

# **Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (Tentative translation)**

(Act No. 114 of October 2, 1998)

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Supplementary Provisions

Mankind has over time experienced hardship 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 mankind.

Advances in medical science and medical care and considerable improvement of sanitation have enabled people to overcome a variety of infectious diseases. However, infectious diseases still remain a threat to humankind in new forms, through the emergence of undiscovered infectious diseases, through the resurgence of known infectious diseases, or with the development of international interpersonal exchanges.

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

In light of such changing circumstances surrounding infectious diseases and the situation surrounding patients of infectious diseases and other persons placed in similar situations, it is desirable to ensure high-quality and appropriate medical care for such persons and to promptly and appropriately address infectious diseases, while respecting their human rights.

From this standpoint, this Act is established to fundamentally overhaul conventional measures concerning the prevention of infectious diseases and to promote integrated measures concerning the prevention of 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 concerning the prevention of infectious diseases and medical care for patients with infectious diseases in order to prevent outbreaks and the spreading of infectious diseases, and thereby to improve and promote public health.

### **(Basic Principles)**

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

purpose of preventing the outbreak or spread of any infectious diseases are to be promoted in an integrated and systematic manner through gaining an in-depth understanding of the circumstances surrounding patients with infectious diseases and other persons in a similar situation, and giving full respect to the human rights of those persons, so that those governments can address new infectious diseases or other infectious diseases promptly and adequately by instantly coping with changing circumstances surrounding health and medical care and the development of international exchange, while taking into account international trends in relation to measures implemented for the same purpose.

(Responsibilities of 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 of examination of pathogens, etc., and educate personnel engaged in the prevention of infectious diseases and improve their professional qualities, while endeavoring to implement necessary measures to enable patients with infectious diseases to receive high-quality and appropriate 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 placed in similar circumstances.
- (2) The national and local governments must mutually coordinate and pay due regard to regional characteristics in order that 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, etc. and to promote research and development of medicines, ensure the stable supply of the referenced medicines for the medical care of infectious diseases, and facilitate the examination of pathogens, etc. for medical care for infectious diseases, and to ensure international coordination, while endeavoring to offer 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 give due regard so as not to infringe on the human rights of patients with infectious diseases and other persons placed in similar circumstances.

(Responsibilities of Physicians)

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

(2) Establishers and administrators of hospitals, clinics, organizations engaged in the examination of pathogens, etc., welfare facilities for the elderly, or other similar facilities must implement necessary measures to prevent any outbreak 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 for the prevention of infectious diseases and endeavor to contribute to the prevention of infectious diseases.

(2) Operators of businesses handling animals or the like (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 or places where a large, non-specific group of persons visit) must endeavor to acquire the knowledge and skills for the prevention of infectious diseases, appropriately handle animals or animal corpses, and implement other necessary measures so as not to transmit 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 a Class I Infectious Disease, a Class II Infectious Disease, a Class III Infectious Disease, a Class IV Infectious Disease, a Class V Infectious Disease, a Novel Influenza Infection, etc., a Designated Infectious Disease, or 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 involving SARS coronavirus within the genus Betacoronavirus as a pathogen);
  - (v) Middle East respiratory syndrome (limited to the one involving MERS coronavirus within the genus Betacoronavirus as a pathogen); and
  - (vi) avian influenza (limited to the one involving any influenza A virus within the genus Influenzavirus A as a pathogen and involving a serosubtype which is specified by Cabinet Order as being highly likely to mutate into a pathogen of a Novel Influenza Infection, etc. (excluding novel coronavirus infections listed in paragraph (7), item (iii) and reemerging coronavirus infections listed in item (iv) of the same paragraph. The same applies in paragraph (6), item (i) and paragraph (25), item (i).) (hereinafter referred to 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 set forth in the preceding items, any known Infectious Diseases specified by Cabinet Order as a disease which is transmissible to

human beings through animals or animal corpses, food or drink, clothing, bedding, or other physical items and which are likely to affect the health of citizens as seriously as the diseases set forth 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 Influenza Infection, etc.);
  - (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 set forth 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 the health of citizens as seriously as the diseases set forth in the preceding items.
- (7) The term "Novel Influenza Infection, etc." as used in this Act means either of the following Infectious Diseases:
- (i) novel influenza (meaning a type of influenza which involves a virus newly becoming transmissible from person to person as a pathogen and which is deemed to be likely to seriously affect the lives and health of the public in the event of its rapid spread across the country because the public are not immunized against this Infectious Disease in general);
  - (ii) reemerging influenza (meaning a type of influenza specified by the Minister of Health, Labour and Welfare as that which once caused a global pandemic but for which a long period of time has passed since the most recent global pandemic, and which is deemed to be likely to seriously affect the lives and health of the public in the event of its rapid spread across the country because a large majority of the existing public are not immunized against this Infectious Disease in general).
  - (iii) novel coronavirus disease (meaning a type of disease which involves a coronavirus newly becoming transmissible from person to person as a pathogen and which is deemed to be likely to seriously affect the lives and health of the public in the event of its rapid spread across the country because the public are not immunized against this Infectious Disease in general); and
  - (iv) reemerging coronavirus disease (meaning a type of Infectious Disease specified by the Minister of Health, Labour and Welfare as that which once caused a global pandemic but for which a long period of time has passed

since the most recent global pandemic, and which is deemed to be likely to seriously affect the lives and health of the public in the event of its rapid spread across the country because a large majority of the existing public are not immunized against this Infectious Disease in general).

- (8) The term "Designated Infectious Disease" as used in this Act means an already-known Infectious Disease (excluding Class I Infectious Diseases, Class II Infectious Diseases, Class III Infectious Diseases, and Novel Influenza Infection, etc.) specified by Cabinet Order as a disease which would be likely to seriously affect the health of the public in the event of its spread if the provisions of Chapters III to 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 deemed to be transmittable from person to person, which involves pathological conditions or therapeutic outcomes apparently different from those of any already known Infectious Disease, and which could cause a serious condition if developing the disease, and which is deemed to be likely to seriously affect the lives and health of the public in the event of the spread of the disease.
- (10) The term "Suspected Disease Carrier" as used in this Act means a person who is suspected to have contracted an Infectious Disease in light of 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 who 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 of a Class I Infectious Disease, a Class II Infectious Disease or a Novel Influenza Infection, etc.
- (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 of a Class I Infectious Disease, a Class II Infectious Disease or a Novel Influenza Infection, etc.

- (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 Influenza Infection, etc.
- (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 Influenza Infection, etc. or a Designated Infectious Disease, or a person with symptoms of a New Infectious Disease based on the notification pursuant to the provisions of Article 36-2, paragraph (1) (limited to the notification that includes the measures listed in item (i) of the same paragraph) or the medical care agreement prescribed in Article 36-3, paragraph (1) (limited to a medical care agreement that include the measures set forth in the same 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 equivalent thereto; 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 the notification pursuant to the provisions of Article 36-2, paragraph (1) (limited to the notification that includes the measures listed in items (ii) or (iii) of the same paragraph) or the medical care agreement pursuant to Article 36-3, paragraph (1) (limited to those 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 the 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, etc." as used in this Act means a pathogen or Toxin of any Infectious Disease.
- (20) The term "Toxin" as used in this Act means a substance which is produced by a pathogen of an Infectious Disease and which is capable of causing the onset of disease or death if entering the human body, including substances such as those artificially synthesized and representing a structural formula identical to that of a certain natural toxin (hereinafter referred to as a "Synthetic Toxin").

- (21) The term "Specified Pathogens, etc." as used in this Act means Class I Pathogens, etc., Class II Pathogens, etc., Class III Pathogens, etc., and Class IV Pathogens, etc.
- (22) The term "Class I Pathogens, etc." as used in this Act means the Pathogens, etc. set forth below (excluding Pathogens, etc. 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 Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics (Act No. 145 of 1960) or certified under the provisions of Article 23-2-23, paragraph (1) of the same Act or other Pathogens, etc. equivalent thereto (hereinafter referred to as "Medicines or Other Substances") which are designated by the Minister of Health, Labour and Welfare as substances highly unlikely to cause the development of a disease in humans):
- (i) Guanarito virus, Sabia virus, Junin virus, Machupo virus, and Lassa virus, within the genus Arenavirus;
  - (ii) Ivory Coast ebolavirus, Zair ebolavirus, Sudan ebolavirus, and Reston ebolavirus, within the genus Ebolavirus;
  - (iii) variola virus (also known as smallpox virus), within the genus Orthopoxvirus;
  - (iv) Crimean-Congo haemorrhagic fever virus, within the genus Nairovirus;
  - (v) Lake Victoria marburgvirus, within the genus Marburgvirus;
  - (vi) beyond what is set forth in the preceding items, the Pathogens, etc. specified by Cabinet Order as being pathogenic to the same degree as the substances set forth in the preceding items and being likely to have extremely serious effects on the lives and health of the public.
- (23) The term "Class II Pathogens, etc." as used in this Act means the Pathogens, etc. set forth below (excluding the Medicines or Other Substances designated by the Minister of Health, Labour and Welfare as substances highly unlikely to cause the development of a disease in humans):
- (i) *Y. pestis* (also known as plague bacillus), within the genus *Yersinia*;
  - (ii) *C. botulinum* (also known as *Bacillus botulinus*), within the genus *Clostridium*;
  - (iii) SARS coronavirus, within the genus Betacoronavirus;
  - (iv) *B. anthracis* (also known as *Bacillus anthracis*), within the genus *Bacillus*;
  - (v) *F. tularensis* subsp. *holarctica*, within the genus *Francisella*;
  - (vi) botulinum toxin (including Synthetic Toxins representing a structural formula identical to that of botulinum toxin);
  - (vii) beyond what is set forth in the preceding items, the Pathogens, etc. specified by Cabinet Order as being pathogenic to the same degree as the substances set forth in the preceding items and being likely to seriously

affect the lives and health of the public.

(24) The term "Class III Pathogens, etc." as used in this Act means the Pathogens, etc. set forth below (excluding the Medicines or Other Substances designated by the Minister of Health, Labour and Welfare as substances highly unlikely to cause the development of a disease in humans):

- (i) *C. burnetii*, within the genus *Coxiella*;
- (ii) *M. tuberculosis* (also known as tubercle bacillus), within the genus *Mycobacterium* (limited to such substances that have resistance 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 genus *Lyssavirus*;
- (iv) beyond what is set forth in the preceding three items, the Pathogens, etc. specified by Cabinet Order as being pathogenic to the same degree as the substances set forth in the preceding three items and being likely to affect the lives and health of the public.

(25) The term "Class IV Pathogens, etc." as used in this Act means the Pathogens, etc. set forth below (excluding the Medicines or Other Substances designated by the Minister of Health, Labour and Welfare as substances highly unlikely to cause the development of a disease in humans):

- (i) influenza A viruses, within the genus *Influenzavirus A* (limited to those involving a serosubtype specified by Cabinet Order (excluding pathogens of a Novel Influenza Infection, etc.) or any pathogen of a Novel Influenza Infection, etc.);
- (ii) *E. coli* (also known as coliform bacteria), within the genus *Escherichia* (limited to *Enterohaemorrhagic Escherichia coli*);
- (iii) poliovirus, within the genus *Enterovirus*;
- (iv) *C. parvum*, within the genus *Cryptosporidium* (limited to those representing genotype 1 or genotype 2);
- (v) *S. enterica*, within the genus *Salmonella* (limited to those involving typhi or paratyphi A as a serosubtype);
- (vi) Shiga toxin (including the Synthetic Toxins representing a structural formula identical to that of Shiga toxin);
- (vii) *S. sonnei*, *s. dysenteriae*, *s. flexneri*, and *s. boydii*, within the genus *Shigella* (also known as dysentery bacillus);
- (viii) *V. cholera* (also known as cholera bacillus), within the genus *Vibrio* (limited to those involving O1 or O139 as a serotype);
- (ix) yellow fever virus, within the genus *Flavivirus*;
- (x) *M. tuberculosis*, within the genus *Mycobacterium* (excluding the pathogens set forth in item (ii) of the preceding paragraph);
- (xi) beyond what is set forth in the preceding items, the Pathogens, etc. specified by Cabinet Order as being pathogenic to the same degree as the

substances set forth in the preceding items and being likely to affect the health of the public.

- (26) When the Minister of Health, Labour and Welfare intends to propose to establish, revise or abolish 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) The Suspected Disease Carriers of a Class I Infectious Disease or the Suspected Disease Carriers of any of the Class II Infectious Diseases specified by Cabinet Order are deemed as patients of the Class I Infectious Disease or patients of the Class II Infectious Disease respectively, and the provisions of this Act apply.

- (2) If a person is a Suspected Disease Carrier of a Novel Influenza Infection, etc. and there are reasonable grounds for suspecting that they are infected with that Infectious Disease, the person is deemed as a patient with the Novel Influenza Infection, etc. and the provisions of this Act apply.

(3) The Asymptomatic Carriers of a Class I Infectious Disease or the Asymptomatic Carriers of a Novel Influenza Infection, etc. is deemed as patients of the Class I Infectious Disease or patients of the Novel Influenza Infection, etc. respectively, 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 the basic guideline for promoting the prevention of Infectious Diseases in an integrated manner (hereinafter referred to as the "Basic Guideline").

(2) The Basic Guideline is to provide for the following:

- (i) basic direction for promoting the prevention of Infectious Diseases;
- (ii) matters concerning measures to prevent the outbreak 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, etc.;
- (v) matters concerning systems for the examination of Pathogens, etc. and the improvement of examination capabilities;

- (vi) matters concerning the ensuring of the systems to provide medical care for Infectious Diseases;
- (vii) matters concerning the ensuring of the systems for the transfer of 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 the ensuring of the systems for the provision of medical care pertaining to Infectious Diseases, and the ensuring of the systems specified by Order of the Ministry of Health, Labour and Welfare as necessary for measures to prevent the outbreak of Infectious Diseases or the spread of Infectious Diseases;
- (x) matters concerning the securing of accommodation facilities prescribed in Article 44-3, paragraph (2) or Article 50-2, paragraph (2);
- (xi) matters concerning the improvement of the environment for life during recuperation for the persons subject to voluntary restraint due to a Novel Influenza Infection, etc. prescribed in Article 44-3-2, paragraph (1), or the persons subject to voluntary restraint due to New Infectious Diseases prescribed in Article 50-3, paragraph (1);
- (xii) matters concerning the comprehensive coordination pursuant to the provisions of Article 44-5, paragraph (1) (including the 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 the securing of materials for infectious disease countermeasures, etc. prescribed in Article 53-16, paragraph (1);
- (xiv) matters concerning the promotion of public awareness and dissemination of information on Infectious Diseases, and matters concerning respecting the human rights of patients with Infectious Diseases and other persons placed in similar circumstances;
- (xv) matters concerning the development and enhancement of qualifications of human resources for the prevention of Infectious Diseases;
- (xvi) matters concerning the securing of health center systems for the prevention of Infectious Diseases;
- (xvii) matters concerning the securing of the systems to properly treat Specified Pathogens, etc.;
- (xviii) matters concerning measures to prevent the outbreak and spread of an Infectious Disease, to examine Pathogens, etc., and to provide medical care in emergencies (including matters concerning the securing 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 evaluations of the effectiveness of the measures concerning the prevention of 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 (hereinafter referred to 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 as 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 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 publicize the same without delay.

(Prevention Programs)

Article 10 (1) Prefectural governments must formulate a program for implementing measures to prevent Infectious Diseases (hereinafter referred to 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 the outbreak and spread of an Infectious Disease in line with regional circumstances;
  - (ii) matters concerning gathering information, surveys, and research on Infectious Diseases and Pathogens, etc.;
  - (iii) matters concerning systems for the examination of Pathogens, etc. and the improvement of examination capabilities;
  - (iv) matters concerning the securing of the systems to provide medical care for Infectious Diseases;
  - (v) matters concerning the securing of the systems for the transfer of patients with Infectious Diseases;
  - (vi) matters concerning targets related to the ensuring of the systems for the provision of medical care pertaining to Infectious Diseases, and the ensuring of the systems specified by Order of the Ministry of Health, Labour and Welfare as necessary for measures to prevent the outbreak of Infectious Diseases or the spread of Infectious Diseases;
  - (vii) matters concerning the securing of accommodation facilities prescribed in Article 44-3, paragraph (2) or Article 50-2, paragraph (2);
  - (viii) matters concerning the improvement of the environment for life during recuperation for the persons subject to voluntary restraint due to a Novel Influenza Infection, etc. prescribed in Article 44-3-2, paragraph (1), or the

- persons subject to voluntary restraint due to New Infectious Diseases 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 qualifications of human resources for the prevention of Infectious Diseases;
  - (xi) matters concerning the securing of health center systems for the prevention of Infectious Diseases; and
  - (xii) matters concerning measures to prevent the outbreak and spread of an Infectious Disease, to examine Pathogens, etc., and to provide medical care in emergencies (including the securing of the systems for coordination with the national government and communications among local governments).
- (3) In the prevention program set forth in paragraph (1), in addition to the matters listed in the items of the preceding paragraph, efforts are to be made to establish 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 the same when it is deemed necessary. The same applies whenever a prefectural government deems 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 necessary advice to prefectures with regard to 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, in order to ensure the consistency of measures for preventing Infectious Diseases in its area and to utilize its expert knowledge, the prefectural government must discuss the matter with the prefectural coordination council prescribed in paragraph (1) of the following Article in advance.
- (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 (hereinafter referred to as "city, etc. having a public health center")) in advance.
- (8) In 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 Influenza, etc. (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) The Minister of Health, Labour and Welfare, when the Minister finds it necessary, 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 status of achievement of 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 publicize the contents thereof 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) A city, etc. having 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 the area of the city.
- (15) The prevention programs set forth in the preceding paragraph provide for the following matters in the referenced city, etc. having 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 the ensuring of the systems for the facilitation of examinations of Pathogens, etc., and the ensuring of the systems specified by Order of the Ministry of Health, Labour and Welfare as necessary for measures to prevent the outbreak of Infectious Diseases 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 a city, etc. having a public health center, and matters concerning the dissemination of knowledge on Infectious Diseases.
- (17) In formulating or revising a prevention program, a city, etc. having 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 Influenza, etc.
- (18) The provisions of paragraphs (4) through (6) and (9) through (13) will apply mutatis mutandis to the prevention programs established by a city, etc. having

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 the area of the city, etc. having 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 submission 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 same 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 the same 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 engaged in the examination of Pathogens, etc., and administrators of accommodation facilities must endeavor to cooperate as necessary to ensure the necessary systems in the area to contribute to the promotion of the achievement 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 the outbreak and spread of an Infectious Disease, a council (hereinafter referred to as a "prefectural coordination council" in this Article) consisting of prefectural governments, cities, etc. having 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 set forth in each item of Article 9 of the Fire Defense Organization Act (Act No. 226 of 1947)), and other relevant organizations is to be organized.

