the provisions of this Act, such as the contributions to ensure early epidemic medical care, is to have the effect of renewal of the statute of limitations.

(Calculation of a Period of Time)

Article 64-5 The provisions of the Civil Code concerning the calculation of a period of time apply *mutatis mutandis* to the calculation of a period of time prescribed in this Act or orders based on this Act.

(Appeals)

Article 65 (1) If a person is dissatisfied with a determination regarding a request for administrative review concerning any disposition imposed by the mayor of a city or special ward with a public health center (limited to those related to Type I statutory entrusted functions) as part of the affairs prescribed in this Act, the person may file a request for re-examination with the Minister of Health, Labour and Welfare.

(2) If the authority to impose a disposition under the Type I statutory entrusted functions, which constitutes part of the affairs that the mayor of a city or special ward with a public health center is supposed to conduct pursuant to the provisions of Chapter III or Article 64, has been delegated to the officials serving as a subsidiary organ of that city or ward or to the head of an administrative organ under the control of that city or special ward, and if a determination referred to in Article 255-2, paragraph (2) of the Local Autonomy Act is made on a request for re-examination filed in connection with any disposition imposed by the officials or the head of the administrative organ based on the entrustment, the person dissatisfied with the determination may file a request for further examination or review with the Minister of Health, Labour and Welfare pursuant to the provisions of Article 252-17-4, paragraphs (5) through (7) of that Act.

(Classification of Administrative Affairs)

Article 65-2 The affairs which prefectural governments or cities and special wards with a public health center are supposed to conduct pursuant to the provisions of Chapter III (excluding Article 12, paragraph (8), paragraphs (2) and (3) of that Article as applied mutatis mutandis in paragraph (9) of that Article, paragraphs (2) and (3) of that Article as applied mutatis mutandis in paragraph (4) of that article which is applied mutatis mutandis in Article 12, paragraph (9), Article 14, Article 14-2, and Article 16), Chapter IV (excluding Article 18, paragraphs (5) and (6), Article 19, paragraphs (2) and (7), and Article 20, paragraphs (6) and (8) (including cases where they are applied mutatis mutandis in Article 26), Article 24, and Article 24-2 (including cases where it is applied mutatis mutandis in Article 26 or 49-2)), Article 26-3 (including cases where they are applied mutatis mutandis in Article 44-3-5, paragraph (6)), Article 26-4, Article 32, Article 33, Chapter VI, Section 1 (excluding Article 36-8, paragraph (4)), Article 36-19, paragraph (4) and Article 36-22 (including cases where these provisions are applied mutatis mutandis in Article 36-23, paragraph (4) and Article 36-24, paragraph (2)), Article 36-37, Article 38, paragraph (2) (limited to the part related to designated medical institutions for class I infectious diseases, designated medical institutions for

class I agreement, and designated medical institutions for class II agreement), paragraphs (5), (7) and (8), paragraphs (10) and (11) of the latter Article (limited to the part related to designated medical institutions for class I infectious diseases, designated medical institutions for class I agreement, and designated medical institutions for class II agreement), Article 44-3, paragraphs (1), (2), (4) through (6), and (11), Article 44-3-5, Article 44-3-6, Article 44-4-2 and Article 44-5, paragraph (4) (including cases where these provisions are applied mutatis mutandis in Article 44-8), Article 44-6, Chapter XIII (excluding Article 46, paragraphs (5) and (7), Article 50, paragraph (10), Article 36, paragraphs (1) and (2) as applied mutatis mutandis in Article 36, paragraph (5) which is applied mutatis mutandis in Article 50, paragraph (12), Article 44-3, paragraphs (7) through (10) as applied mutatis mutandis in Article 50-2, paragraph (4), Article 50-3, Article 50-4, Article 51, paragraph (1) as applied mutatis mutandis in paragraph (4) of that article, and Article 44-5, paragraph (3) as applied mutatis mutandis in Article 51-4, paragraph (2) and paragraph (3)), Chapter X, Article 63-3, paragraph (1), and Article 63-4, will be the Type I statutory entrusted functions.

(Delegation of Authority)

Article 65-3 (1) The authority of the Minister of Health, Labour and Welfare provided for in this Act may be delegated to the Director-General of a Regional Bureau of Health and Welfare pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(2) The authority delegated to the Director-General of a Regional Bureau of Health and Welfare pursuant to the provisions of the preceding paragraph may be further delegated to the Director-General of a Regional Branch Bureau of Health and Welfare pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Transitional Measures)

Article 66 If an order or ordinance is established, revised, or repealed based on the provisions of this Act, necessary transitional measures (including transitional measures on penal provisions) may be stipulated in the order or ordinance, within the limits reasonably deemed to be necessary in connection with that establishment, revision, or abolition.

Chapter XV Penal Provisions

Article 67 (1) A person who emits class I pathogens and toxins without good reason and, by doing so, endangers the public, will be punished by imprisonment for life or for not less than two years or by a fine of not more

than 10 million yen.

- (2) An attempt to commit the crime referred to in the preceding paragraph will be punished.
- (3) A person preparing with the intention of committing a crime referred to in paragraph (1) will be punished by imprisonment for not more than five years or by a fine of not more than 2.5 million yen; provided, however, that a person who turns themselves in for committing a crime referred to in that paragraph before its commencement may be given a reduced punishment or be granted an absolute discharge.

Article 68 (1) When a person has violated the provisions of Article 56-4, the person who has committed the violation is subject to punishment by imprisonment for not more than 10 years or by a fine of not more than five million yen.

- (2) A person committing a crime referred to in the preceding paragraph with the intention of facilitating the commission of a crime referred to in paragraph (1) of the preceding Article will be punished by imprisonment for not more than 15 years or by a fine of not more than seven million yen.
- (3) An attempt of any of the crimes stated in the preceding two paragraphs will be punished.
- (4) A person preparing with the intention of committing a crime referred to in paragraph (1) or (2) will be punished by imprisonment for not more than three years or by a fine of not more than two million yen.

Article 69 (1) When a person falls under either of the following items, the person who has committed the violation will be punished by imprisonment for not more than seven years or by a fine of not more than three million yen:

- (i) when possessing class I pathogens and toxins in violation of the provisions of Article 56-3; or
 - (ii) when transferring or receiving class I pathogens and toxins in violation of the provisions of Article 56-5.
- (2) A person committing a crime referred to in the preceding paragraph with the intention of facilitating the commission of a crime referred to in Article 67, paragraph (1) will be punished by imprisonment for not more than 10 years or by a fine of not more than five million yen.
 - (3) An attempt to commit any of the crimes stated in the preceding two paragraphs will be punished.

Article 70 When a person has imported class II pathogens and toxins without obtaining the permission under Article 56-12, paragraph (1), the person who has committed the violation will be punished by imprisonment for not more

than five years or by a fine of not more than 2.5 million yen.

Article 71 When a person falls under either of the following items, the person who has committed the violation will be punished by imprisonment for not more than three years or by a fine of not more than two million yen:

- (i) when possessing class II pathogens and toxins without obtaining the permission referred to in the main clause of Article 56-6, paragraph (1); or
- (ii) when transferring or receiving class II pathogens and toxins in violation of the provisions of Article 56-15.

Article 72 When a person falls under any of the following items, the person who has committed the violation will be punished by imprisonment for not more than one year or by a fine of not more than one million yen:

- (i) when changing any of the matters stated in Article 56-6, paragraph (2), items (ii) through (iv) without obtaining the approval referred to in the main clause of Article 56-11, paragraph (1);
- (ii) when a person changes any of the matters stated in Article 56-12, paragraph (2), items (ii) through (vii) in violation of the provisions of Article 56-11, paragraph (1) as applied mutatis mutandis pursuant to Article 56-14 following the deemed replacement of terms, without obtaining the approval referred to in the main clause of that paragraph;
- (iii) when a person violates the provisions of Article 56-19, paragraph (1);
- (iv) when a person violates the provisions of Article 56-22, paragraph (1);
- (v) when a person violates the provisions of Article 56-29, paragraph (1) or an order made under the provisions of Article 56-37;
- (vi) when a person fails to make a report under the provisions of Article 56-30 or makes a false report;
- (vii) when a person refuses, obstructs, or avoids an entry, inspection, or forcible collection under the provisions of Article 56-31, paragraph (1) or fails to answer or gives a false answer to any question in an interview under that paragraph; or
- (viii) when a person refuses, obstructs, or avoids any entry or inspection under the provisions of Article 56-38, paragraph (2) or fails to answer or gives a false answer to any question in an interview under that paragraph.