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

(3) When there has been an announcement of outbreaks, etc. pertaining to a

Novel Influenza Infection, etc. as prescribed in Article 16, paragraph (2), the prefectural government is to hold a prefectural coordination council and endeavor to discuss the implementation of measures necessary to prevent the outbreak and spread of the Infectious Disease.

- (4) With regard to the matters agreed upon 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 the ones 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 publicize the guidelines to facilitate investigations into the causes of those Infectious Diseases, prevention of their outbreak and spread, provision of medical care, promotion of research and development, international coordination, and promotion of other integrated preventive measures customized for respective Infectious Diseases (hereinafter referred to 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 Publication of Information on Infectious Diseases**

(Notification by Physicians)

Article 12 (1) If a physician has diagnosed either of the following persons, the physician must file a notification with the prefectural governor (in the case of a city, etc. having a public health center, the mayor of the city; hereinafter the same applies 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))) via 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 particulars specified by Order of the Ministry of Health, Labour and Welfare immediately if the person is the one set forth in item (i), or the person's age, gender and other

matters specified by Order of the Ministry of Health, Labour and Welfare within seven days if the person is the one set forth in item (ii):

- (i) a patient with a Class I Infectious Disease, a patient or Asymptomatic Carrier of a Class II Infectious Disease, a Class III Infectious Disease or a 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 Influenza Infection, etc., 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 the 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 content of the notification to the Minister of Health, Labour and Welfare by electronic or magnetic means (means a means of using an electronic data processing system or any other means of using 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 hereinafter) with regard to the notification pertaining to a person listed in item (i) of the same paragraph and within the period specified by Order of the Ministry of Health, Labour and Welfare with regard to the notification pertaining to a person listed in item (ii) of the same 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 contents of the notification to the persons specified in the respective items by electronic or magnetic means:
- (i) a person who resides outside the area under the prefectural jurisdiction: The prefectural governor who has jurisdiction over the place of residence (if the place of residence is within the area of a city, etc. having a public health center, the mayor of the city, etc. having a public health center and the prefectural governor who has 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, etc. having a public health center within the area under the prefectural jurisdiction: The mayor of a city, etc. having a public health center who has 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, etc. having 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 who has jurisdiction over the area of the city, etc. having 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, etc. having a public health center" in the same item is deemed to be replaced with "the mayor of a city, etc. having a public health center other than the city, etc. having a public health center."

- (5) A physician who should make 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 should make a report or notification (hereinafter referred to as "report, etc." in this Article) of the content of the notification pursuant to the provisions of paragraph (2) or (3) (including the cases where these provisions are applied mutatis mutandis pursuant to the preceding paragraph), or a person who should receive the report, etc. may inspect it.
- (6) A physician who should make 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 set forth in the preceding paragraph) must endeavor to submit the notification by electronic or magnetic means so that a person who should make a report, etc. of the content of the notification and a person who should receive the report, etc. may inspect it.
- (7) When a notification under the provisions of paragraph (1) has been made by the method prescribed in the preceding two paragraphs, the person who is to make a report, etc. is deemed to have made the report, etc.
- (8) A physician who provides patients of any of the chronic Infectious Diseases specified by Order of the Ministry of Health, Labour and Welfare with medical treatment must file a notification with the prefectural governor via the chief of the nearest public health center every fiscal year, to report their age, gender, 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.
- (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 pertaining to a person listed in item (i) of the

same paragraph and within the period specified by Order of the Ministry of Health, Labour and Welfare, with regard to the notification pertaining to a person listed in item (ii) of the same 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 has diagnosed a monkey or other animal specified by Cabinet Order with Ebola haemorrhagic fever, Marburg virus disease, or any other Infectious Disease as specified by Cabinet Order, and concludes that they are highly likely to infect human beings, which are designated from Class I Infectious Diseases, Class II Infectious Diseases, Class III Infectious Diseases, Class IV Infectious Diseases or a Novel Influenza Infection, etc., and has determined that the monkey or animal is infected or suspected to be infected with the relevant Infectious Disease, the veterinarian must immediately file a notification with the prefectural governor via the chief of the nearest public health center, stating 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 hereinafter in this Article) and other particulars specified by Order of the Ministry of Health, Labour and Welfare, which must be filed for each of those Infectious Diseases; provided, however, that this does not apply when the animal is intentionally infected with the relevant Infectious Disease for the purpose of experimentation.

- (2) The owner of an animal specified by Cabinet Order must file 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 the same paragraph when the animal is not diagnosed by a veterinarian; provided, however, that this does not apply if the animal is intentionally infected with the relevant Infectious Disease for the purpose of experimentation.
- (3) The prefectural governor receiving a notification filed 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 content 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 contents of the notification to

the person specified in the items by electronic or magnetic means:

- (i) an animal raised outside the area under the prefectural jurisdiction: The prefectural governor who has jurisdiction over the location where the animal was bred (in the case where the place is within the area of a city, etc. having a public health center, the mayor of the city, etc. having a public health center and the prefectural governor who has jurisdiction over the location); and
  - (ii) an animal raised inside the area under the jurisdiction of the mayor of a city, etc. having a public health center in the area under the prefectural jurisdiction: The mayor of a city, etc. having a public health center who has 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, etc. having 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 who has jurisdiction over the area of the city, etc. having 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, etc. having a public health center" in the same item is deemed to be replaced with "the mayor of a city, etc. having a public health center other than the city, etc. having a public health center."
- (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 the same 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 content" in paragraph (6) of the same Article is deemed to be replaced with "report or notification (hereinafter referred to as "reports, etc." 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 the same Article)," the term "paragraph (1)" in paragraph (7) of the same Article is be deemed to be replaced with "paragraph (1) of the immediately following Article," and the term "the preceding two paragraphs" in paragraph (7) of the same Article is deemed to be replaced with "the preceding paragraph applied *mutatis mutandis* pursuant to paragraph (6) of the same Article."

(7) The provisions from paragraphs (1) and (3) to the preceding paragraph apply mutatis mutandis when a veterinarian having examined the corpse of an animal specified by Cabinet Order as referred to in paragraph (1) determines in their examination after 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 the same paragraph, and the provisions from paragraphs (2) to the preceding paragraph apply mutatis mutandis when the owner 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 the same paragraph.

(Ascertaining the Status of Outbreaks and the Progress 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, subject to the consent of their establisher, which are responsible for filing 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 of a hospital or clinic designated under the provisions of the preceding paragraph (hereinafter referred to 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 the Asymptomatic Carriers of the Class V Infectious Diseases specified by Order of the Ministry of Health, Labour and Welfare; hereinafter the same applies in this paragraph) or diagnosed a suspected case for 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 file a notification with the prefectural governor who has 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 matters specified by Order of the Ministry of Health, Labour and Welfare of the patient or deceased.

- (3) A prefectural governor receiving a notification filed under the provisions of the preceding paragraph must report its content 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 the same Article apply mutatis mutandis to the report pursuant to the provisions of the preceding paragraph. In this case, the term "physician who should" in paragraph (5) and paragraph (6) of same Article is deemed to be replaced with "administrator of a designated notification organization who should," the term "a report or notification (hereinafter referred to as "report, etc." in this Article) of the content of the notification pursuant to the provisions of paragraph (2) or (3) (including the cases where these provisions are applied mutatis mutandis pursuant to the preceding paragraph)" in paragraph (5) of the same Article is deemed to be replaced with "report (hereinafter referred to as "report" in this Article) of the content of the notification pursuant to the provisions of Article 14, paragraph (3)," the term "the report, etc." in the same paragraph is deemed to be replaced with "the report," the term "report, etc." in paragraphs (6) and (7) of the same Article is deemed to be replaced with "report," and the term "paragraph (1)" in the same 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 the advance notice period of not less than 30 days.
- (6) If the administrator of a designated notification organization violates the provisions of paragraph (2), or if a designated notification organization is deemed to be incompetent to perform the duty of notification pursuant to the provisions of the same paragraph, the prefectural governor may rescind 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 a serious condition if developing the disease, or there is an outbreak or risk of an outbreak, the Minister is to notify the prefectural governor to that effect.
- (8) A prefectural governor who has received a notification may, when a physician in a hospital or clinic other than a designated notifying body located within the area under the jurisdiction of the prefectural governor diagnoses a patient with the 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 matters specified by Order of the Ministry of Health, Labour and Welfare of the patient or deceased person. In this case, the physician who is requested to make the notification must not refuse 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 the same 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 should" in paragraphs (5) and (6) of the same Article is deemed to be replaced with "physician at a hospital or clinic other than a designated notification organization who should," the term "a report or notification (hereinafter referred to as "report, etc." in this Article) of the content of the notification pursuant to the provisions of paragraph (2) or (3) (including the cases where these provisions are applied mutatis mutandis pursuant to the preceding paragraph)" in paragraph of the same Article is deemed to be replaced with "report (hereinafter simply referred to as "report" in this Article) of the content of the notification pursuant to the provisions of paragraph (3) of the same Article applied mutatis mutandis in Article 14, paragraph (9)," the term "the reports, etc." in the same paragraph is deemed to be replaced with "report," the term "reports, etc." in paragraphs (6) and (7) of the same Article is deemed to be replaced with "report," and the term "paragraph (1)" in the same 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 sanitation inspection stations, subject to the consent of their establisher, who is responsible for submitting specimens of 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 sanitation inspection station designated under the provisions of the preceding paragraph (hereinafter referred to as "designated submitting organization" in this Article) must submit a part of the specimens of 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 same paragraph or the pathogens of the relevant Infectious Disease 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 the same 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 sanitation inspection stations) has examined specimens of the patient or pathogens of the relevant Infectious Disease.

- (3) Prefectural governors must conduct an examination of the specimens or the pathogens of 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 deems 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 the advance notice period of not less than 30 days.
- (7) If the administrator of a designated submitting organization violates the provisions of paragraph (2), or if a designated submitting organization is deemed to be incompetent to perform the duty of submission pursuant to the provisions of the same paragraph, the prefectural governor may rescind the designation under the provisions of paragraph (1).

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

Article 15 (1) When a prefectural governor deems it necessary for the purpose of preventing the outbreak of an Infectious Disease or clarifying the status of outbreaks, progress, and the cause of outbreaks, the prefectural governor may direct its relevant officials to question the patients, Suspected Disease Carriers or Asymptomatic Carriers of a Class I Infectious Disease, a Class II Infectious Disease, a Class III Infectious Disease, a Class IV Infectious Disease, a Class V Infectious Disease or a Novel Influenza Infection, etc., a person with symptoms of a New Infectious Disease, or the owners or administrators of animals likely to transmit an Infectious Disease to human beings or their corpses, and other persons concerned, or to carry out necessary investigations.

- (2) When the Minister of Health, Labour and Welfare deems it urgently necessary for the purpose of preventing the outbreak or spread of an Infectious Disease, the Minister may direct relevant officials to question the patients, Suspected Disease Carriers or Asymptomatic Carriers of a Class I Infectious Disease, a Class II Infectious Disease, a Class III Infectious Disease, a Class IV Infectious Disease, a Class V Infectious Disease or a Novel Influenza Infection, etc., a person with symptoms of a New Infectious Disease, or the owners or administrators of animals likely to transmit an Infectious Disease to human beings or their corpses, and other persons concerned, or to carry out necessary investigations.
- (3) When a prefectural governor deems it necessary in the course of the investigations carried out under the provisions of paragraph (1), the prefectural governor may direct relevant officials to request that any person set forth in the following items submit the specimens or pathogens of the Infectious Disease prescribed in the respective item or accept the collection of the specimens by the relevant officials, or request that the custodian (meaning a person who exercises parental authority or a guardian; the same applies hereinafter) of any person set forth in items (i) to (iii) submit the specimens set forth in the respective item or have the person set forth in the respective item accept the collection of the specimens by the relevant officials:
- (i) a patient, Suspected Disease Carrier or Asymptomatic Carrier of a Class I Infectious Disease, a Class II Infectious Disease or a Novel Influenza Infection, etc., or a person who is suspected of being infected with the relevant Infectious Disease on reasonable grounds: specimens of the person;
  - (ii) a patient, Suspected Disease Carrier or Asymptomatic Carrier of a Class III Infectious Disease, a Class IV Infectious Disease or a Class V Infectious Disease, or a person who is suspected of being infected with the relevant Infectious Disease on reasonable grounds: specimens of the person;
  - (iii) a person with symptoms of a New Infectious Disease or a person who is suspected of being infected with a New Infectious Disease on reasonable grounds: specimens of the person;
  - (iv) the owner or administrator of an animal likely to transmit a Class I Infectious Disease, a Class II Infectious Disease or a Novel Influenza Infection, etc. to human beings or the corpse of such an animal: specimens of 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 human beings or the corpse of such an animal: specimens of the animal or its corpse;
  - (vi) the owner or administrator of an animal likely to transmit a New Infectious Disease to human beings or the corpse of such an animal:

- specimens of the animal or its corpse;
- (vii) a person possessing the specimens referred to in item (i) or pathogens of an Infectious Disease prescribed in the same paragraph 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 the same paragraph 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 the same paragraph 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 the same paragraph 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) The prefectural governor is to, in order to prevent the outbreak of Infectious Diseases or to prevent the spread of Infectious Diseases by promptly detecting patients with Infectious Diseases, 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 type of facility or work in which the Infectious Diseases have occurred, the status of the occurrence and spread of Infectious Diseases of each type, 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 necessary investigations carried out under the provisions of paragraph (2).
- (7) A person who has been asked questions or requested a necessary investigation pursuant to the provisions of paragraph (1) or paragraph (2) (excluding specified patients, etc. prescribed in the following paragraph) must endeavor to cooperate with the questions or necessary investigation.
- (8) A prefectural governor or the Minister of Health, Labour and Welfare, when a person who is a patient with a Class 1 Infectious Disease, Class 2 Infectious Disease, or a Novel Influenza Infection, etc., or a person with symptoms of a

New Infectious Disease (hereinafter referred to as "specified patients, etc.") does not cooperate with the questions or necessary investigations by the employees pursuant to the provisions of paragraphs (1) and (2) without reasonable grounds if they find it necessary for the purpose of preventing the outbreak or spread of those Infectious Diseases, may order the specified patients, etc. to respond to the questions or 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 the same Article is extended by Cabinet Order in paragraph (2) of the same 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 the same Article is extended by Cabinet Order in paragraph (2) of the same Article))).

- (9) The orders of the preceding paragraph are the minimum necessary for the purpose of preventing the outbreak or spread of an Infectious Disease, in light of risks of spreading the Infectious Disease to the public, the severity of pathological conditions when infected with the Infectious Disease, and other circumstances.
- (10) When issuing an order set forth in paragraph (8), the prefectural governor or the Minister of Health, Labour and Welfare must, at the same time, notify the person who receives 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 in cases where there is an urgent need for orders to be issued without giving written notice of such 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 set forth in paragraph (8), deliver a document stating the reasons set forth 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, etc. having a public health center (hereinafter referred to as "prefectural governors, etc."), pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, must report the result of questions or necessary investigations conducted pursuant to the provisions of paragraph (1) by electronic or magnetic means (meaning a method

using an electronic data processing system or any other method using 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, etc. having a public health center, the Minister of Health, Labour and Welfare and the prefectural governor who has jurisdiction over the area of the city, etc. having a public health center).

- (14) A prefectural governor, etc. must, when specified by Order of the Ministry of Health, Labour and Welfare as the case where it is deemed necessary to prevent the spread of an Infectious Disease in the area under the jurisdiction of another prefectural governor, etc., notify the other prefectural governor, etc. by electronic or magnetic means of the results of the questions conducted pursuant to the provisions of paragraph (1) or the necessary investigation pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (15) When the Minister of Health, Labour and Welfare deems it necessary to personally conduct an examination, excluding the case of a request 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 referenced officials under the provisions of paragraph (3).
- (16) When a prefectural governor deems it particularly necessary for the purpose of questioning or 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 the Pathogens, etc., or other research and development or examinations in connection with Infectious Diseases (hereinafter referred to as "Infectious Diseases Research Institute") or to provide other necessary cooperation.
- (17) The provisions of paragraph (12) apply mutatis mutandis to the employees dispatched pursuant to the provisions of the preceding paragraph.
- (18) 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 the same Act) stating the instructions given to the person having the health problem or other matters specified by Order of the Ministry of Health, Labour and Welfare (including cases where such a notice is given pursuant to the provisions of Article 34-2, paragraph (3) of the same Act), the prefectural governor may direct the prefecture's officials to question the person with the health problem or other persons concerned or to carry out necessary investigations.