Article 73 (1) If a physician becomes aware of any secret of an individual while conducting a medical examination to ascertain whether or not the individual is a patient with an infectious disease (including a suspected disease carrier or asymptomatic carrier of the infectious disease, or a person with symptoms of a new infectious disease; the same applies below in paragraph (1) of Article 74) or providing medical treatment for that infectious disease and the physician

divulges that secret without reasonable grounds, the physician will be punished by imprisonment for not more than one year or by a fine of not more than one million yen.

- (2) The provisions of the preceding paragraph also apply when a government employee or former government employee who was engaged in the affairs concerning any of the following matters divulges, without reasonable grounds, a secret of any individual which they became aware of while executing their duties for those affairs: acceptance of a notification under the provisions of Articles 12 through 14 (including cases where they are applied *mutatis mutandis* pursuant to a Cabinet Order based on the provisions of Article 44-9, paragraph (1) (including cases where the period specified by Cabinet Order as referred to in paragraph (1) of that Article is extended pursuant to a Cabinet Order referred to in paragraph (2) of that Article; the same applies below) and the cases where they are applied pursuant to a Cabinet Order based on the provisions of Article 53, paragraph (1) (including cases where the period specified by Cabinet Order as referred to in paragraph (1) of that Article is extended pursuant to a Cabinet Order referred to in paragraph (2) of that Article; the same applies below)); receipt of the specimens or pathogens of an infectious disease under the provisions of Article 14-2, paragraph (2) (including cases where it is applied *mutatis mutandis* pursuant to a Cabinet Order based on the provisions of Article 44-9, paragraph (1) or applied pursuant to a Cabinet Order based on the provisions of Article 53, paragraph (1)); examination of the specimens or pathogens of an infectious disease under the provisions of Article 14-2, paragraph (3) (including cases where it is applied *mutatis mutandis* pursuant to a Cabinet Order based on the provisions of Article 44-9, paragraph (1) or applied pursuant to a Cabinet Order based on the provisions of Article 53, paragraph (1)), or under the provisions of Article 26-3, paragraph (5) (including cases where it is applied *mutatis mutandis* pursuant to a Cabinet Order based on the provisions of Article 44-9, paragraph (1), or applied *mutatis mutandis* in Article 50, paragraph (2), or applied pursuant to a Cabinet Order based on the provisions of Article 53, paragraph (1)); interviews or investigations under the provisions of Article 15 (including cases where it is applied *mutatis mutandis* pursuant to a Cabinet Order based on the provisions of Article 44-9, paragraph (1) or applied pursuant to a Cabinet Order based on the provisions of Article 53, paragraph (1)), under the provisions of Article 15-2, paragraph (1), or under the provisions of Article 15-3, paragraph (2) (including cases where they are applied with the replacement of terms pursuant to the provisions of paragraph (7) of that Article), or reporting or interviewing under the provisions of paragraph (1) of that Article; receipt or collection of specimens under the provisions of Article 16-3, paragraph (1) or (2) (including cases where they are applied *mutatis mutandis* pursuant to a

Cabinet Order based on the provisions of Article 44-9, paragraph (1) or applied pursuant to a Cabinet Order based on the provisions of Article 53, paragraph (1)) or under the provisions of Article 44-11, paragraph (1) or (2); collection of specimens under the provisions of Article 16-3, paragraph (3) or (4) (including cases where they are applied mutatis mutandis pursuant to a Cabinet Order based on the provisions of Article 44-9, paragraph (1) or applied pursuant to a Cabinet Order based on the provisions of Article 53, paragraph (1)) or under the provisions of Article 44-11, paragraph (3) or (4); examination of specimens under the provisions of Article 16-3, paragraph (7) (including cases where it is applied mutatis mutandis pursuant to a Cabinet Order based on the provisions of Article 44-9, paragraph (1) or applied pursuant to a Cabinet Order based on the provisions of Article 53, paragraph (1)), under the provisions of Article 26-4, paragraph (5) (including cases where it is applied mutatis mutandis pursuant to a Cabinet Order based on the provisions of Article 44-9, paragraph (1), or applied mutatis mutandis in Article 50, paragraph (3), or applied pursuant to a Cabinet Order based on the provisions of Article 53, paragraph (1)), or under the provisions of Article 44-11, paragraph (5); medical examinations under the provisions of Article 17 (including cases where it is applied mutatis mutandis pursuant to a Cabinet Order based on the provisions of Article 44-9, paragraph (1) or applied pursuant to a Cabinet Order based on the provisions of Article 53, paragraph (1)), Article 45, or Article 53-2; hospitalization under the provisions of Article 19 or 20 as applied mutatis mutandis in Article 19, 20 or 26 (including cases where they are applied mutatis mutandis pursuant to a Cabinet Order based on the provisions of Article 44-9, paragraph (1) or applied pursuant to a Cabinet Order based on the provisions of Article 53, paragraph (1)) or under the provisions of Article 46; receipt of the specimens or pathogens of an infectious disease under the provisions of Article 26-3, paragraph (1) (including cases where they are applied mutatis mutandis in Article 44-3-5, paragraph (6) or Article 50-6, paragraph (6)) or (2) (including cases where they are applied mutatis mutandis pursuant to a Cabinet Order based on the provisions of Article 44-9, paragraph (1) or applied pursuant to a Cabinet Order based on the provisions of Article 53, paragraph (1)), including cases where that receipt is performed pursuant to the provisions of Article 50, paragraph (1) or (7); forcible collection of the specimens or pathogens of an infectious disease under the provisions of Article 26-3, paragraph (3) (including cases where they are applied mutatis mutandis in Article 44-3-5, paragraph (6) and Article 50-6, paragraph (6)) or (4) (including cases where they are applied mutatis mutandis pursuant to a Cabinet Order based on the provisions of Article 44-9, paragraph (1) or applied pursuant to a Cabinet Order based on the provisions of Article 53, paragraph (1)), including cases where that forcible collection is performed pursuant to the provisions of Article 50, paragraph (1)