- (2) The prefectural governor must notify the Minister of Health, Labour and Welfare of the result of the questioning 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 the same Act) stating the matters reported with regard to a person prescribed in Article 18, paragraph (4) of the same Act pursuant to the provisions of the same paragraph (including cases where such a notice is given pursuant to the provisions of Article 34-2, paragraph (3) of the same Act), the prefectural governor may ask the person to report their body temperature and other health conditions during the period specified by the quarantine station chief pursuant to the provisions of Article 18, paragraph (1) of the same Act, or direct the prefecture's officials to question the person.

- (2) If the prefectural governor confirms as a result of the reporting or questioning under the provisions of the preceding paragraph that the person has any health problem, the prefectural governor must, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, immediately make a report to that effect to the Minister of Health, Labour and Welfare and the prefectural governor may direct relevant officials to question the person or other persons concerned or to carry out necessary investigations.
- (3) The prefectural governor must report the result of the questioning 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) The Minister of Health, Labour and Welfare, when requested by a prefectural governor and 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, is to personally implement the measures prescribed in paragraph (1) on behalf of the prefectural governor, if the Minister deems 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 the same Act (limited to those for which the provisions of Article 18, paragraph (5) of the same Act are applied by Cabinet Order), or a New Infectious Disease prescribed in Article 34-2, paragraph (1) of the same Act (limited to those for which the affairs prescribed in Article 18, paragraph (5) of the same Act are implemented according to the provisions of paragraph (3) of the same Article) in the area of the prefectural government or the city, etc. having 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 to that effect.
- (7) With regard to the application of the provisions of paragraphs (2) and (4) in cases where 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 to that effect to the Minister of Health, Labour and Welfare and the prefectural governor may direct relevant officials to question the person" in paragraph (2) is deemed to be "notification to that effect to the prefectural governor who has jurisdiction over the location of the residence. In this case, the prefectural governor who has received the notification, may direct relevant officials to question those persons to whom the notification pertains" 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) In addition to what is provided for in the preceding two paragraphs, 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.

(Publication of Information, etc.)

- 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 publicize the information on the status of outbreaks, the progress, and causes of the 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 appropriate means.
- (2) A prefectural governor, from the time when the announcement is made pursuant to the provisions of Article 44-2, paragraph (1), Article 44-7, paragraph (1), or Article 44-10, paragraph (1) (hereinafter referred to as "announcement of outbreaks, etc. pertaining to a Novel Influenza Infection, etc."), until the 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, etc. to the effect that it is no longer recognized as a Novel Influenza Infection, etc." in Article 36-2, paragraph (1) and Article 63-4), may request necessary cooperation from the mayors of municipalities when it is deemed necessary to enhance the understanding of residents regarding the information on the situation, trends, and causes of the occurrence of Infectious Diseases for which the announcement of outbreaks, etc. of a Novel Influenza Infection, etc. has been made.
- (3) When a prefectural governor finds it necessary for a request for cooperation pursuant to the provisions of the preceding paragraph, the prefectural governor may provide the mayor of the municipality with information specified by Order of the Ministry of Health, Labor and Welfare, such as the number of patients with a Novel Influenza Infection, etc. or a Designated Infectious Disease or with symptoms of a New Infectious Disease (limited to those who have a place of residence within the area of the prefectural government), the name of the municipality in which the person resides, the date and time when it is found that the person is a patient with a Novel Influenza Infection, etc. or a Designated Infectious Disease or a person with symptoms of a New Infectious Disease.
- (4) In the publication 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, etc.)

- Article 16-2 (1) When it is deemed particularly necessary for the purpose of preventing the outbreak or spread of an Infectious Disease, the Minister of Health, Labour and Welfare and prefectural governors may establish measures

necessary to prevent the outbreak or spread of the Infectious Disease and request physicians, medical institutions, organizations of those with relevant expertise or medical-related personnel regarding medical care, or private business operators or Infectious Diseases Research Institute that is engaged in the inspection of pathogens, etc. and other inspections related to Infectious Diseases for the cooperation necessary to implement the measures, taking into consideration pathological conditions of the patients of the Infectious Disease, the number of such patients, other circumstances for the outbreak or spread of the Infectious Disease, and the circumstances of the inspection of pathogens, etc.

- (2) In cases where the Minister of Health, Labour and Welfare and the prefectural governor have made a request for cooperation pursuant to the provisions of the preceding paragraph, 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 the same paragraph.
- (3) In cases where the Minister of Health, Labour and Welfare and the prefectural governor have made recommendations pursuant to the provisions of the preceding paragraph, if the person who received the recommendation did not follow the recommendation without reasonable grounds, the Minister and the prefectural governor may make this public.

#### **Chapter IV Restrictions on Work Attendance and Other Measures**

##### **(Collection of Specimens)**

- Article 16-3 (1) When a prefectural governor deems it necessary for the purpose of preventing the spread of a Class I Infectious Disease, a Class II Infectious Disease or a Novel Influenza Infection, etc., the prefectural governor may recommend that the person set forth in Article 15, paragraph (3), item (i) submit the specimens prescribed in the same item or accept the collection of the specimens by relevant officials, or recommend that the person's custodian submit the specimens or have the person accept the collection of the specimens 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 the pathogens of the Infectious Disease prescribed in the same item which are separated from the specimens which are the subject of the intended recommendation; hereinafter the same applies 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 deems it particularly

necessary for the purpose of preventing the spread of a Class I Infectious Disease, a Class II Infectious Disease or a Novel Influenza Infection, etc., the Minister may recommend that a person set forth in Article 15, paragraph (3), item (i) submit the specimens prescribed in the same item or accept the collection of the specimens by relevant officials, or recommend that the person's custodian submit the specimens or have the person accept the collection of the specimens by the 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 the same item which are separated from the specimens which are the subject of the intended recommendation; hereinafter the same applies 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 necessary extent for examination, direct relevant officials to collect the specimens prescribed in Article 15, paragraph (3), item (i) from the person set forth in the same 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 necessary for examination, direct relevant officials to collect the specimens prescribed in Article 15, paragraph (3), item (i) from the person set forth in the same 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 are pressing needs for recommending the submission or collection of specimens or for implementing a measure of collecting specimens before making a notification of the matters 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 the same paragraph to 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 of collecting specimens.

- (7) The prefectural governor must examine the specimens submitted or collected by the relevant officials in accordance with the provisions of paragraph (1) or the specimens which the prefectural governor directed the 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 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.
- (9) When the Minister of Health, Labour and Welfare deems 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 the relevant officials under the provisions of paragraph (1) or a part of the specimens which the prefectural governor directed the relevant officials to collect pursuant to the provisions of paragraph (3).
- (10) When a prefectural governor deems it particularly necessary for the purpose of recommending the submission or collection of specimens under the provisions of paragraph (1), directing relevant officials to collect specimens under the provisions of paragraph (3), or examining 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 Diseases Research Institute and to provide other necessary cooperation.
- (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 the relevant officials to implement a measure of collecting specimens pursuant to the provisions of paragraph (4).

(Medical Examinations)

Article 17 (1) When a prefectural governor deems it necessary for the purpose of preventing the spread of a Class I Infectious Disease, a Class II Infectious Disease, a Class III Infectious Disease or a Novel Influenza Infection, etc., the prefectural governor may recommend that a person who is suspected to be infected with the relevant Infectious Disease on reasonable grounds take a medical examination conducted by a physician to ascertain whether the person is infected with the relevant Infectious Disease or not, or recommend to the custodian of the person who is suspected to be infected with the relevant

Infectious Disease on reasonable grounds 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 suspected to be infected with the Infectious Disease of the recommendation upon reasonable grounds for doing so.

(Restrictions on Attendance at Work)

Article 18 (1) When a prefectural governor receives a notification filed 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 Infectious Disease, a Class III Infectious Disease or a Novel Influenza Infection, etc., if the prefectural governor deems it necessary for the purpose of preventing the spread of the relevant Infectious Disease, the prefectural governor may notify the person or their custodian of the content 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 the same paragraph, the patient or Asymptomatic Carrier must not perform any of the job duties specified by Order of the Ministry of Health, Labour and Welfare for the respective Infectious Disease which bring 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 the respective Infectious Disease as the length of time required for the elimination of such 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 the same paragraph.
- (4) Upon receipt of 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 in respect of whom the request is made is a patient or Asymptomatic Carrier of the Infectious Disease based on which the provisions of the same paragraph are applied, or whether or not the period prescribed in the same 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 opinions of the Infectious Diseases examination committee prescribed in Article 24, paragraph (1) established in the public health center who 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 opinions of the Infectious Diseases 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 Diseases examination committee the content of the notice it has given.

(Hospitalization)

Article 19 (1) When a prefectural governor deems it necessary for the purpose of preventing 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 other than a Designated Medical Institution for Specified Infectious Diseases or a Designated Medical Institution for Class I Infectious Diseases, as deemed appropriate by the prefectural governor.

- (2) When a prefectural governor makes a recommendation under the provisions of the preceding paragraph, the prefectural governor must give appropriate explanations to the patient who is subject to the recommendation or their custodian and endeavor to gain their understanding.

- (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 in 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 the same paragraph, in a hospital or clinic other than a Designated Medical Institution for Specified Infectious Diseases or a Designated Medical Institution for Class I Infectious Diseases, as deemed appropriate by the prefectural governor).

- (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) in another hospital or clinic which is deemed appropriate by the prefectural governor.

- (6) The sum of the 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) If issuing a recommendation under the provisions of paragraph (1) or implementing a measure of hospitalization under the provisions of paragraph (3), the prefectural governor must, without delay, make a report to the Infectious Diseases examination committee prescribed in Article 24, paragraph (1) established in the public health center who has jurisdiction over the location of the hospital or clinic where the referenced patient is hospitalized.

Article 20 (1) When a prefectural governor deems it necessary for the purpose of preventing 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 in 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 other than a Designated Medical Institution for Specified Infectious Diseases or a Designated Medical Institution for Class I Infectious Diseases, as deemed appropriate by the prefectural governor, 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 in 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 the same paragraph, in a hospital or clinic other than a Designated Medical Institution for Specified Infectious Diseases or a Designated Medical Institution for Class I Infectious Diseases, as deemed appropriate by the prefectural governor) 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 in another hospital or clinic other than those in which the patient is currently hospitalized, as deemed appropriate by the prefectural governor, 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 deems it necessary to continue

the hospitalization of the patient who has been so 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 opinions of the Infectious Diseases examination committee prescribed in Article 24, paragraph (1) established in the public health center who has jurisdiction over the location of the hospital or clinic where the referenced patient is hospitalized.
- (6) If the prefectural governor intends to make a recommendation under the provisions of paragraph (1), the prefectural governor must give appropriate explanations to the patient or their custodian and endeavor to gain their understanding, 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 such opportunity to express 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 in which 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, such administrator of the hospital or clinic must give notice to the

prefectural governor to that effect.

- (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) Upon receipt of 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 for the purpose of preventing the outbreak or spread of an Infectious Disease, in light of risks of spreading the Infectious Disease to the public, the severity of pathological conditions when infected 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 of medical examination under the provisions of paragraph (2) of the same Article, recommends hospitalization under the provisions of Article 19, paragraph (1) or Article 20, paragraph (1), implements a measure of 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 the same Article.

(Committee for the Examination of Infectious Diseases)

- Article 24 (1) A committee for examination of Infectious Diseases (hereinafter referred to as "Infectious Diseases examination committee" in this Article) will be established in each public health center.
- (2) Notwithstanding the provisions of the preceding paragraph, a prefectural government with two or more health centers may establish a single Infectious Diseases examination committee for two or more public health centers when it is deemed particularly necessary.
  - (3) The Infectious Diseases examination committee will take charge of the following affairs:
    - (i) deliberation of 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 burden of expenses based on an application filed under the provisions of Article 37-2, paragraph (1); and
- (ii) statement of 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 Diseases 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 in Designated Medical Institutions for Infectious Diseases, persons with relevant knowledge and experience in medical care for patients with infectious diseases (excluding physicians in Designated Medical Institutions for Infectious Diseases), persons with relevant knowledge and experience in law, and persons with relevant knowledge and experience in the 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 Diseases examination committee are specified by Prefectural Ordinance.

(Filing of 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 any treatment received by the patient.
- (2) If the patient prescribed in the preceding paragraph or their custodian intends to file a complaint under the same paragraph orally, the prefectural governor may direct their designated officials to hear the content of the complaint.
- (3) Upon receipt of a complaint filed, the prefectural governor must handle the complaint in good faith and notify the person who filed the complaint of the result of the handling.

(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; hereinafter the same applies 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 the same 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 the 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 the same 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 the 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 to that effect.
- (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 the patients whose period of hospitalization exceeds 30 days), the Minister must hear the opinion of the Councils, etc. (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 of 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 of 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 pathological conditions 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 the same 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 pathological conditions of that Infectious Disease" and, in addition to the foregoing, necessary technical replacement of terms in connection with these provisions is specified by Cabinet Order.

- (2) The provisions of Articles 19 through 23, Article 24-2, and the preceding Article apply mutatis mutandis to the patients of a Novel Influenza Infection, etc. In this case, the term "a patient" in Article 19, paragraph (1) is deemed to be replaced with "a patient (for patients with Novel Influenza Infections, etc. (limited to those specified by Order of the Ministry of Health, Labour and Welfare in consideration of the severity of pathological conditions), limited to those specified by Order of the Ministry of Health, Labour and Welfare taking into consideration of the Infectious Disease or the risk that the severity of pathological conditions when infected 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 the same paragraph and paragraph (3) of the same 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 have been replaced with "can transfer," and, in addition to the foregoing, necessary technical replacement of terms in connection with these provisions is specified by Cabinet Order.

(Special Provisions for the Hospitalization of Tuberculosis Patients)

Article 26-2 For the purpose of applying 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 to tuberculosis patients, the phrase "the location of the hospital or clinic where the referenced patient is hospitalized" in Article 19, paragraph (7) is deemed to be replaced with "the place of residence of the referenced 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 the same Article is deemed to be replaced with "not more than 10 days (or not more than 30 days, in case of the hospitalization under the main clause of paragraph (1))," the phrase "the location of the hospital or clinic where the referenced patient is hospitalized" in paragraph (5) of the same Article is deemed to be replaced with "the place of residence of the referenced patient."

## **Chapter V Disinfection and Other Measures**

(Forcible Collection of Specimens)

- Article 26-3 (1) When a prefectural governor deems it necessary for the purpose of preventing the outbreak or spread of a Class I Infectious Disease, a Class II Infectious Disease or a Novel Influenza Infection, etc., the prefectural governor may order a person set forth 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 deems it particularly necessary for the purpose of preventing the outbreak or spread of a Class I Infectious Disease, a Class II Infectious Disease or a Novel Influenza Infection, etc., the Minister may order a person set forth 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 set forth in the same 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 set forth in the same 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 referenced 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 deems 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 referenced officials under the provisions of paragraph (3).
- (8) If a prefectural governor deems it particularly necessary for the purpose of ordering the submission of the specimens or the pathogens of the Infectious Disease under the provisions of paragraph (1), directing relevant officials to implement forcible collection of the specimens or the pathogens of the Infectious Disease under the provisions of paragraph (3), or conducting the 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 Diseases Research Institute and to provide other necessary cooperation.

#### (Collection of Specimens)

Article 26-4 (1) If a prefectural governor deems it necessary for the purpose of preventing the outbreak or spread of a Class I Infectious Disease, a Class II Infectious Disease or a Novel Influenza Infection, etc., the prefectural governor may order a person set forth in Article 15, paragraph (3), item (iv) to submit

the specimens prescribed in the same item or to accept the collection of the specimens by relevant officials.

- (2) If the Minister of Health, Labour and Welfare deems it particularly necessary for the purpose of preventing the outbreak or spread of a Class I Infectious Disease, a Class II Infectious Disease or a Novel Influenza Infection, etc., the Minister may order a person set forth in Article 15, paragraph (3), item (iv) to submit the specimens prescribed in the same item or to accept the collection of the specimens 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 prescribed in the same item 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 prescribed in the same item 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 referenced officials collected thereunder, or the specimens collected by the referenced 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 deems 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 referenced officials collected thereunder, or a part of the specimens collected by the referenced officials based on the prefectural governor's direction under the provisions of paragraph (3).
- (8) When a prefectural governor deems it particularly necessary for the purpose of ordering the submission or collection of the specimens under the provisions of paragraph (1), directing relevant officials to implement a measure of collecting the specimens under the provisions of paragraph (3), or examining

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 Diseases Research Institute and to provide other necessary cooperation.