or (7); receipt or collection of specimens under the provisions of Article 26-4, paragraph (1) or (2) (including cases where they are applied mutatis mutandis pursuant to a Cabinet Order based on the provisions of Article 44-9, paragraph (1) or applied pursuant to a Cabinet Order based on the provisions of Article 53, paragraph (1)), including cases where that receipt or collection is performed pursuant to the provisions of Article 50, paragraph (1) or (7); collection of specimens under the provisions of Article 26-4, paragraph (3) or (4) (including cases where they are applied mutatis mutandis pursuant to a Cabinet Order based on the provisions of Article 44-9, paragraph (1) or applied pursuant to a Cabinet Order based on the provisions of Article 53, paragraph (1)), including cases where that collection is performed pursuant to the provisions of Article 50, paragraph (1) or (7); measures (including cases where they are implemented based on the provisions of Article 50, paragraph (1), (7) or (10)) prescribed under the provisions of Article 27 (including cases where it is applied mutatis mutandis pursuant to a Cabinet Order based on the provisions of Article 44-9, paragraph (1), and cases where it is applied pursuant to a Cabinet Order under the provisions of Article 53, paragraph (1)), Article 28 (including cases where it is applied pursuant to a Cabinet Order based on the provisions of Article 44-4, paragraph (1) (including cases where the period of the Cabinet Order under the provisions of paragraph (1) of that Article is extended by the Cabinet Order under the provisions of paragraph (2) of that Article; the same applies below in this paragraph and Article 77, paragraph (1)), cases where it is applied mutatis mutandis pursuant to a Cabinet Order based on the provisions of Article 44-9, paragraph (1), and cases where it is applied pursuant to a Cabinet Order based on the provisions of Article 53, paragraph (1), Article 29 or 30 (including cases where it is applied mutatis mutandis pursuant to a Cabinet Order under the provisions of Article 44-9, paragraph (1), and cases where it is applied pursuant to a Cabinet Order under the provisions of Article 53, paragraph (1)), or Articles 31 through 33, or Article 35 (including cases where it is applied pursuant to a Cabinet Order under the provisions of Article 44-4, paragraph (1), cases where it is applied pursuant to a Cabinet Order under the provisions of Article 44-9, paragraph (1), and cases where it is applied pursuant to a Cabinet Order under the provisions of Article 53, paragraph (1)); requests for reports or cooperation under the provisions of Article 44-3, paragraph (1) or paragraph (2) (including cases where they are applied mutatis mutandis pursuant to a Cabinet Order based on Article 44-9, paragraph (1) or under the provisions of Article 50-2, paragraph (1) or paragraph (2); provisions of meals, etc. under the provisions of Article 44-3, paragraph (7) or (8) (including cases where they are applied mutatis mutandis pursuant to a Cabinet Order based on the provisions of Article 44-9, paragraph (1)), or under the provisions of Article 50-2, paragraph

(4)); cooperation of the mayor of a municipality under the provisions of Article 44-3, paragraph (9) (including cases where they are applied mutatis mutandis pursuant to a Cabinet Order based on the provisions of Article 44-9, paragraph (1), and cases where they are applied mutatis mutandis pursuant to Article 50-2, paragraph (4)); acceptance of specimens or pathogens under the provisions of Article 44-3-5, paragraph (3) or paragraph (5) (including cases where they are applied mutatis mutandis pursuant to a Cabinet Order based on the provisions of 44-9, paragraph (1)), or under the provisions of Article 50-6, paragraph (3) or paragraph (5); implementation of the examination prescribed under the provisions of Article 44-3-5, paragraph (4) (including cases where it is applied mutatis mutandis pursuant to a Cabinet Order based on the provisions of Article 44-9, paragraph (1)), or under the provisions of Article 50-6, paragraph (4); acceptance of notifications under the provisions of Article 44-3-6 (including cases where it is applied mutatis mutandis pursuant to a Cabinet Order based on the provisions of Article 44-9, paragraph (1)), or under the provisions of Article 50-7; or detailed examination under the provisions of Article 53-13.

(3) The provisions of paragraph (1) also apply when any other government employee or former government employee divulges, without reasonable grounds, any secret referred to in the preceding paragraph which they became aware of while executing their duties for relevant affairs.

Article 73-2 When a person (if the person is a juridical person, an officer) who has been entrusted with a request for a report pursuant to the provisions of Article 44-3, paragraphs (1) or (2) (including cases where these provisions are applied mutatis mutandis by Cabinet Order pursuant to the provisions of Article 44-9, paragraph (1)) or Article 50-2, paragraphs (1) or (2) pursuant to the provisions of Article 44-3, paragraphs (4) or (5) (including cases where these provisions are applied mutatis mutandis by Cabinet Order pursuant to the provisions of Article 44-9, paragraph (1) and cases where they are applied mutatis mutandis pursuant to Article 50-2, paragraph (4)), or an officer or a person who was that person has divulged, without reasonable grounds, any confidential information of any person they have become aware of in relation to the affairs related to the entrustment, they are to be punished by imprisonment for not more than one year or a fine of not more than one million yen.

Article 73-3 A person falling under any of the following items will be punished by imprisonment for not more than one year, a fine of not more than 500,000 yen, or both:

- (i) when a person informs others of the anonymous infectious disease-related information that was learned through the use of anonymous information on

infectious diseases or uses it for an unreasonable purpose or in violation of the provisions of Article 56-45,;

(ii) when a person violates an order made under the provisions of Article 56-47.

Article 74 (1) If, while executing their duties, a person becomes aware that a certain individual is a patient with an infectious disease and the person divulges that secret without reasonable grounds, the person will be punished by imprisonment for not more than six months or by a fine of not more than 500 thousand yen.

(2) A person failing to make a report under the provisions of Article 15-3, paragraph (1), making a false report, or failing to answer or giving a false answer to any question in an interview conducted by the official under the provisions of that paragraph will be punished by imprisonment for not more than six months or by a fine of not more than 500 thousand yen.

Article 75 When a person falls under any of the following items, the person who has committed the violation will be punished by a fine of not more than three million yen:

(i) when violating any condition referred to in Article 56-9, paragraph (1) (including cases where it is applied mutatis mutandis in Article 56-11, paragraph (4) or Article 56-14);

(ii) when failing to submit a notification under the provisions of the main clause of Article 56-16, paragraph (1) or the provisions of Article 56-17 or submitting a false notification;

(iii) when failing to submit a notification under the provisions of Article 56-22, paragraph (2) or submitting a false notification;

(iv) when violating the provisions of Article 56-24 (limited to the part related to holders of specified class I pathogens and toxins or permitted holder of class II pathogens and toxins);

(v) when failing to submit a notification under the provisions of Article 56-27, paragraph (1) or submitting a false notification, and transporting class I pathogens and toxins, class II pathogens and toxins, or class III pathogens and toxins;

(vi) when violating the provisions of Article 56-27, paragraph (4);

(vii) when violating an order made under the provisions of Article 56-32; or

(viii) when violating an order made under the provisions of Article 56-36.