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

Article 27 (1) When a prefectural governor deems it necessary for the purpose of preventing the outbreak or spread of a Class I Infectious Disease, a Class II Infectious Disease, a Class III Infectious Disease, a Class IV Infectious Disease or a Novel Influenza Infection, etc., the prefectural governor may order, with regard to the places where a patient with the relevant Infectious Disease stays or stayed or where there is or was the corpse of a person who had died of the relevant Infectious Disease, and other areas contaminated or suspected to have been contaminated with pathogens of the relevant 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 deems it difficult to prevent the outbreak or spread of a Class I Infectious Disease, a Class II Infectious Disease, a Class III Infectious Disease, a Class IV Infectious Disease or a Novel Influenza Infection, etc. by means of 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 the relevant Infectious Disease stays or stayed or where there is or was the corpse of the person who had died of the relevant Infectious Disease, and other areas contaminated or suspected to have been contaminated with pathogens of the relevant 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 deems it necessary for the purpose of preventing the outbreak or spread of a Class I Infectious Disease, a Class II Infectious Disease, a Class III Infectious Disease or a Class IV Infectious Disease, the prefectural governor may designate the areas where rodents, insects or the like which are contaminated or suspected to have been contaminated with pathogens of the relevant Infectious Disease exist, and order the persons responsible for administration of those areas or the persons acting on their behalf to exterminate such rodents, insects or the like, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(2) When a prefectural governor deems it difficult to prevent the outbreak or

spread of a Class I Infectious Disease, a Class II Infectious Disease, a Class III Infectious Disease or a Class IV Infectious Disease by means of an order prescribed in the preceding paragraph, the prefectural governor may designate the areas where rodents, insects or the like which are contaminated or suspected to have been contaminated with pathogens of the relevant Infectious Disease exist, and instruct relevant municipal governments who have jurisdiction over those areas or direct the prefecture's officials to exterminate such rodents, insects or the like, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Measures Regarding Physical Items)

Article 29 (1) When a prefectural governor deems it necessary for the purpose of preventing the outbreak or spread of a Class I Infectious Disease, a Class II Infectious Disease, a Class III Infectious Disease, a Class IV Infectious Disease or a Novel Influenza Infection, etc., the prefectural governor may, with regard to food or drink, clothing, bedding, and other physical items contaminated or suspected to have been contaminated with pathogens of the relevant 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 the prevention of the outbreak or spread of the relevant Infectious Disease, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(2) When a prefectural governor deems it difficult to prevent the outbreak or spread of a Class I Infectious Disease, a Class II Infectious Disease, a Class III Infectious Disease, a Class IV Infectious Disease or a Novel Influenza Infection, etc. by means of an order prescribed in the preceding paragraph, the prefectural governor may instruct relevant municipal governments to disinfect food or drink, clothing, bedding and other physical items contaminated or suspected to have been contaminated with pathogens of the relevant Infectious Disease, or direct the prefecture's officials to disinfect or discard them or implement other necessary measures for the prevention of the outbreak or spread of the relevant Infectious Disease, 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 deems it necessary for the purpose of preventing the outbreak or spread of a Class I Infectious Disease, a Class II Infectious Disease, a Class III Infectious Disease or a Novel Influenza Infection, etc., the prefectural governor may restrict or prohibit the relocation of the corpses contaminated or suspected to have been contaminated with pathogens of the relevant Infectious Disease.

- (2) The corpses contaminated or suspected to have been contaminated with pathogens of a Class I Infectious Disease, a Class II Infectious Disease, a Class III Infectious Disease or a Novel Influenza Infection, etc. 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 I Infectious Disease, a Class II Infectious Disease, a Class III Infectious Disease or a Novel Influenza Infection, etc. may be either cremated or buried within 24 hours.

(Restrictions on the Use of Water for Daily Life)

Article 31 (1) When a prefectural governor deems it necessary for the purpose of preventing the outbreak or spread of a Class I Infectious Disease, a Class II Infectious Disease or a Class III Infectious Disease, the prefectural governor may order the administrator responsible for the water for daily life contaminated or suspected to have been contaminated with pathogens of the relevant Infectious Disease to restrict or prohibit the use or supply of the water for a specified period.

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

(Measures Taken for Buildings)

Article 32 (1) When a prefectural governor deems it necessary for the purpose of preventing the outbreak or spread of a Class I Infectious Disease, and it is difficult to achieve this by means of disinfection, the prefectural governor may restrict or prohibit entry into the buildings contaminated or suspected to have been contaminated with 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 a measure prescribed in the preceding paragraph, the prefectural governor may seal off the buildings contaminated or suspected to have been contaminated with pathogens of the Infectious Disease or implement other necessary measures for the building for the prevention of the Infectious Disease, in accordance with the standards specified by Cabinet Order, only when it is deemed to be particularly necessary.

(Restriction or Blocking of Traffic)

Article 33 If a prefectural governor deems it particularly necessary for the purpose of preventing the spread of a Class I Infectious Disease, and it is difficult to achieve the purpose by means of 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 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 for the purpose of preventing the outbreak or spread of an Infectious Disease.

(Questioning and Investigations)

Article 35 (1) When a prefectural governor deems it necessary for the purpose of implementing any of the measures prescribed in Articles 26-3 to 33, the prefectural governor may direct relevant officials to enter the places where patients of a Class I Infectious Disease, a Class II Infectious Disease, a Class III Infectious Disease, a Class IV Infectious Disease or a Novel Influenza Infection, etc. stay or stayed, the places where there are or were the corpses of persons who had died of the relevant Infectious Disease, the places where there are or were animals likely to transmit the relevant Infectious Disease to human beings, the places where there are or were the corpses of those animals which had died of the relevant Infectious Disease, and other areas contaminated or suspected to have been contaminated with pathogens of the relevant Infectious Disease, and question the patients, Suspected Disease Carriers or Asymptomatic Carriers of a Class I Infectious Disease, a Class II Infectious Disease, a Class III Infectious Disease, a Class IV Infectious Disease or a Novel Influenza Infection, etc., the owners or administrators of animals likely to transmit the relevant Infectious Disease to human beings or their corpses, and other persons concerned, or carry out 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 having been granted for criminal investigation.

(4) The provisions of the preceding three paragraphs apply *mutatis mutandis* when the Minister of Health, Labour and Welfare deems it necessary for the purpose of implementing or directing 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 deems it necessary for the purpose of implementing 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 therefor, and other matters specified by Order of the Ministry of Health, Labour and Welfare; provided, however, that this does not apply when there are pressing needs for implementing the measure before making a notification of those matters in writing.
- (2) In the case referred to in the proviso of the preceding paragraph, the prefectural governor must issue a written document stating the implementation of the referenced measure, the reasons therefor, and other matters specified by Order of the Ministry of Health, Labour and Welfare as referred to in the same 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 the implementation of the measure, the reasons therefor, and other matters specified by Order of the Ministry of Health, Labour and Welfare at an appropriate 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, etc.

(Obligation, etc. of Public Medical Institutions, etc., 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 promptly and accurately take necessary measures to ensure a system for providing medical care pertaining to a Novel Influenza Infection, etc., Designated Infectious Disease, or New Infectious Disease during the period from the announcement of outbreaks, etc. pertaining to a Novel Influenza Infection, etc., until the announcement, etc. to the effect that it is no longer recognized as a Novel Influenza Infection, etc. (hereinafter referred to as the "period for announcement of outbreaks, etc. of a Novel Influenza Infection, etc." 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 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 (hereinafter referred to as "public medical institutions, etc."), located within the jurisdiction of the prefectural governor, and regional medical care support hospitals (refers to regional medical care support hospitals as set forth in Article 4, paragraph (1) of the same Act; the same applies hereinafter) and advanced treatment hospitals (refers to advanced treatment hospitals set forth in Article 4-2, paragraph (1) of the same Act; the same applies hereinafter), of the measures to be taken by the relevant medical institutions during the announcement period of the outbreak of a Novel Influenza Infection, etc. among the following measures (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 promptly and appropriately take necessary measures to ensure a system for providing medical care pertaining to a Novel Influenza Infection, etc., Designated Infectious Diseases, or New Infectious Diseases), the method of sharing the expenses required for the measures, and other matters specified by Order of the Ministry of Health, Labour and Welfare:

- (i) hospitalizing a patient with a Novel Influenza Infection, etc. or a Designated Infectious Disease, or a person with symptoms of a New Infectious Disease, and providing necessary medical care;
- (ii) providing medical care for a suspected patient with a Novel Influenza

- Infection, etc. or a Designated Infectious Disease, or a person with whom there are reasonable grounds for suspecting they may have a referenced Infectious Disease, or a person with whom there are reasonable grounds for suspecting they may have a New Infectious Disease;
- (iii) providing medical services specified by Order of the Ministry of Health, Labour and Welfare set forth in Article 44-3-2, paragraph (1) (including the 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 to request a report of the body temperature and other health conditions of a patient with a Novel Influenza Infection, etc. 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 the 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 Influenza Infection, etc. or a Designated Infectious Disease, or a person with symptoms of a New Infectious Disease;
  - (v) securing medical care personnel for Novel Influenza Infections, etc. prescribed in Article 44-4-2, paragraph (1), relevant persons to the prevention of Novel Influenza Infections, etc. prescribed in the paragraph, medical care personnel for Designated Infectious Diseases prescribed in the same paragraph as applied mutatis mutandis by replacing terms pursuant to Article 44-8, relevant persons to the prevention of Designated Infectious Diseases prescribed in the same paragraph as applied mutatis mutandis by replacing terms pursuant to the same Article, medical care personnel for New Infectious Diseases prescribed in Article 51-2, paragraph 1, or relevant persons to the prevention of New Infectious Diseases prescribed in the same paragraph, and dispatching the referenced 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 medical institution, etc., 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 publicize the contents of the notice pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Conclusion, etc. of Agreements with Medical Institutions)

Article 36-3 (1) In order to swiftly and accurately take necessary measures to ensure a system for providing medical care related to a Novel Influenza Infection, etc., Designated Infectious Disease, or New Infectious Disease during the period for announcement of outbreaks, etc. of a Novel Influenza Infection, etc., 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 (hereinafter referred to as "medical care agreement") that includes the following matters as specified by Order of the Ministry of Health, Labour and Welfare:

- (i) among the measures listed in the items of paragraph (1) of the preceding Article, the measures to be taken by the medical institution during the period for announcement of outbreaks, etc. of a Novel Influenza Infection, etc.;
  - (ii) in cases specified for the implementation of stockpiling of personal protective equipment prescribed in Article 53-16, paragraph (1), the contents thereof;
  - (iii) the method of bearing the expenses required for the measures set forth 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 publicize 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 is to be prescribed by Order of the Ministry of Health, Labour and Welfare.

(Instructions, etc. by a Prefectural Governor)

Article 36-4 (1) When a prefectural governor finds that an administrator of a public medical institution, etc. 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) in cases where the reference public medical institutions, etc. have concluded medical care agreements, measures based on the relevant medical care agreement.

(2) When a prefectural governor finds that an administrator of a public medical institution, etc. (excluding public medical institution, etc.; hereinafter the same applies in this Article) has not taken any of the following measures without reasonable grounds, the prefectural governor may 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) in cases where the reference medical institutions have concluded medical care agreements, measures based on the relevant medical measures agreements.

(3) The prefectural governor may, when the prefectural governor finds it necessary in cases where the administrator of a medical institution does not follow the recommendation prescribed in the preceding paragraph without reasonable grounds, give necessary instructions to the administrator.

(4) In cases where the prefectural governor has given instructions pursuant to the provisions of paragraph (1) or the preceding paragraph, if the public medical institution, etc. or the administrator of the medical institution who received these instructions does not follow the instructions without reasonable grounds, the prefectural governor may make this public.

(Reports, etc. 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 medical institution, etc., 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 pertaining to the measures, and other

- matters; and
- (ii) in the case where the medical institution has concluded a medical care agreement, the status of implementation of measures based on the medical care agreement, the status of operation of the medical institution pertaining to the 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 measures based on the medical care agreement, the status of the operation of the medical institution pertaining to the measures, and other matters.
  - (3) When a prefectural governor requests a report pursuant to the provisions of the preceding two paragraphs, an 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 in cases where there are reasonable grounds.
  - (4) A prefectural governor who has received a report pursuant to the provisions of the preceding paragraph must make a report of the content of the report by electronic or magnetic means (meaning a method using an electronic data processing system or any other method using information and communications technology specified by Order of the Ministry of Health, Labour and Welfare; hereinafter the same applies in the following paragraph and paragraph (6)) to the Minister of Health, Labour and Welfare and announces it.
  - (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 should make a report pursuant to the provisions of paragraph (3) must make the report by electronic or magnetic means in which the contents of the report can be viewed by the person who should make the report pursuant to the provisions of the preceding paragraph and the person who should receive 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 should make a report pursuant to the provisions of paragraph (3) must endeavor to made the report by electronic or magnetic means in which the contents of the report can be viewed by the person who should make the report pursuant to the provisions of paragraph (iv) and the person who should receive the report.
  - (7) When an administrator of a medical institution that should 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) The Minister of Health, Labour and Welfare may, when the Minister finds it necessary, provide 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, publicize the contents of the report.

(Conclusion, etc. of Agreements with Organizations Engaged in the Examination of Pathogens, etc.)

Article 36-6 (1) In order to swiftly and accurately take necessary measures to ensure a system for providing medical care related to an Infectious Disease such as inspections pertaining to a Novel Influenza Infection, etc., Designated Infectious Disease, or New Infectious Disease during the period for announcement of outbreaks, etc. of a Novel Influenza Infection, etc., to ensure accommodation facilities, and other measures, the prefectural governors, etc. is to consult with the administrators of organizations engaged in the examination of Pathogens, etc., accommodation facilities, and other organizations or facilities specified by Order of the Ministry of Health, Labour and Welfare (hereinafter referred to as "organizations engaged in the examination of Pathogens, etc."), and, when an agreement is reached, conclude an agreement (hereinafter referred to as "examination, etc. measures agreement") 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 engaged in the examination of Pathogens, etc. during the period for announcement of outbreaks, etc. of a Novel Influenza Infection, etc., according to the categories of organizations engaged in the examination of Pathogens, etc. listed in (a) through (c) below:

(a) Organizations engaged in the examination of Pathogens, etc.: collecting a specimen or conducting an examination of a specimen from a suspected patient with a Novel Influenza Infection, etc. or a Designated Infectious Disease, or a person with whom there are reasonable grounds for suspecting they may have a referenced Infectious Disease, or a person with

- whom there are reasonable grounds for suspecting they may 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 specified for the implementation of stockpiling of personal protective equipment prescribed in Article 53-16, paragraph (1), the contents thereof;
  - (iii) the method of bearing the expenses required for the measures set forth in the preceding two items;
  - (iv) the term of the examination, etc. measures agreement;
  - (v) measures in the event the examination, etc. measures 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 examination, etc. measures agreement.
- (2) When a prefectural governor, etc. has concluded an examination, etc. measures agreement, the prefectural governor is to publicize the contents of the examination, etc. measures agreement 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 examination, etc. measures agreement are to be prescribed by Order of the Ministry of Health, Labour and Welfare.

(Instructions, etc. by a Prefectural Governor, etc.)

- Article 36-7 (1) When a prefectural governor, etc. finds that an administrator of an organization engaged in the examination of Pathogens, etc. with which an examination, etc. measures agreement. has been concluded has not taken measures based on the examination, etc. measures agreement without reasonable grounds, the prefectural governor may recommend the administrator to take the necessary measures.
- (2) When the administrator of an organization engaged in the examination of Pathogens, etc. does not follow the recommendation as prescribed in the preceding paragraph without reasonable grounds, the prefectural governor, etc. may give necessary instructions to the administrator if the prefectural governor finds it necessary.
  - (3) In cases where the prefectural governor, etc. has given instructions pursuant to the provisions of the preceding paragraph, if the administrator of an organization engaged in the examination of Pathogens, etc. who received the

instructions does not follow the instructions without reasonable grounds, the prefectural governor may make this public.

(Reports, etc. on the Status of Implementation of Measures under Examination, etc. Measures Agreements)

Article 36-8 (1) When a prefectural governor, etc. finds it necessary, they may, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, request the manager of an organization engaged in the examination of Pathogens, etc. with which an examination, etc. measures agreement has been concluded to report the status of implementation of measures under the examination, etc. measures agreement and the status of operation of the organization, etc. pertaining to the measures and other matters.

(2) When a prefectural governor, etc. requests a report pursuant to the provisions of the preceding paragraph, an administrator of an organization engaged in the examination of Pathogens, etc. must promptly report the matters listed in the items of the same paragraph, except in cases where there are reasonable grounds.

(3) A prefectural governor who has received a report pursuant to the provisions of the preceding paragraph must make a report of the content of the report to the Minister of Health, Labour and Welfare, and the mayor of a city, etc. having a public health center who has received a report to the prefectural governor, by electronic or magnetic means (meaning a method using an electronic data processing system or any other method using information and communications technology specified by Order of the Ministry of Health, Labour and Welfare) and publicize it. In this case, the prefectural governor receiving the report must promptly report the contents of the report to the Minister of Health, Labour and Welfare.

(4) The Minister of Health, Labour and Welfare and the prefectural governor may, when they find it necessary, provide necessary advice or assistance to the prefectural governor and to the mayor of a city, etc. having a public health center respectively with regard to the matters prescribed in paragraph (1) for which a report pursuant to the provisions of the preceding paragraph has been received.

(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, publicize the contents of the report.

## **Section 2 Measures to Ensure Medical Care Levels at the Initial Period of an Epidemic, etc.**

(Measures to Ensure Medical Care Levels at the Initial Period of an Epidemic)

Article 36-9 (1) A prefectural governor is to, during the period from the month that includes the day on which the announcement of outbreaks, etc. pertaining to a Novel Influenza Infection, etc. was made until the month that includes the day on which the period specified by Cabinet Order has elapsed, in cases where it is recognized that a medical institution in the area of the prefectural government has taken the measures (hereinafter referred to as "medical care agreement, etc. measures" 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 providing medical care quickly and accurately from the early stage after the outbreak of a Novel Influenza Infection, etc., 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 fees for the medical institution (hereinafter referred to as the "target medical institution") in the month that includes the day on which the medical institution is deemed to have taken medical care agreement, etc. measures is less than the amount calculated pursuant to the provisions of a Cabinet Order as the amount of medical fees for the target medical institution in the month specified by a Cabinet Order prior to the announcement of outbreaks, etc. pertaining to a Novel Influenza Infection, etc., take measures (hereinafter referred to as "measures to ensure medical care levels at the initial period of an epidemic") to have the target medical institution pay the expenses required to ensure medical care levels at the initial period of an epidemic (hereinafter referred to as "expenses required to ensure medical care levels at the initial period of an epidemic").

(2) A prefectural governor may entrust the affairs pertaining to the measures to ensure medical care levels at the initial period of an epidemic pursuant to the provisions of the preceding paragraph to the Health Insurance Claims Review and Reimbursement Services (hereinafter referred to as "Reimbursement Services") or the Federation of National Health Insurance Associations (hereinafter referred to as "National Health Insurance Federation").

(Amount of Expenses Required to Ensure Medical Care Levels at the Initial Period of an Epidemic)

Article 36-10 Expenses required to ensure Medical Care Levels at the Initial Period of an Epidemic 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 fees of the target medical institution during the period from the month that includes the day on which the announcement of outbreaks,

etc. pertaining to a Novel Influenza Infection, etc. was made until the month that includes the day on which the period specified by Cabinet Order referred to in paragraph (1) of the preceding Article has elapsed, and the amount specified by Cabinet Order referred to in the same paragraph is to be the amount calculated pursuant to the provisions of a Cabinet Order as the difference between the amount of the medical fees of the target medical institution as calculated pursuant to the provisions of a Cabinet Order as set forth in the same paragraph in a month as prescribed in the Article.

(Payment of Expenses)

Article 36-11 A prefectural government is to pay expenses necessary for measures to ensure medical care levels at the initial period of an epidemic and expenses necessary for the execution of affairs concerning measures to ensure medical care levels at the initial period of an epidemic.

(National Government Grants)

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

(Subsidy to Ensure Medical Care Levels at the Initial Period of an Epidemic)

Article 36-13 (1) The amount equivalent to half of the cost required for measures to ensure medical care levels at the initial period of an epidemic paid by a prefectural government pursuant to the provisions of Article 36-11 is to be appropriated by a subsidy to ensure medical care levels at the initial period of an epidemic 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 set forth in the preceding paragraph is to be allocated from the contributions to ensure medical care levels at the initial period of an epidemic collected by the Reimbursement Services pursuant to the provisions of paragraph (1) of the following Article.

(Obligation for the Collection and Payment of Contribution to Ensure Medical Care Levels at the Initial Period of an Epidemic, etc.)

Article 36-14 (1) The Reimbursement Services, in order to allocate funds to the expenses required for the operations listed in the items of Article 36-25, paragraph (1) (excluding items (iii) and (iv)), during the period from the month that includes the day on which the announcement of outbreaks, etc. pertaining to a Novel Influenza Infection, etc. was made until the month that includes the day on which the period specified by Cabinet Order referred to in Article 36-9,

paragraph (1) has elapsed, for each month in which measures to ensure medical care levels at the initial period of an epidemic were implemented, is to collect contributions to ensure medical care levels at the initial period of an epidemic 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) set forth 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 set forth in Article 48 of the Act on Assurance of Medical Care for Elderly People (hereinafter referred to as "insurers, etc.").

(2) The Reimbursement Services is to collect contributions for administrative expenses related to ensure medical care levels at the initial period of an epidemic from insurers, etc. every fiscal year in order to allocate them to the expenses required for the administration of affairs related to the business listed in the items of Article 36-25, paragraph (1) (excluding items (iii) and (iv)).

(3) Insurers, etc. are to bear 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 (hereinafter referred to as "contributions to ensure medical care levels at the initial period of an epidemic, etc.").

(Amount of Contribution to Ensure Medical Care Levels at the Initial Period of an Epidemic)

Article 36-15 The amount of contributions to ensure medical care levels at the initial period of an epidemic to be collected from insurers, etc. 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 required for measures to ensure medical care levels at the initial period of an epidemic in the month in which the measures to ensure medical care levels at the initial period of an epidemic were implemented, during the period from the month that includes the day on which the announcement of outbreaks, etc. pertaining to a Novel Influenza Infection, etc. was made until the month that includes the day on 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 fees paid to a target medical institution by insurers, etc. pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Amount of Contributions for Administrative Expenses Related to Ensure Medical Care Levels At The Initial Period of An Epidemic)

Article 36-16 The amount of contributions for administrative expenses related to ensure medical care levels at the initial period of an epidemic to be paid by insurers, etc. 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 required for the administrative processing related to the duties 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 prescribed in Article 7, paragraph (4) of the Act on Assurance of Medical Care for Elderly People pertaining to insurers, etc. and insured persons of medical care for elderly people prescribed in Article 50 of the same Act, calculated pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Special Provisions on the Amount of Contribution to Ensure Medical Care Levels at the Initial Period of an Epidemic, etc. in the Case of the Merger, etc. of Insurers)

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

(Decision, Notification, etc. of Contribution to Ensure Medical Care Levels at the Initial Period of an Epidemic, etc.)

Article 36-18 (1) The Reimbursement Services must, for each month in which measures to ensure medical care levels at the initial period of an epidemic are implemented during the period from the month that includes the day on which the announcement of outbreaks, etc. pertaining to a Novel Influenza Infection, etc. was made until the month that includes the day on which the period specified by Cabinet Order referred to in Article 36-9, paragraph (1) has elapsed, determine the amount of contributions to ensure medical care levels at the initial period of an epidemic to be paid by insurers, etc., and notify the insurers, etc. of the amount of contributions to ensure medical care levels at the initial period of an epidemic to be paid by insurers, etc., the method of payment, the deadline for payment, and other necessary matters.

(2) The Reimbursement Services must determine, for each fiscal year, the amount of contribution for administrative expenses related to ensuring medical

care levels at the initial period of an epidemic to be paid by insurers, etc., and notify the insurers, etc. of the amount of contribution for administrative expenses related to ensuring early epidemic medical care to be paid by the insurers, etc., the method of payment, the deadline for payment, and other necessary matters.

- (3) When it becomes necessary to change the amount of contribution to ensure medical care levels at the initial period of an epidemic, etc. after the amount of contribution to ensure early epidemic medical care, etc. has been determined pursuant to the provisions of the preceding two paragraphs, the Reimbursement Services must change the amount of contribution to ensure medical care levels at the initial period of an epidemic, etc. to be paid by the insurer, etc. and notify the insurer, etc. of the amount of the contribution to ensure medical care levels at the initial period of an epidemic, etc. after the change.
- (4) The Reimbursement Services must, when the amount of contributions to ensure medical care levels at the initial period of an epidemic paid by insurers, etc. (hereinafter referred to as "amount paid" in this paragraph) is less than the amount of contributions to ensure medical care levels at the initial period of an epidemic after the change (hereinafter referred to as "amount after change" in this paragraph) pursuant to the provisions of the preceding paragraph, notify the method of payment, the time limit for payment, and other necessary matters concerning the shortfall amount with the notice pursuant to the provisions of the preceding paragraph, and, when the amount paid exceeds the amount after change, must appropriate the amount in excess for unpaid contributions to ensure medical care levels at the initial period of an epidemic, 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, etc. fails to pay the contribution to ensure medical care levels at the initial period of an epidemic, etc. by the due date, the Reimbursement Services must demand the payment by designating a due date.
- (2) When the Reimbursement Services makes a demand pursuant to the provisions of the preceding paragraph, it is to send a demand letter to the insurer, etc. In this case, the time limit to be specified by the reminder must be the day on which ten days or more have elapsed from the date on which the reminder is issued.
  - (3) When an insurer, etc. who has received a demand pursuant to the provisions of paragraph (1) fails to fully pay the contribution to ensure medical care levels at the initial period of an epidemic, etc. pertaining to the demand and the

delinquency charge pursuant to the provisions of the following Article by the designated time limit, 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) When the Reimbursement Services has demanded payment of the contribution to ensure medical care levels at the initial period of an epidemic, etc. 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 due date 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 amount of the contribution to ensure medical care levels at the initial period of an epidemic, etc. pertaining to the demand; provided, however, that this does not apply when the amount of the contribution to ensure early epidemic medical care, etc. pertaining to the demand is less than 1,000 yen.

- (2) In the case referred to in the preceding paragraph, if a part of the amount of the contribution to ensure medical care levels at the initial period of an epidemic, etc. has been paid, the amount of the contribution to ensure medical care levels at the initial period of an epidemic, etc., which is the basis of the calculation of the amount of the delinquency charge pertaining to the period after the date of the payment, is to be the amount after deducting the amount of the contribution to ensure early epidemic early medical care, etc. paid.

- (3) When the amount of the contribution to ensure medical care levels at the initial period of an epidemic, etc. set forth 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) Delinquency charges are not to be collected in any of the following cases; provided, however, that in the case referred to in item (iii), such execution is suspended or limited to the amount corresponding to the period under suspension:

- (i) when the person has fully paid the contribution to ensure medical care levels at the initial period of an epidemic, etc. by the time limit specified in

- the demand letter;
- (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 contribution to ensure medical care levels at the initial period of an epidemic, etc.; or
  - (iv) when it is found that there are unavoidable circumstances for not paying the contribution to ensure medical care levels at the initial period of an epidemic, etc.

(Grace of Payment)

Article 36-21 (1) In the event that, due to unavoidable circumstances, it is deemed extremely difficult for the insurer, etc. to pay the contribution to ensure medical care levels at the initial period of an epidemic, etc., 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 insurer, etc., and postpone part of the payment for a period not exceeding one year from the due date.

(2) The Reimbursement Services must, when granting a suspension pursuant to the provisions of the preceding paragraph, notify the insurer, etc. of the amount of the contribution to ensure medical care levels at the initial period of an epidemic, etc. pertaining to the postponement, the period 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 the same Article with regard to the contribution to ensure medical care levels at the initial period of an epidemic, etc. pertaining to the postponement during the period of the postponement.

(Collection of Reports, etc.)

Article 36-22 (1) The Minister of Health, Labour and Welfare or the prefectural governor may, when they find it necessary for the calculation of the amount of the contribution to ensure medical care levels at the initial period of an epidemic, etc., request insurers, etc. for reports on their business 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 Required to Ensure Medical Care Levels at the Initial Period of an Epidemic)

Article 36-23 (1) Target medical institutions, during the period from the month that includes the day on which the announcement of outbreaks, etc. pertaining to a Novel Influenza Infection, etc. was made, until the month that includes the day on which the period specified by Cabinet Order referred to in Article 36-9, paragraph (1) has elapsed, if the total amount of the medical fees of the target medical institutions and the income related to the expenses required for ensuring medical care levels at the initial period of an epidemic implemented in the month of the outbreak, and other income specified by Cabinet Order, exceed the amount calculated as the amount of the medical fees of the target medical institutions in the month specified by the same Cabinet Order, must return the difference to the prefectural government as an amount specified by Cabinet Order (hereinafter referred to 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, etc. in accordance with the amount of the contributions to ensure medical care levels at the initial period of an epidemic collected from the insurer, etc. pursuant to the provisions of Article 36-14, paragraph (1).

(3) A prefectural government may entrust the affairs pertaining to the return of money pursuant to the provisions of paragraph (1) and the affairs pertaining to the return to the insurer, etc. 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 expenses required to ensure medical care levels at the initial period of an epidemic prescribed in paragraph (1). In this case, any necessary technical replacement of terms is to be specified by Cabinet Order.

(Reimbursement of Expenses Required to Ensure Medical Care Levels at the Initial Period of an Epidemic)

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 required to ensure medical care levels at the initial period of an epidemic 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 required to ensure medical care levels at the initial period of an epidemic 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 business 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 business (hereinafter referred to as "services related to measures to ensure medical care levels at the initial period of an epidemic"):

- (i) collecting the contribution to ensure medical care levels at the initial period of an epidemic, etc. from insurers, etc.;
  - (ii) granting a subsidy to ensure medical care levels at the initial period of an epidemic to prefectural governments;
  - (iii) conducting affairs pertaining to measures to ensure medical care levels at the initial period of an epidemic entrusted by the prefectural governor pursuant to the provisions of Article 36-9, paragraph (2);
  - (iv) conducting affairs pertaining to the return of 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 pertaining to the return of money to insurers, etc., and affairs pertaining to the return of expenses required to ensure medical care levels at the initial period of an epidemic; and
  - (v) conducting business incidental to the business 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 medical care levels at the initial period of an epidemic 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 a statement of operation procedures and obtain approval from the Minister of Health, Labour and Welfare prior to commencing the services related to measures to ensure medical care levels at the initial period of an epidemic. The same applies when this is changed.

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

(Reports, etc.)

Article 36-27 The Reimbursement Services, in addition to requesting insurers, etc. to report on the number of policyholders and other matters specified by Order of the Ministry of Health, Labour and Welfare every fiscal year, may, when it finds it necessary for the business 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 pertaining to services related to measures to ensure medical care levels at the initial period of an epidemic, separate from accounting pertaining to other business.

(Approval of Budget, etc.)

Article 36-29 The Reimbursement Services must prepare a budget, business plan and financial plan for each business year with regard to the services related to measures to ensure medical care levels at the initial period of an epidemic, and prior to the start of the relevant business year, obtain approval from the Minister of Health, Labour and Welfare. The same applies when this is changed.

(Financial Statements, etc.)

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

(2) When submitting financial statements 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 to it the business report and the settlement of accounts prepared in accordance with the budgetary divisions for the business year, as well as the auditor's written opinion on the financial statements and settlement of accounts.

(3) The Reimbursement Services must, when it has obtained approval from the Minister of Health, Labour and Welfare pursuant to the provisions of paragraph (1), make a public notice of the financial statements or the gist thereof 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 set forth in the preceding paragraph must be kept at the principal 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 business year, with regard to the services related to measures to ensure medical care levels at the initial period of an epidemic, when profits have been generated in the calculation of profit and loss, the Reimbursement Services must compensate for the losses carried over from the previous business year, and if there is any residual amount, the amount of the residual amount must be arranged as a reserve fund.
- (2) In each business year, when a loss is incurred in the calculation of profit and loss with regard to the services related to measures to ensure medical care levels at the initial period of an epidemic, the Reimbursement Services must arrange 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 arranged as a loss carried forward.
- (3) The Reimbursement Services may allocate the reserve under paragraph (1) to the expenses required for the business 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 obtaining the approval of the Minister of Health, Labour and Welfare, borrow long-term or short-term borrowings or issue bonds with regard to the services related to measures to ensure medical care levels at the initial period of an epidemic.
- (2) Long-term borrowings and bonds pursuant to the provisions of the preceding paragraph must be redeemed within two years.
- (3) Short-term borrowings pursuant to the provisions of paragraph (1) must be redeemed within the relevant business 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) Short-term borrowings refinanced pursuant to the provisions of the proviso to the preceding paragraph must be redeemed within one year.
- (5) In cases where the Reimbursement Services issues bonds pursuant to the provisions of paragraph (1), the Reimbursement Services may use the method of 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 set forth 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) The Reimbursement Services may, with the authorization of the Minister of Health, Labour and Welfare, 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 set forth in paragraph (1) are to be specified by Cabinet Order.

(Government Guarantees)

Article 36-33 Notwithstanding 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 the grants to ensure medical care levels at the initial period of an epidemic by the Reimbursement Services and for the implementation of the affairs set forth in Article 36-25, paragraph (1), item (iii), within the limit 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 in the course of services related to measures to ensure medical care levels at the initial period of an epidemic at the initial period of an epidemic, 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 set forth 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 set forth 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 pertaining to the services related to measures to ensure medical care levels at the initial period of an epidemic are to be prescribed by Order of the Ministry of Health, Labour and Welfare.

(Collection of Reports, etc.)

Article 36-37 (1) The Minister of Health, Labour and Welfare or the prefectural governor may collect reports on the status of the operations or property of the Reimbursement Services or the person entrusted pursuant to the provisions of Article 36-25, paragraph (2) (hereinafter referred to 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 medical care levels at the initial period of an epidemic; 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 medical care levels at the initial period of an epidemic or finds it necessary to carry out a disposition under the provisions of Article 11, paragraph (2) or paragraph (3) of the same Act with regard to services related to measures to ensure medical care levels at the initial period of an epidemic for the president, director or auditor of the Reimbursement Services, the prefectural governor must notify the Minister of Health, Labour and Welfare to that effect with the reasons attached.

(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 medical care levels at the initial period of an epidemic are deemed to be the business prescribed in Article 15 of the same Act.

(Requests for Administrative Review)

Article 36-39 A person who is dissatisfied with the disposition of the Reimbursement Services under this Act or the inaction thereof may file an application for examination with the Minister of Health, Labour and Welfare. In this case, the Minister of Health, Labour and Welfare is to deem the application of 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 to be the higher administrative authority of the Reimbursement Services.

(Delegation to 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 medical care levels at the initial period of an epidemic are to be prescribed by Order of the Ministry of Health, Labour and Welfare.

### **Section 3 Medical Services, etc. 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 bear the following expenses for medical services received by the patient (including a person with symptoms of a New Infectious Disease; the same applies hereinafter 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 such expenses:

- (i) diagnosis;
- (ii) supply of medicines or therapeutic materials;
- (iii) medical procedures, surgery and other therapy; and
- (iv) caring and other nursing incidental to 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 deemed to be capable of paying the expenses referred to in paragraph (1) in whole or in part, the prefectural government is not required

to bear the expenses under the provisions of the same paragraph to the extent the person is capable, notwithstanding the provisions of the same 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 impose all or part of the burden pursuant to the provisions of the same paragraph, notwithstanding 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 bear all or part of the expenses set forth in paragraph (1).
- (4) An application referred to in paragraph (1) must be filed with the prefectural governor via the chief of the public health center who has jurisdiction over the place of residence of the patient.