Article 76 When a person falls under any of the following items, the person who has committed the violation will be punished by a fine of not more than one million yen:

(i) when failing to submit a notification under the provisions of Article 56-11,

- paragraph (2) (including cases where it is applied mutatis mutandis in Article 56-14) or submitting a false notification, and making a change prescribed in the proviso of Article 56-11, paragraph (1);
- (ii) when failing to submit a notification under the provisions of Article 56-16, paragraph (2), Article 56-28, or Article 56-29, paragraph (3) or submitting a false notification;
 - (iii) when violating the provisions of Article 56-21;
 - (iv) when failing to keep the books or make entries in the books or making false entries in the books in violation of the provisions of Article 56-23, paragraph (1) or failing to retain the books in violation of the provisions of paragraph (2) of that Article; or
 - (v) when failing to follow an order to stop, refusing a request for presentation, refusing or obstructing an inspection, or failing to follow an order, as demanded by a police officer under the provisions of Article 56-27, paragraph (5).

Article 77 (1) When a person falls under any of the following items, the person who has committed the violation will be punished by a fine of not more than 500 thousand yen:

- (i) when a physician fails to submit a notification under the provisions of Article 12, paragraph (1) or (8) or the provisions of paragraph (1) of that Article as applied mutatis mutandis in paragraph (10) of that Article (including cases where they are applied mutatis mutandis pursuant to a Cabinet Order based on the provisions of Article 44-9, paragraph (1)), excluding the notifications related to a new infectious disease;
- (ii) when a veterinarian fails to submit a notification under the provisions of Article 13, paragraph (1) or the provisions of paragraph (1) of that Article as applied mutatis mutandis in paragraph (7) of that Article (including cases where these provisions are applied mutatis mutandis pursuant to a Cabinet Order based on the provisions of Article 44-9, paragraph (1));
- (iii) when failing to answer or giving a false answer to any question in an interview conducted by the officials under the provisions of Article 15-2, paragraph (1) or Article 15-3, paragraph (2) (including cases where these provisions are applied by replacing terms pursuant to the provisions of paragraph (7) of that Article), or refusing, obstructing, or avoiding any inspection by the officials under those provisions;
- (iv) when receiving a notice under the provisions of Article 18, paragraph (1) (including cases where it is applied mutatis mutandis pursuant to a Cabinet Order based on the provisions of Article 44-9, paragraph (1) or applied pursuant to a Cabinet Order based on the provisions of Article 53, paragraph (1)) and violating the provisions of Article 18, paragraph (2) (including cases

- where it is applied mutatis mutandis pursuant to a Cabinet Order based on the provisions of Article 44-9, paragraph (1) or applied pursuant to a Cabinet Order based on the provisions of Article 53, paragraph (1));
- (v) when failing to follow an order made by a prefectural governor (or the mayor of a city or special ward with a public health center) (including cases where it is issued pursuant to the provisions of Article 50, paragraph (1)) based on the provisions of Article 27, paragraph (1) (including cases where it is applied mutatis mutandis pursuant to a Cabinet Order based on the provisions of Article 44-9, paragraph (1) or applied pursuant to a Cabinet Order based on the provisions of Article 53, paragraph (1)), based on the provisions of Article 28, paragraph (1) (including cases where it is applied pursuant to a Cabinet Order based on the provisions of Article 44-4, paragraph (1), or applied mutatis mutandis pursuant to a Cabinet Order based on the provisions of Article 44-9, paragraph (1), or applied pursuant to a Cabinet Order based on the provisions of Article 53, paragraph (1)), based on the provisions of Article 29, paragraph (1) or Article 30, paragraph (1) (including cases where they are applied mutatis mutandis pursuant to a Cabinet Order based on the provisions of Article 44-9, paragraph (1) or applied pursuant to a Cabinet Order based on the provisions of Article 53, paragraph (1)), or based on the provisions of Article 31, paragraph (1), Article 32, paragraph (1), or Article 33 (including cases where they are applied pursuant to a Cabinet Order based on the provisions of Article 44-4, paragraph (1), or applied mutatis mutandis pursuant to a Cabinet Order based on the provisions of Article 44-9, paragraph (1), or applied pursuant to a Cabinet Order based on the provisions of Article 53, paragraph (1));
- (vi) when violating the provisions of Article 30, paragraph (2) which is enforced pursuant to the provisions of Article 30, paragraph (2) (including cases where it is applied mutatis mutandis pursuant to a Cabinet Order based on the provisions of Article 44-9, paragraph (1) or applied pursuant to a Cabinet Order based on the provisions of Article 53, paragraph (1)) or pursuant to the provisions of Article 50, paragraph (1);
- (vii) when failing to answer or giving a false answer in an interview conducted by the officials under the provisions of Article 35, paragraph (1) (including cases where it is applied pursuant to a Cabinet Order based on the provisions of Article 44-9, paragraph (1), or applied mutatis mutandis pursuant to a Cabinet Order based on the provisions of Article 44-9, paragraph (1), or applied pursuant to a Cabinet Order based on the provisions of Article 53, paragraph (1)) or under the provisions of Article 35, paragraph (1) which is enforced pursuant to the provisions of Article 50, paragraph (1), (7), or (10), or refusing, obstructing or avoiding any inspection by the officials under the provisions of Article 35, paragraph (1) (including