(Medical Services for Tuberculosis Patients)

Article 37-2 (1) For the purpose of widespread development of proper medical care for tuberculosis, a prefectural government may, upon receipt of an application filed by a tuberculosis patient residing in any area under the prefecture's jurisdiction or their custodian, bear 95% of the expenses required 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 via the chief of the public health center who has 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 Diseases examination committee prescribed in Article 24, paragraph (1) established in the public health center.
- (4) When six months have passed since the filing of an application referred to in paragraph (1), the payment of the expenses by the prefectural government based on the application are to be discontinued.

(Designated Medical Institutions for Infectious Diseases)

Article 38 (1) Designated Medical Institutions for Specified Infectious Diseases are to be designated by the Minister of Health, Labour and Welfare, subject to

the consent of the establisher of the respective medical institution, and further subject to consultations with the prefectural governor who has jurisdiction over the location of the medical institution.

- (2) The Designated Medical Institutions for Class I Infectious Diseases, Designated Medical Institutions for Class II Infectious Diseases, Designated Medical Institutions for Class I Agreement, Designated Medical Institutions for Class II Agreement, and Designated Medical Institutions for Tuberculosis are to be designated by a prefectural governor, subject to the consent of the establisher of the respective medical institution, which is to be selected from the hospitals (hospitals or clinics in the case of Designated Medical Institutions for Class I Agreement, and hospitals, clinics or pharmacies in the case of Designated Medical Institutions for Class II Agreement and Designated Medical Institutions 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, the Designated Medical Institutions 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 bears 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 of a Class I Infectious Disease, a Class II Infectious Disease or a Novel Influenza Infection, etc., the Designated Medical Institutions 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 of a Class I Infectious Disease, a Class II Infectious Disease or a Novel Influenza Infection, etc., the Designated Medical Institutions 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 of a Class II Infectious Disease or a Novel Influenza Infection, etc., the Designated Medical Institutions 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 of a

Novel Influenza Infection, etc. or a Designated Infectious Disease and persons with symptoms of a New Infectious Disease, the Designated Medical Institutions 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) Designated Medical Institutions 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 set forth in Article 44-3-2, paragraph (1) (including the 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, the Designated Medical Institutions 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 to that effect at least one year (or 30 days, in case of a Designated Medical Institution for Tuberculosis) prior to the date of declination, to the Minister of Health, Labour and Welfare in cases of Designated Medical Institutions for Specified Infectious Diseases, or to the prefectural governor in cases of Designated Medical Institutions for Class I Infectious Diseases, Designated Medical Institutions 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 Institutions for Tuberculosis.
- (11) If a Designated Medical Institution for Infectious Diseases violates any provisions of paragraphs (3) through (9), or is otherwise deemed to be incompetent in providing the medical services prescribed in the preceding two Articles, the Minister of Health, Labour and Welfare may rescind the designation of the institution if it is a Designated Medical Institution for Specified Infectious Diseases, or the prefectural governor may rescind the designation of the institution if it is a Designated Medical Institution for Class I Infectious Diseases, a Designated Medical Institutions 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 Institutions 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 payment 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 bear the expenses under the provisions of Article 37, paragraph (1) or Article 37-2, paragraph (1) to the extent covered by the benefits granted under the foregoing laws.

(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 payment 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 the same Act will not be made to the extent covered by the expenses borne by the prefectural government for that patient.

(Claims for, and Examination and Payment of Medical Fees)

Article 40 (1) Designated Medical Institutions for Infectious Diseases are to claim the portion of medical fees 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 governor.

(2) Prefectural governments must pay the expenses referred to in the preceding paragraph to the Designated Medical Institutions for Infectious Diseases.

(3) Prefectural governors may from time to time examine the content of medical care provided and the medical fees claimed by the Designated Medical Institutions for Infectious Diseases, and decide the amounts of medical fees which the respective Designated Medical Institutions for Infectious Diseases are entitled to claim under the provisions of paragraph (1).

(4) Designated Medical Institutions 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 fees 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 medical fees review committee provided for in the National Health Insurance Act, and other reviewing bodies for medical care issues as specified by Cabinet Order.

- (6) Prefectural governments 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 fees to the Designated Medical Institutions for Infectious Diseases.
- (7) A request for administrative review may not be filed with regard to any decision on the amounts of medical fees under the provisions of paragraph (3).

(Standards for Medical Fees)

Article 41 (1) The medical fees payable for the medical services set forth 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 the Designated Medical Institutions for Infectious Diseases are governed by the rules applicable to the medical fees for health insurance.

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

(Special Provisions for Medical Services in Emergencies)

Article 42 (1) If a patient (including a person with symptoms of a New Infectious Disease; hereinafter the same applies 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) ; hereinafter the same applies in this paragraph) or pursuant to the provisions of Article 46 has received the medical services set forth 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; hereinafter the same applies 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 Institutions 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 such medical treatment in an amount calculated in the same way

as applicable to the amount to be borne under the provisions of Article 37, paragraph (1) or Article 37-2, paragraph (1). The same applies when such 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 set forth 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 deemed to have been truly necessary at the time the patient received them.

(Requests for Reports and Inspections)

Article 43 (1) If deemed necessary for the purpose of ensuring that the expenses prescribed in Article 37, paragraph (1) and Article 37-2, paragraph (1) are properly borne, the prefectural governor (or either the Minister of Health, Labour and Welfare or the prefectural governor, with regard to the Designated Medical Institutions for Specified Infectious Diseases; hereinafter the same applies 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 check the records of medical services and other books and documents (including electronic or magnetic records (which means 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 the same paragraph without reasonable grounds, the prefectural governor may instruct temporary suspension of, or suspend the payment of medical fees to, the Designated Medical Institution for Infectious Diseases.

(Delegation to 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 fees and for entrustment of affairs for processing such payments referred to in Article 40, and other necessary matters related to the payment of expenses prescribed in this Section are specified by Order of the Ministry of Health, Labour and Welfare.

## **Chapter VII Novel Influenza Infection**

(Publication of Information on the Outbreak of Novel Influenza Infection and Measures to Be Implemented)

Article 44-2 (1) When the Minister of Health, Labour and Welfare recognizes the outbreak of a Novel Influenza Infection, etc., the Minister must promptly publicize to that effect and the area facing the outbreak, while publicizing the information on that Infectious Disease pursuant to the provisions of Article 16, paragraph (1), and sequentially publicizing the means of examining the pathogen, pathological conditions, means of diagnosis and medical treatment, and means of infection prevention, measures to be implemented pursuant to the provisions of this Act, and other information necessary for the prevention of the outbreak or spread of that Infectious Disease in newspapers, by broadcasting, via the Internet, or by any other appropriate means.

(2) In the publication of the information under the provisions of the preceding paragraph, due regard must be paid to protect personal information.

(3) If the Infectious Disease which is the subject of the information publicized pursuant to the provisions of paragraph (1) is no longer recognized as a Novel Influenza Infection, etc. because a large majority of the public have acquired immunity to that Infectious Disease or due to any other reason, the Minister of Health, Labour and Welfare must promptly make this public.

(Reporting or Cooperation in the Prevention of Infection)

Article 44-3 (1) When a prefectural governor deems it necessary for the purpose of preventing the spread of a Novel Influenza Infection, etc., the prefectural governor may request a person who is suspected to be infected with that Infectious Disease on reasonable grounds to report their body temperature and other health conditions, or request the person to refrain from leaving their residence or other equivalent place or otherwise provide cooperation necessary for preventing transmission of that Infectious Disease during the period to be specified in light of 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 deems it necessary for the purpose of preventing the spread of a Novel Influenza Infection, etc. (limited to those specified by Order of the Ministry of Health, Labour and Welfare in consideration of 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 health conditions, 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 appropriate for preventing the spread of the Infectious Disease; The same applies in paragraph (11) and paragraph (1) of the same Article) or their residence or other equivalent place or otherwise provide cooperation necessary for preventing 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 where 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 deemed appropriate by the prefectural governor.
- (5) A prefectural governor may entrust the implementation of a 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 set forth in item (iii) of the same 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 set forth in the same item)) or any other person deemed appropriate by the prefectural governor.
- (6) A person entrusted pursuant to the provisions of the preceding two paragraphs must report the content of the report pursuant to the provisions of paragraph (1) or paragraph (2) to the prefectural governor who made the entrustment.
- (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 goods or services necessary for daily life (hereinafter referred to 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, as necessary, make a request for cooperation to the mayor of the municipality.
- (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 with justifiable grounds to suspect that they have a Novel Influenza Infection, etc. on a patient with a Novel Influenza Infection, etc. 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 Influenza Infection, etc. prescribed in the same paragraph within the area under the jurisdiction of the prefectural governor and the situation of the occurrence and spread of the Infectious Disease.

(Medical Services for Persons Subject to Voluntary Restraint Due to a Novel Influenza Infection, etc.)

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 Influenza Infection, etc. (hereinafter referred to as "person subject to voluntary restraint due to a Novel Influenza Infection, etc.") who is requested to cooperate in not going out of their accommodation facility, their residence, or other equivalent place thereto pursuant to the provisions of paragraph (2) of the preceding Article, or their custodian, the prefectural government is to bear the expenses required for medical services specified by Order of the Ministry of Health, Labour and Welfare that persons subject to voluntary restraint due to a Novel Influenza Infection, etc. receive from a Designated Medical Institution for Class II Agreement.

- (2) The provisions of Article 37, paragraph (2) apply mutatis mutandis to the burden set forth in the preceding paragraph, the provisions of paragraph (4) of the same Article apply mutatis mutandis to the application set forth in the preceding paragraph, and the provisions of Articles 39 through 41 and Article 43 apply mutatis mutandis to the case set forth in the same paragraph.

(Special Provisions for Emergency, etc. Medical Services for Persons Subject to Voluntary Restraint Due to a Novel Influenza Infection, etc.)

Article 44-3-3 (1) Except for the cases specified by Order of the Ministry of

Health, Labour and Welfare, if persons subject to voluntary restraint due to a Novel Influenza Infection, etc. who live in the area receive 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 borne pursuant to the provisions of the same paragraph at the application of persons subject to voluntary restraint due to a Novel Influenza Infection, etc. or their custodian. The same applies in cases where the persons subject to voluntary restraint due to a Novel Influenza Infection, etc. receive the medical services prescribed by Order of the Ministry of Health, Labour and Welfare as referred to in the same paragraph from a Designated Medical Institution for Class II Agreement in the same paragraph, and the medical services has been provided without filing the application set forth in the same 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 persons subject to voluntary restraint due to a Novel Influenza Infection, etc. only if the medical services are deemed to have been truly necessary at the time the patient received them.

(Delegation to 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 burden of expenses prescribed in this Chapter are to be specified by Order of the Ministry of Health, Labour and Welfare.

(Requests, etc. for Submission of Specimens of a Novel Influenza Infection, etc.)

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 Influenza Infection, etc. and the severity of pathological conditions when infected with the Infectious Disease and other necessary information during the period from the case where the announcement pursuant to the provisions of Article 44-2, paragraph (1) to the case where the announcement pursuant to the provisions of paragraph (3) of the same Article, 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 of the patient with the Infectious Disease.

- (2) The Minister of Health, Labour and Welfare is to, when the Minister has made a request pursuant to the provisions of the preceding paragraph, notify the prefectural governor (if the location is within a city, etc. having a public health center, the mayor of the city, etc. having a public health center who has jurisdiction over the location; the same applies in the following paragraph and paragraph (5)) who has jurisdiction over the location of the person who received the request to that effect.
- (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 set forth in the same 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, etc. having a public health center, the Minister and the prefectural governor who has jurisdiction over the area of the city, etc. having a public health center).
- (5) When the Minister of Health, Labour and Welfare deems 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 Influenza Infection, etc." in paragraph (1) of the same Article is deemed to be replaced with "a Novel Influenza Infection, etc.," and the term "the specimens or pathogens of the Infectious Disease prescribed in the relevant item" in the same paragraph and paragraph (3) of the same Article is deemed to be replaced with "the specimens or pathogens of a Novel Influenza Infection, etc."

(Notification of Discharge, etc. of Patients with a Novel Influenza Infection, etc.)

Article 44-3-6 If a patient with a Novel Influenza Infection, etc. 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 file a notification with the prefectural governor who has jurisdiction over the location of the Designated Medical Institution for Infectious Diseases and the Minister of Health (or, if the location is within the area of a city, etc. having a public health center, the mayor of the city, etc. having a public health center, prefectural governor and the Minister) by electronic or magnetic means regarding the matters specified by Order of the Ministry of Health, Labour and Welfare about the patient.

(Application of Provisions for Measures Taken for Buildings)

- Article 44-4 (1) If deemed particularly necessary for the purpose of preventing the outbreak or spread of a Novel Influenza Infection, etc., 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 pertaining 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 not longer than one year specified by Cabinet Order if it is deemed particularly necessary to continue applying the provisions which apply to the referenced Infectious Disease under the Cabinet Order referred to in the same 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 such period.
- (3) When the Minister of Health, Labour and Welfare intends to propose to establish, revise or abolish 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 abolished.
- (4) In the case referred to in the proviso of the preceding paragraph, the Minister of Health, Labour and Welfare must promptly report the content of its proposed draft of the Cabinet Order to the Health Science Council.

(Assistance, etc. by Other Prefectural Governors, etc.)

- Article 44-4-2 (1) A prefectural governor may, during the period from the announcement pursuant to the provisions of Article 44-2, paragraph (1) to the announcement pursuant to the provisions of paragraph (3) of the same Article,

request other prefectural governors for support in securing physicians, nurses, and other medical personnel responsible for treating patients with Novel Influenza Infections, etc. (hereinafter referred to as "medical care personnel for Novel Influenza Infections, etc." in this Article and the following Article), or physicians, nurses, and other medical-related personnel engaged in work related to ensuring the system to provide medical care to prevent outbreaks and the spreading of Novel Influenza Infections, etc. (excluding medical care personnel for Novel Influenza Infections, etc.; hereinafter referred to as "relevant persons to the prevention of Novel Influenza Infections, etc." 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 Influenza Infections, etc. during the period from the announcement pursuant to the provisions of Article 44-2, paragraph (1) to the announcement pursuant to the provisions of paragraph (3) of the same Article, when all of the following items apply:

(i) it is found that it is difficult to secure medical care personnel for Novel Influenza Infections, etc. even if measures based on a notice (limited to a notice that includes the measures set forth in item (v) of the same 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 such an agreement (limited to a medical care agreement that includes the measures set forth in the same item) are appropriately 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 Influenza Infection, etc.;

(iii) it is found that support by other prefectural governors for securing medical care personnel for Novel Influenza Infections, etc. cannot be smoothly implemented only by the 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 the outbreak or spread of a Novel Influenza Infection, etc. during the period from the announcement pursuant to the provisions of Article 44-2, paragraph (1) to the announcement pursuant to the provisions of paragraph (3) of the same Article, and if the prefectural governor finds that support by other prefectural governors

pertaining to securing relevant persons to the prevention of Novel Influenza Infections, etc. will not be smoothly implemented only by the 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 to the prevention of Novel Influenza Infections, etc.

- (4) In cases where the Minister of Health, Labour and Welfare has received a request for 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 outbreak of a Novel Influenza Infection, etc. throughout the country, the content 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 Influenza Infections, etc. or relevant persons to the prevention of Novel Influenza Infections, etc.
- (5) Beyond what is provided for in the preceding paragraph, even in cases where the Minister of Health, Labour and Welfare does not request the coordination of support under paragraph (2) or paragraph (3) if the Minister finds it urgently necessary to coordinate support for securing human resources on a wide-area basis in order to prevent the spread of a Novel Influenza Infection, etc., in comprehensive consideration of the situation and trends of the outbreak of a Novel Influenza Infection, etc. on a nationwide basis, during the period from the case where the announcement pursuant to the provisions of Article 44-2, paragraph (1) to the case where the announcement pursuant to the provisions of paragraph (3) of the same Article, the Minister may request the prefectural governor for support in securing medical care personnel for Novel Influenza Infections, etc. or relevant persons to the prevention of Novel Influenza Infections, etc.
- (6) During the period from the case where the announcement pursuant to the provisions of Article 44-2, paragraph (1) to the case where the announcement pursuant to the provisions of paragraph (3) of the same Article, when the Minister of Health, Labour and Welfare finds it particularly urgently necessary for the support in securing human resources over a wide area in light of the situation of the spread of a Novel Influenza Infection, etc., in comprehensive consideration of the situation, trends, and other circumstances of the outbreak of a Novel Influenza Infection, etc. on a nationwide basis, the Minister may request public medical institutions, etc. and other medical institutions specified by Order of the Ministry of Health, Labour and Welfare for support in securing medical care personnel for Novel Influenza Infections, etc. or relevant

persons to the prevention of Novel Influenza Infections, etc. 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.

(Burden of Expenses Required for Support When Receiving Assistance from Other Prefectural Governors, etc.)

Article 44-4-3 A prefectural government that has received support for securing medical care personnel for Novel Influenza Infections, etc. or relevant persons to the prevention of Novel Influenza Infections, etc. from other prefectural governors, public medical institutions, etc., 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 bear the expenses required for the support.