- cases where it is applied pursuant to a Cabinet Order based on the provisions of Article 44-4, paragraph (1), or applied mutatis mutandis pursuant to a Cabinet Order based on the provisions of Article 44-9, paragraph (1), or applied pursuant to a Cabinet Order based on the provisions of Article 53, paragraph (1) or under the provisions of Article 35, paragraph (1) which is enforced pursuant to the provisions of Article 50, paragraph (1), (7), or (10);
- (viii) when failing to make a report under the provisions of Article 36-22, paragraph (1) (including when applied mutatis mutandis pursuant to Article 36-23, paragraph (4) and Article 36-24, paragraph (2)), or making a false report or refusing, obstructing, or evading an inspection under these provisions;
- (ix) when failing to make a report or submit documents or other items under the provisions of Article 36-27, or making a false report or submitting a false item;
- (x) when failing to make a report under the provisions of Article 53-23, paragraph (1), or making a false report or refusing, obstructing, or evading an inspection under the provisions of that paragraph;
- (xi) when importing designated animals in violation of the provisions of Article 54 or Article 55, paragraph (1), (2), or (4) (including cases where they are applied mutatis mutandis pursuant to a Cabinet Order based on the provisions of Article 44-9, paragraph (1) or applied pursuant to a Cabinet Order based on the provisions of Article 53, paragraph (1));
- (xii) when importing notifiable animals or the like in violation of the provisions of Article 56-2, paragraph (1); or
- (xiii) when failing to submit or present a report or books and documents pursuant to the provisions of Article 56-46, paragraph (1), making a false report or submitting or presenting false books and documents, failing to answer questions pursuant to the provisions of that paragraph or giving a false answer in an interview, or refusing, obstructing, or avoiding the entry and inspection pursuant to the provisions of the paragraph.
- (2) When an officer or employee of the Reimbursement Services or a trustee has failed to make a report under the provisions of Article 36-37, paragraph (1) or has made a false report, or has refused, obstructed, or challenged an inspection pursuant to the provisions of that paragraph, they are to be punished by a fine of not more than 500 thousand yen.

Article 77-2 When failing to submit a notification under the provisions of Article 53-16, paragraph (3) (including cases where it is applied mutatis mutandis pursuant to Article 53-18, paragraph (2) following the deemed replacement of terms), a person who has committed the violation will be punished by a fine of

not more than 200 thousand yen.

Article 78 The crimes referred to in Article 67 are governed by Article 4-2 of the Penal Code (Act No. 45 of 1907).

Article 78-2 The crimes referred to in Article 73-3 will also apply to a person who has committed the crimes stated in that Article outside Japan.

Article 79 (1) If the representative of a corporation (including an association or foundation that is not a juridical person and for which a representative person or administrator has been specified (referred to below as an "association or foundation without juridical personality" in this Article); the same applies below in this Article) (including an administrator of an association or foundation without juridical personality), or an agent, employee, or another staff member of a corporation or an individual commits a crime referred to in Article 67 or commits a violation referred to in Articles 68 through 72, Article 73-3, Article 75, Article 76, Article 77, paragraph (1), items (x) through (xiii) or Article 77-2 in connection with the services performed by the corporation or individual, the offender will be punished, and also the corporation or individual in question will be punished by a fine referred to in the respective provision.

(2) Where the provisions of the preceding paragraph apply to an association or foundation without juridical personality, the representative or administrator of the association or foundation without juridical personality is to represent the association or foundation without juridical personality in its procedural acts, and the provisions of an act concerning the criminal procedure when a juridical person is the accused or a suspect are to apply *mutatis mutandis*.