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

Article 44-5 (1) During the period from the case where the announcement pursuant to the provisions of Article 44-2, paragraph (1) to the case where the announcement pursuant to the provisions of paragraph (3) of the same Article, when the Minister of Health, Labour and Welfare deems it necessary for the purpose of preventing the spread of Infectious Diseases to go beyond the area of the prefectural government to secure human resources for the prevention of Novel Influenza Infections, etc. 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), 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) A prefectural governor may, when the prefectural governor finds it necessary, 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 the same paragraph when deemed 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 the same 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 Influenza Infection, etc. implemented by the prefectural governors, medical institutions and other relevant persons.

- (5) The Minister of Health, Labour and Welfare, when carrying out comprehensive coordination pursuant to the provisions of paragraph (1), 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 of the Progress of Novel Influenza Infections, etc.)

Article 44-6 (1) When a prefectural governor has conducted any affairs concerning a Novel Influenza Infection, etc. under the provisions of this Act or any Cabinet Order based on this Act, the prefectural governor must report their content 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 the same Article in connection with a Novel Influenza Infection, etc.

## **Chapter VII-2 Designated Infectious Diseases**

(Publication 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 when infected with a Designated Infectious Disease is serious and there is a risk of a nationwide rapid spread, the Minister must promptly publicize to the effect, and while publicizing the information on that Designated Infectious Disease pursuant to the provisions of Article 16, paragraph (1), and sequentially publicizing the means of examining the pathogen, pathological conditions, means of diagnosis and medical treatment, and means 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 appropriate means.

- (2) In the publication of the information under the provisions of the preceding

paragraph, due regard must be paid to protect personal information.

- (3) If the Designated Infectious Disease which is the subject of the information publicized 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 have acquired immunity to that Designated Infectious Disease or due to any other reason, the Minister of Health, Labour and Welfare must promptly make this 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 Influenza Infections, etc." 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 to the prevention of Novel Influenza Infections, etc." in the same Article is deemed to be replaced with "relevant persons to the prevention of Designated Infectious Diseases," the term "secure human resources for the prevention of Novel Influenza Infections, etc. 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 the prevention of Novel Influenza Infections, etc.," 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 the period not longer than one year specified by Cabinet Order.

- (2) The period specified by Cabinet Order as referred to in the preceding paragraph may be extended for a period not longer than one year as specified by Cabinet Order if it is deemed 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 the same 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 abolish 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**

(Publication 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 the outbreak of a New Infectious Disease, the Minister must promptly publicize to that effect and the area facing the outbreak, while publicizing the information on that New Infectious Disease pursuant to the provisions of Article 16, paragraph (1), and sequentially publicizing the means of examining the pathogen, pathological conditions, means of diagnosis and medical treatment, and means of infection prevention, measures to be implemented pursuant to the provisions of this Act, and other information necessary for the prevention of the outbreak or spread of the New Infectious Disease in newspapers, by broadcasting, via the Internet, or by any other appropriate means.

(2) In the publication of the information under the provisions of the preceding paragraph, due regard must be paid to protect personal information.

(Collection of Specimens of New Infectious Diseases)

Article 44-11 (1) When a prefectural governor deems it necessary for the purpose of preventing the spread of a New Infectious Disease, the prefectural governor may recommend that the person set forth in Article 15, paragraph (3), item (iii) submit the specimens prescribed in the same item or accept the collection of the specimens by relevant officials, or recommend that the person's custodian submit the specimens or have the person accept the collection of the specimens 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 pathogens of the New Infectious Disease separated from the specimens which are the subject of the intended recommendation; hereinafter the same applies 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 deems it particularly necessary for the purpose of preventing the spread of a New Infectious Disease, the Minister may recommend that the person set forth in Article 15, paragraph (3), item (iii) submit the specimens prescribed in the same item or accept the collection of the specimens by relevant officials, or recommend that the person's custodian submit the specimens or have the person accept the collection of the specimens 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 referenced officials to collect the specimens prescribed in Article 15, paragraph (3), item (iii) from the person set forth in the same 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 referenced officials to collect the specimens prescribed in Article 15, paragraph (3), item (iii) from the person set forth in the same item who is the subject of the recommendation.
- (5) Prefectural governors must conduct an examination of the specimens which were submitted in accordance with the provisions of paragraph (1) or which the referenced officials collected thereunder, or the specimens collected by the referenced 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 deems 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 referenced officials collected thereunder, or a part of the specimens collected by the referenced officials based on the prefectural governor's direction under the provisions of paragraph (3).
- (8) When a prefectural governor deems it particularly necessary for the purpose of recommending the submission or collection of the specimens under the provisions of paragraph (1), directing relevant officials to implement a measure of collecting the specimens under the provisions of paragraph (3), or examining 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 Diseases Research Institute and to provide other necessary cooperation.

(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 of 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 deems it necessary for the purpose of preventing the spread of a New Infectious Disease, the prefectural governor may recommend that a person who is suspected to be infected with the New Infectious Disease on reasonable grounds 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 suspected to be infected with the New Infectious Disease who is the subject of the recommendation on reasonable grounds.

(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 of 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 deems it necessary for the purpose of preventing 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 in consideration of the severity of pathological conditions), limited to those specified by Order of the Ministry of Health, Labour and Welfare, taking into consideration the pathological condition of the New Infectious Disease or the

risk of the severity of pathological conditions when infected with the New Infectious Disease will become 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 other than a Designated Medical Institution for Specified Infectious Diseases or a Designated Medical Institution for Class I Agreement, as deemed appropriate by the prefectural governor.

- (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 the same paragraph, in a hospital or clinic other than a Designated Medical Institution for Specified Infectious Diseases or a Designated Medical Institution for Class I Agreement, as deemed appropriate by the prefectural governor) 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 other than those in which the person is currently hospitalized, as deemed appropriate by the prefectural governor, 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 deems 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 appropriate explanations to the person with symptoms of the New Infectious Disease or their custodian and endeavor to gain their understanding, 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 such opportunity to express 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.

(Transfer of 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 hospitalized pursuant to the provisions of the preceding Article to the hospital in which the hospitalization is made.

(Discharge of 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 the New Infectious Disease for which the hospitalization was made to the public, 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 to the effect that the person is unlikely to spread to the public the New Infectious Disease for which the hospitalization was made.

(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) Upon receipt of 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 the hospitalization was made.

(Minimum Necessary Measures)

Article 48-2 The measures implemented pursuant to the provisions of Articles 44-11 through 47 must be the minimum necessary for the purpose of preventing the outbreak or spread of a New Infectious Disease in light of risks of spreading the New Infectious Disease to the public, the severity of

pathological conditions when infected 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 hospitalization measures prescribed in paragraph (2) or (3) of the same Article, or extends the period of hospitalization prescribed in paragraph (4) of the same 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 deems it necessary for the purpose of preventing 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 the same 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 the same 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 the same 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 deems it particularly necessary for the purpose of preventing the outbreak or 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 the same 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 the same Article apply mutatis mutandis when the Minister of Health, Labour and Welfare directs relevant officials to implement a measure prescribed in paragraph (1) of the same Article as applied mutatis mutandis in paragraph (4) of the same 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 the same Article apply mutatis mutandis when the Minister of Health, Labour and Welfare implements or directing 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 deems it necessary for the purpose of preventing the outbreak or 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 the same 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 the same Article apply mutatis mutandis when a mayor of a municipality directs relevant officials to implement a measure prescribed in paragraph (1) of the same Article as applied mutatis mutandis in paragraph (5) of the same 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 the same 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 for the purpose of preventing the outbreak or spread of a New Infectious Disease.

(Reporting or Cooperation in the Prevention of Infection)

Article 50-2 (1) When a prefectural governor deems it necessary for the purpose of preventing the spread of a New Infectious Disease, the prefectural governor may request a person who is suspected to be infected with that New Infectious Disease on reasonable grounds to report their body temperature and other health conditions, or request the person to refrain from leaving their residence or other equivalent place or otherwise provide cooperation necessary for preventing transmission of that New Infectious Disease during the period to be specified in light of 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 deems it necessary for the purpose of preventing the spread of a New Infectious Disease (limited to those specified by Order of the Ministry of Health, Labour and Welfare in consideration of 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 health conditions, 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 appropriate for preventing the spread of the New Infectious Disease) or their residence or other equivalent place or otherwise provide cooperation necessary for preventing 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 to the request, except where 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 Influenza Infection, etc." in paragraph (10) of the same Article is deemed to be replaced with "a New Infectious Disease," the term "paragraph (2)" in the same paragraph is deemed to be replaced with "Article 50-2, paragraph (2)," the term "patients with a Novel Influenza Infection, etc." in the same paragraph and paragraph (11) of the same Article is deemed to be replaced with "persons with symptoms of a New Infectious Disease," the term "the same paragraph" in the same paragraph is deemed to be replaced with "Article 50-2, paragraph (2)," the term "Infectious Disease" in the same paragraph is deemed to be replaced with "New Infectious Disease," and the term "accommodation facilities" in the same paragraph is deemed to be replaced with "accommodation facilities prescribed in the same 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 (hereinafter referred to 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 any place equivalent thereto pursuant to the provisions of paragraph (2) of the preceding Article, or their custodian, the prefectural government is to bear the expenses required for 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 burden set forth in the preceding paragraph, the provisions of paragraph (4) of the same Article apply mutatis mutandis to the application set forth in the preceding paragraph, and the provisions of Articles 40, Article 41, and Article 43 apply mutatis mutandis to the case set forth in the same paragraph.

(Special Provisions for Emergency, etc. 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 persons subject to voluntary restraint due to New

Infectious Diseases who live in the area receive 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 borne pursuant to the provisions of the same paragraph at the application of persons subject to voluntary restraint due to New Infectious Diseases or their custodian. The same applies in cases where the persons subject to voluntary restraint due to a New Infectious Disease receive 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 has been provided without filing the application set forth in the same 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 persons subject to voluntary restraint due to New Infectious Diseases only if the medical services are deemed to have been truly necessary at the time the patient received them.

(Delegation to 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 burden of expenses prescribed in this Chapter are to be specified by Order of the Ministry of Health, Labour and Welfare.

(Requests, etc. 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 when infected with the New Infectious Disease and other necessary information during the period from the case where the announcement pursuant to the provisions of Article 44-10, paragraph (1) to the case where it is abolished by Cabinet Order pursuant to the provisions of Article 53, paragraph (1), 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 of persons with symptoms of the New Infectious Disease.

- (2) The Minister of Health, Labour and Welfare is to, when the Minister has

made a request pursuant to the provisions of the preceding paragraph, notify the prefectural governor (if the location is within a city, etc. having a public health center, the mayor of the city, etc. having a public health center who has jurisdiction over the location; the same applies in the following paragraph and paragraph (5)) who has jurisdiction over the location of the person who received the request to that effect.

- (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 set forth in the same 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, etc. having a public health center, the Minister and the prefectural governor who has jurisdiction over the area of the city, etc. having a public health center).
- (5) When the Minister of Health, Labour and Welfare deems 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 Influenza Infection, etc." in paragraph (1) of the same 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 the same paragraph and paragraph (3) of the same Article is deemed to be replaced with "the specimens of persons with symptoms of a New Infectious Disease or pathogens of a New Infectious Disease."

(Notification of Discharge, etc. 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 file a notification with the prefectural governor who has jurisdiction over the location of the Designated Medical Institution for Infectious Diseases and

the Minister of Health (or, if the location is within the area of a city, etc. having a public health center, the mayor of the city, etc. having a public health center, prefectural governor and the Minister) by electronic or magnetic means regarding the matters specified by Order of the Ministry of Health, Labour and Welfare about the 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 content 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) Upon receipt of 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 for the purpose of ensuring 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 the same Article, pursuant to the provisions of Article 50, paragraph (10).

(Assistance, etc. by Other Prefectural Governors, etc.)

- Article 51-2 (1) A prefectural governor may, during the period from the announcement pursuant to the provisions of Article 44-10, paragraph (1) until the abolition of the Cabinet Order in Article 53, paragraph (1), request other prefectural governors for support in securing physicians, nurses, and other medical personnel responsible for treating persons with symptoms of New Infectious Diseases (hereinafter referred to as "medical care personnel for New

Infectious Diseases" in this Article and the following Article), or physicians, nurses, and other medical-related personnel engaged in work related to ensuring the system to provide medical care to prevent outbreaks and the spreading of the New Infectious Disease (excluding medical care personnel for New Infectious Diseases; hereinafter referred to as "relevant persons to the prevention of 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 announcement pursuant to the provisions of Article 44-10, paragraph (1) until the abolition of the Cabinet Order in Article 53, paragraph (1), 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 set forth in item (v) of the same 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 such an agreement (limited to a medical care agreement that includes the measures set forth in the same item) are appropriately 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 implemented only by the 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 the outbreak or spread of a New Infectious Disease during the period from the announcement pursuant to the provisions of Article 44-10, paragraph (1) until the abolition of the Cabinet Order in Article 53, paragraph (1), and if the prefectural governor finds that support by other prefectural governors pertaining to securing relevant persons to the prevention of New Infectious Diseases will not be smoothly implemented only by the 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 to the prevention of New Infectious Diseases.

- (4) In cases where the Minister of Health, Labour and Welfare has received a request for 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 outbreak of a New Infectious Disease throughout the country, the content 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 to the prevention of New Infectious Diseases.
- (5) Beyond what is provided for in the preceding paragraph, even in cases where the Minister of Health, Labour and Welfare does not request the coordination of support under paragraph (2) or paragraph (3) if the Minister finds it urgently necessary to coordinate support for securing human resources on a wide-area basis in order to prevent the spread of a New Infectious Disease, in comprehensive consideration of the situation and trends of the outbreak of a New Infectious Disease on a nationwide basis, during the period from the case where the announcement pursuant to the provisions of Article 44-10, paragraph (1) to the case where it is abolished by Cabinet Order pursuant to the provisions of Article 53, paragraph (1), the Minister may request the prefectural governor for support in securing medical care personnel for New Infectious Diseases or relevant persons to the prevention of New Infectious Diseases.
- (6) During the period from the case where the announcement pursuant to the provisions of Article 44-10, paragraph (1) to the case where it is abolished by Cabinet Order pursuant to the provisions of Article 53, paragraph (1), when the Minister of Health, Labour and Welfare finds it particularly urgently necessary for the support in securing human resources over a wide area in light of the situation of the spread of a New Infectious Disease, in comprehensive consideration of the situation, trends, and other circumstances of the outbreak of a New Infectious Disease on a nationwide basis, the Minister may request public medical institutions, etc. 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 to the prevention of New Infectious Diseases 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.

(Burden of Expenses Required for Support When Receiving Assistance from Other Prefectural Governors, etc.)

Article 51-3 A prefectural government that has received support for securing medical care personnel for New Infectious Diseases or relevant persons to the prevention of New Infectious Diseases from other prefectural governors, public medical institutions, etc., 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 bear the expenses required for the support.

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

Article 51-4 (1) During the period from the case where the announcement pursuant to the provisions of Article 44-10, paragraph (1) to the case where it is abolished by Cabinet Order pursuant to the provisions of Article 53, paragraph (1), when the Minister of Health, Labour and Welfare deems it necessary for the purpose of preventing the spread of New Infectious Diseases to go beyond the area of the prefectural government to secure human resources for the prevention of 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 Diseases.

(2) A prefectural governor may, when the prefectural governor finds it necessary, 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 the same paragraph when deemed 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 content 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 deems it particularly necessary for the purpose of preventing the outbreak or spread of a New Infectious Disease, or in cases where a prefectural governor has violated the provisions of this Chapter or has failed to manage or execute the affairs pursuant to the provisions of this Chapter, or the Minister deems it particularly necessary for the purpose of preventing 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 content of the instructed measures to the Health Science Council.

(Reports of the Progress of New Infectious Diseases)

- 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 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 sequentially report the content 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 to implement a measure prescribed in Article 50, paragraph (10).

(Designation of New Infectious Diseases by Cabinet Order)

- Article 53 (1) When the national government comes to be able to present measures to be implemented for the pathological conditions peculiar to a New

Infectious Disease and for the prevention of spread thereof as a result of gathering and analyzing the information on that New Infectious 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 not 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 not longer than one year specified by Cabinet Order if it is deemed 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 the same 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 such period.
- (3) When the Minister of Health, Labour and Welfare intends to propose to establish, revise or abolish 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) (hereinafter referred to as "employer" in this Chapter and Chapter XIII), the heads of schools (including specialized training colleges and schools for specialized education, and excluding schools for which the school term is less than one year; the same applies hereinafter), or the heads of correctional institutions or other institutions specified by Cabinet Order (each hereinafter referred to as "specified institution" in this Chapter and Chapter XIII) must provide the persons engaged in the business or services operated by the respective employers, the students, pupils or children of the respective schools, or the persons detained in the respective specified institutions (excluding those before the time of commencement of elementary school) 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, etc. having 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, etc. having 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 those before the time of commencement of elementary school) 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 case of a city, etc. having 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 thereunder, and such 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 the same paragraph for the eligible persons.
- (5) The numbers of medical examinations to be provided under the provisions of paragraph (1) or (3) are 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 at Other Opportunities)

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 prior to the

date designated for the periodical medical examination or the expiration date of the period designated therefor, and the person submits a medical certificate or other document certifying the content of the undergone medical examination to the entity responsible for the periodical medical examination on or before the date or expiration date, 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 under any other unavoidable accidents and such accidents are eliminated within two months, the person must undergo a medical examination within one month after the elimination of such accident and submit a medical certificate or other document certifying the content 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 (hereinafter referred to as "medical examination provider" in this Chapter) has provided a periodical medical examination or received a medical certificate or other 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 other document has been submitted pursuant to the provisions of Article 53-4 or 53-5) to the prefectural governor via the chief of the public health center who has jurisdiction over the location where the periodical medical examination has been provided (or via the chief of the public health center and the mayor of the city, etc. having a public health center when the location is within a city, etc. having a public health center).