Article 80 When a person hospitalized due to a hospitalization recommendation pursuant to the provisions of Article 19, paragraph (1), Article 20, paragraph (1), or Article 19, paragraph (1) as applied *mutatis mutandis* in Article 26, or Article 20, paragraph (1) (including cases where these provisions are applied *mutatis mutandis* by Cabinet Order pursuant to the provisions of Article 44-9, paragraph (1) and cases where they are applied by Cabinet Order pursuant to the provisions of Article 53, paragraph (1); the same applies below in this Article), or Article 46, paragraph (1), or due to hospitalization measures pursuant to the provisions of Article 19, paragraphs (3) or (5), Article 20, paragraphs (2) or (3), or Article 19, paragraphs (3) or (5) as applied *mutatis mutandis* in Article 26, or Article 20, paragraphs (2) or (3) (including cases where these provisions are applied *mutatis mutandis* by Cabinet Order pursuant to the provisions of Article 44-9, paragraph (1) and cases where they are applied by Cabinet Order pursuant to the provisions of Article 53,

paragraph (1)), or Article 46, paragraphs (2) or (3), escapes during the period of hospitalization (including the period extended pursuant to the provisions of Article 20, paragraph (4), or that paragraph as applied mutatis mutandis in Article 26 (including cases where these provisions are applied mutatis mutandis by Cabinet Order pursuant to the provisions of Article 44-9, paragraph (1) and cases where they are applied by Cabinet Order pursuant to the provisions of Article 53, paragraph (1)), or Article 46, paragraph (4)), or the person to be hospitalized (limited to those who have received a notice under the provisions of Article 23, Article 23 as applied mutatis mutandis pursuant to Article 26 (including cases where these provisions are applied mutatis mutandis by Cabinet Order pursuant to the provisions of Article 44-9, paragraph (1) and cases where they are applied by Cabinet Order pursuant to the provisions of Article 53, paragraph (1)), or Article 16-3, paragraph (5) as applied mutatis mutandis pursuant to Article 49) pursuant to the provisions of Article 19, paragraphs (3) or (5), Article 20, paragraphs (2) or (3), or Article 19, paragraphs (3) or (5) as applied mutatis mutandis in Article 26, or Article 20, paragraphs (2) or (3), or Article 46, paragraphs (2) or (3) has, without reasonable grounds, not been hospitalized by the beginning of the period during which they are to be hospitalized, the person is to be punished by a civil fine of not more 500 thousand yen.

Article 81 When a person who has received an order pursuant to the provisions of Article 15, paragraph (8) (including cases where it is applied mutatis mutandis by a Cabinet Order pursuant to the provisions of Article 44-9, paragraph (1) and cases where it is applied by a Cabinet Order pursuant to the provisions of Article 53, paragraph (1)) fails, without reasonable grounds, to answer the questions in an interview conducted by the official pursuant to the provisions of Article 15, paragraphs (1) or (2) (including cases where these provisions are applied mutatis mutandis by a Cabinet Order pursuant to the provisions of Article 44-9, paragraph (1) and cases where they are applied by a Cabinet Order pursuant to the provisions of Article 53, paragraph (1)) or gives a false answer, or refuses, obstructs, or avoids the survey (excluding a request pursuant to the provisions of Article 15, paragraph (3) (including cases where it is applied mutatis mutandis pursuant to paragraph (6) of that Article, cases where it is applied mutatis mutandis pursuant to a Cabinet Order pursuant to the provisions of Article 44-9, paragraph (1), and cases where it is applied by a Cabinet Order pursuant to the provisions of Article 53, paragraph (1))) by the official pursuant to these provisions without reasonable grounds, they are to be punished by a civil fine of not more than 300 thousand yen.

Article 82 When an officer falls under any of the following items, the officer from

the Reimbursement Services who has committed the violation will be punished by a civil fine of not more than 200,000 yen:

- (i) when a person is required to obtain the authorization or approval of the Minister of Health, Labour and Welfare pursuant to the provisions of this Act fails to obtain that authorization or approval; and
- (ii) when a person invests surplus funds in the course of operations in violation of the provisions of Article 36-34.

Article 83 A person falling under any of the following items will be punished by a non-criminal fine of not more than 100 thousand yen:

- (i) a person violating the provisions of Article 56-18, paragraph (1);
- (ii) a person failing to submit a notification under the provisions of Article 56-19, paragraph (2); or
- (iii) a person violating an order made under the provisions of Article 56-33.

Article 84 A person falling under either of the following items will be punished by a non-criminal fine of not more than 50 thousand yen:

- (i) a person failing to submit a notification under the provisions of Article 56-11, paragraph (3) (including cases where it is applied mutatis mutandis pursuant to Article 56-14 following the deemed replacement of terms); or
- (ii) a person failing to submit a notification under the provisions of Article 56-18, paragraph (2).