(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 thereunder 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 the same 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 who has 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 instructions thereunder.

(3) Upon receipt of a notice referred to in the preceding paragraph, the board of education is to give necessary instructions to the referenced schools.

(Delegation to 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 recording 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 via the chief of a public health center which is not the public health center which 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 who has jurisdiction over the place of residence of the patient stating the content 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 for 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 other than those residing 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 who has jurisdiction over the place of residence of the patient stating the content of the notification.

(Tuberculosis Registration Cards)

Article 53-12 (1) The chief of a public health center must keep tuberculosis registration cards, and record on those cards particulars concerning tuberculosis patients and the 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 for whom a notification has been filed under the provisions of Article 12, paragraph (1) or for 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 deems it necessary for the purpose of preventing tuberculosis or in light of medical needs, the chief of the public health center is to conduct X-ray examinations or other detailed examinations by 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 deems it necessary for the purpose of preventing tuberculosis or in light of 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 enrolled on a tuberculosis registration card and to offer guidance for ensuring proper medication of prescribed drugs and other necessary guidance.

- (2) When the chief of a public health center deems it necessary for the purpose of preventing tuberculosis or ensuring effective medical care, the chief of the public health center may ask a hospital, clinic, pharmacy, or other person

specified by Order of the Ministry of Health, Labour and Welfare to offer guidance for ensuring proper medication of prescribed drugs and other necessary guidance to a person enrolled 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 for the prevention of infection as specified by Order of the Ministry of Health, Labour and Welfare.

#### **Chapter IX-2 Materials for Infectious Disease Countermeasures, etc.**

(Requests, etc. Concerning Production)

Article 53-16 (1) The Minister of Health, Labour and Welfare may, when, because it is recognized that 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 Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics, excluding those intended to be used exclusively for animals), medical devices (meaning medical devices prescribed in paragraph (4) of the same Article, excluding those intended to be used exclusively for animals), personal protective equipment (meaning personal equipment to prevent exposure to Pathogens, etc. by wearing them) and other supplies for the prevention of Infectious Diseases and medical care for patients with Infectious Diseases, and supplies and materials (hereinafter referred to as "materials for infectious disease countermeasures, etc.") deemed indispensable for the production of these supplies will be insufficient or that the supply of materials for infectious disease countermeasures, etc. will be insufficient based on a reasonable judgement due to an increase in demand, a decrease in imports or other circumstances, it is deemed necessary to promote the production of materials for infectious disease countermeasures, etc. in order to deal with the situation if it is likely that the occurrence of Infectious Diseases or the spread of Infectious Diseases is likely to seriously affect the lives and health of the public due to the difficulty in preventing the outbreak or spread of Infectious Diseases, request a person engaged in the production of materials for infectious disease countermeasures, etc. (hereinafter referred to as "producers") to

promote the production of the materials for infectious disease countermeasures, etc.

- (2) The Minister of Health, Labour and Welfare is to, when making a request pursuant to the provisions of the preceding paragraph, consult the competent minister for the business (meaning the minister who has jurisdiction over the business producing the materials for infectious disease countermeasures, etc. Hereinafter the same applies 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 concerning the production of the materials for infectious disease countermeasures, etc. pertaining to the request (hereinafter referred to 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) The competent minister for the business may, when the minister finds it particularly necessary to deal with the situation prescribed in paragraph (1) with regard to materials for infectious disease countermeasures, etc. under which the minister has jurisdiction over the business producing, give instructions to the producer who made a notification pursuant to the provisions of the preceding paragraph to change the production plan to which the notification pertained.
- (5) The Minister of Health, Labour and Welfare may request the Minister who has jurisdiction over the place of business to give instructions pursuant to the provisions of the preceding paragraph.
- (6) A producer who has made a notification pursuant to the provisions of paragraph (3) must, in accordance with the production plan pertaining to the notification (in the case of a notification of change in accordance with the provisions of the second sentence of the same Article, the plan after the change; the same applies in the following paragraph.) carry out the production of materials for infectious disease countermeasures, etc. pertaining to the production plan.
- (7) The Minister of Health, Labour and Welfare or the competent minister for the business may, 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 does not produce materials for infectious disease countermeasures, etc. pertaining to the production plan to which the notification pertains without reasonable grounds, make this public.

Article 53-17 (1) The Minister of Health, Labour and Welfare may, when they

find it particularly necessary to deal with the situation prescribed in paragraph (1) of the preceding Article, request the minister with jurisdiction over a capable producer (refers to the minister with jurisdiction over a business that is not engaged in the production of materials for infectious disease countermeasures, etc. and is deemed capable of producing materials for infectious disease countermeasures, etc. (hereinafter referred to as "capable producers" in this paragraph and paragraph (3)); the same applies in the same paragraph) to request a capable producer for cooperation in the production of the materials for infectious disease countermeasures, etc.

- (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 who has jurisdiction over the place of 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 the infectious disease control supplies, etc. from a capable producer who engages in the business under the jurisdiction of the minister.

(Requests, etc. Concerning Import)

Article 53-18 (1) When the Minister of Health, Labour and Welfare finds it necessary to promote the import of materials for infectious disease countermeasures, etc. 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 the materials for infectious disease countermeasures, etc. (hereinafter referred to as "importer") to promote the import of the materials for infectious disease countermeasures, etc.

- (2) The provisions of paragraphs (2) through (7) of Article 53-16 apply mutatis mutandis when making a request to an importer pursuant to the provisions of the preceding paragraph. In this case, the term "production" in paragraph (2) of the same Article is deemed to be replaced with "import," the term "this Article and paragraph (2) of the following Article" in the same paragraph is deemed to be replaced with "this Article," the term "the production of" in paragraph (3) of the same Article is deemed to be replaced with "the import of," the term "production plan" in the same paragraph is deemed to be replaced with "import plan," the term "producing" in paragraph (4) of the same Article is deemed to be replaced with "importing," the term "the producer" in the same paragraph is deemed to be replaced with "the producer who is deemed to be able to import the materials for infectious disease countermeasures, etc. in consideration of the import situation of the materials for infectious disease countermeasures, etc.," the term "production plan" in the same paragraph is deemed to be replaced with "import plan," the term "production plan" in

paragraphs (6) and (7) of the same Article is deemed to be replaced with "import plan," and the term "production" in the same 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 for infectious disease countermeasures, etc. 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 the materials for infectious disease countermeasures, etc. to coordinate the shipment or delivery of the materials for infectious disease countermeasures, etc.

(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 who has jurisdiction over the place of business producing, importing, selling or loaning the materials for infectious disease countermeasures, etc. in advance.

(Instructions, etc. on Sale, Loan, Transport or Retention)

Article 53-20 (1) The Minister of Health, Labour and Welfare may, when, in a specific region, because it is recognized that there is a high probability that the supply of materials for infectious disease countermeasures, etc. will be insufficient or that the supply of materials for infectious disease countermeasures, etc. will be insufficient based on a reasonable judgement due to an increase in demand, a decrease in imports or other circumstances, it is likely that the occurrence of Infectious Diseases or the spread of Infectious Diseases may have a serious impact on the lives and health of citizens due to the difficulty in preventing the outbreak of Infectious Diseases or prevent their spread, and it is deemed necessary to urgently increase the supply of the materials for infectious disease countermeasures, etc. in the specific region, give instructions to persons engaged in the production or import and sale of the materials for infectious disease countermeasures, etc. that they should sell the materials for infectious disease countermeasures, etc. by specifying the time limit and quantity to be sold and sales destination.

(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 give instructions to those engaged in the business of loaning the materials for infectious disease countermeasures, etc. that they should loan the materials for infectious disease countermeasures, etc. by specifying the time limit, quantity and period for loaning, and the 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 give instructions to those engaged in the business of loaning the materials for infectious disease countermeasures, etc. that they should transport the materials for infectious disease countermeasures, etc. by specifying the time limit, quantity, and route for transport, and the conditions for transportation.
- (4) When the Minister of Health, Labour and Welfare may finds it particularly necessary to deal with the situation prescribed in paragraph (1), the Minister may give instructions to those engaged in the business of storing the materials for infectious disease countermeasures, etc. that they should store the materials for infectious disease countermeasures, etc. by specifying the quantity and period for storing, and the 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 who has jurisdiction over the place of business producing, importing, selling, loaning, or transporting and storing the materials for infectious disease countermeasures, etc. 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 this public.

(Financial Measures, etc.)

Article 53-21 The national government may take necessary financial and other measures for producers who have produced materials for infectious disease countermeasures, etc. in accordance with the request under the provisions of Article 53-16, paragraph (1) or the instruction under the provisions of paragraph (4) of the same Article, importers who have imported materials for infectious disease countermeasures, etc. in accordance with the request under the provisions of Article 53-18, paragraph (1), or the instruction under the provisions of Article 53-16, paragraph (4), which is applied *mutatis mutandis* in paragraph (2) of the same Article, and those who have sold, loaned, transported or stored materials for infectious disease countermeasures, etc. 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 who has jurisdiction over the business producing, importing, selling, or loaning materials for infectious disease countermeasures, etc. may request a person engaged in the business of producing, importing, selling, or loaning materials for infectious disease countermeasures, etc. to report on the status of the production, import, selling, or loaning of materials for infectious disease

countermeasures, etc. in order to ascertain the domestic supply and demand of materials for infectious disease countermeasures, etc.

- (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 who has jurisdiction over the business producing, importing, selling, loaning, transporting or storing materials for infectious disease countermeasures, etc. may, to the extent necessary for the enforcement of the provisions of Article 53-16, paragraphs (1) and (2) through (7) (including the 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 those engaged in the business of producing, importing, selling, loaning, transporting or storing materials for infectious disease countermeasures, etc. 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 of 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 human beings (hereinafter referred to 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 permissions of the Minister of Health, Labour and Welfare and the Minister of Agriculture, Forestry and Fisheries are 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 Designated Animals (hereinafter referred to as an "Importer") must attach the certificate issued by the competent governmental organization of the exporting country or its photocopy stating the result of the inspection in the exporting country to the effect that the animals are not infected with any of the Infectious Diseases specified by Cabinet Order for respective Designated Animals or that the animals are not suspected to be infected with such 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 at a 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 for import, and other particulars 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 having filed the notification to change the time or place for the import for which the notification was filed, when it is deemed 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 such 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 deemed necessary for carrying out the inspection referred to in the same 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 in the course of the inspection referred to in paragraph (4) of the same 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 the same Article via the chief of the nearest public health center.
- (2) The prefectural governor receiving a notice under the provisions of the preceding paragraph must immediately report the content 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 implement isolation, disinfection or slaughter or other necessary measures for the Designated Animals prescribed in paragraph (1) 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 human beings 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 human beings (hereinafter referred to as "notifiable animals or the like" in this Article and Article 77, paragraph (1), item (xii)) must file 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 setting out the result of the inspection in the exporting country to the effect 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 such 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, etc.)

Article 56-3 (1) No person may possess Class I Pathogens, etc.; provided, however, that this does not apply in the following cases:

- (i) when a Holder of Specified Class I Pathogens, etc. possesses the Class I Pathogens, etc. specified by Cabinet Order as requiring test and research (hereinafter referred to as "Specified Class I Pathogens, etc.") for the purpose of test and research at a laboratory designated by the Minister of Health, Labour and Welfare;
  - (ii) when a person required to perform sterilization or detoxification (hereinafter referred to as "Sterilization, etc.") of Class I Pathogens, etc. or to transfer Class I Pathogens, etc. pursuant to the provisions of Article 56-22, paragraph (1) (hereinafter referred to as the "Person Obligated to Sterilize and Transfer Class I Pathogens, etc.") possesses Class I Pathogens, etc. pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare until the person completes the Sterilization, etc. or transfer (hereinafter referred to as "Sterilization and Transfer") thereof;
  - (iii) when a person undertaking the transportation entrusted by a person prescribed in the preceding two items possesses the entrusted Class I Pathogens, etc. for the purpose of completing the transportation thereof; or
  - (iv) when an employee of any of the persons prescribed in the preceding three items possesses the Class I Pathogens, etc. in the course of duties.
- (2) A "Holder of Specified Class I Pathogens, etc." 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 other juridical person specified by Cabinet Order which is designated by the Minister of Health, Labour and Welfare for respective types of Specified Class I Pathogens, etc. as being capable of properly possessing Specified Class I Pathogens, etc.

(Prohibition of Import of Class I Pathogens, etc.)

Article 56-4 No person may import Class I Pathogens, etc.; provided, however, that this does not apply when a Holder of Specified Class I Pathogens, etc. (meaning a Holder of Specified Class I Pathogens, etc. prescribed in paragraph

(2) of the preceding Article; the same applies hereinafter) imports Specified Class I Pathogens, etc. designated by the Minister of Health, Labour and Welfare as being required to be procured from foreign countries.

(Prohibition of the Transfer and Receipt of Class I Pathogens, etc.)

Article 56-5 No person may transfer or receive Class I Pathogens, etc.; provided, however, that this does not apply in the following cases:

- (i) when a Holder of Specified Class I Pathogens, etc. transfers Specified Class I Pathogens, etc. to another Holder of Specified Class I Pathogens, etc. or receives the same from another Holder of Class I Pathogens, etc. or from a Person Obligated to Sterilize and Transfer Class I Pathogens, etc., 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, etc. transfers Specified Class I Pathogens, etc. to a Holder of Specified Class I Pathogens, etc. 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, etc.)

Article 56-6 (1) A person intending to possess Class II Pathogens, etc. 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, etc. pursuant to the provisions of Article 56-22, paragraph (1) (hereinafter referred to as "Person Obligated to Sterilize and Transfer Class II Pathogens, etc.") possesses Class II Pathogens, etc. pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare until the person completes the Sterilization and Transfer thereof;
  - (ii) when a person undertaking the transportation entrusted by a person having obtained the permission referred to in the main clause of this paragraph (hereinafter referred to as "Permitted Holder of Class II Pathogens, etc.") or by a Person Obligated to Sterilize and Transfer Class II Pathogens, etc. possesses the entrusted Class II Pathogens, etc. for the purpose of completing the transportation thereof; or
  - (iii) when an employee of a Permitted Holder of Class II Pathogens, etc. or a person prescribed in the preceding two items possesses Class II Pathogens, etc. in the course of 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

particulars 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) types of Class II Pathogens, etc. (or the types and quantities if they are Toxins);
- (iii) purpose and method of possession; and
- (iv) location, structure and facilities of the laboratory for the storage, use and Sterilization, etc. of Class II Pathogens, etc. (hereinafter referred to as "Laboratory for Handling Class II Pathogens, etc.").

(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, etc. due to 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 thereunder and for whom five years have yet to elapse since the day on which the execution of sentence was completed or the sentence ceased to be applicable;
- (v) a person whose permission has been rescinded under the provisions of Article 56-35, paragraph (2) and for whom five years have yet to elapse since the date of the rescission (or if the permission is rescinded 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 person equivalent thereto, including any person who is deemed to have the same or a higher control over the corporation than the members executing business, directors, executive officers or other persons equivalent thereto whether or not they are an adviser, consultant or person having any other designation; hereinafter the same applies in this Article) at any time during the period of sixty days prior to the date on which the notice of disposition of the rescission 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 rescission);
- (vi) a person having filed 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 rescission of permission under the provisions of Article 56-35, paragraph (2) and ending on the date of the rescission or the date on which the cancellation of the rescission is determined (excluding those whose filing 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 filed the notification (excluding corporations whose filing of the notification is on reasonable grounds), or an employee specified by Cabinet Order of the individual who filed the notification (excluding those whose filing of the notification is on reasonable grounds) at any time during the period of 60 days prior to 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 deemed to conform to 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, etc. conform to the technical standards specified by Order of the Ministry of Health, Labour and Welfare and there is no risk of the outbreak or spread of any Infectious Disease caused by Class II Pathogens, etc.

(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 for the purpose of preventing the outbreak or spread of an Infectious Disease caused by Class II Pathogens, etc., 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, etc. 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, etc. intends to change any of the matters set forth in Article 56-6, paragraph (2), items (ii) through (iv), it 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 the Permitted Holder of Class II Pathogens, etc. intends to make a minor change prescribed in the proviso of the preceding paragraph, it must notify the Minister of Health, Labour and Welfare to that effect in advance pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(3) If the Permitted Holder of Class II Pathogens, etc. has changed any matter set forth in Article 56-6, paragraph (2), item (i), it must notify the Minister of Health, Labour and Welfare within 30 days from the date of such 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, etc.)

Article 56-12 (1) A person intending to import Class II Pathogens, etc. 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 particulars 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) types of Class II Pathogens, etc. to be imported (or the types and quantities if they are Toxins);
- (iii) purpose of import;
- (iv) exporter's personal name or entity name and address;
- (v) period for import;
- (vi) means of transportation; and
- (vii) 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 deemed to conform to all of the following items:

- (i) the applicant is a Permitted Holder of Class II Pathogens, etc.;
- (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 the outbreak or spread of any Infectious Disease caused by Class II Pathogens, etc.

(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 pertaining to the permissions 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 the same 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 the same

Article is deemed to be replaced with "Articles 56-9 and 56-13."

(Restriction on the Transfer and Receipt of Class II Pathogens, etc.)

Article 56-15 No person may transfer or receive Class II Pathogens, etc., except in any of the following cases:

- (i) when a Permitted Holder of Class II Pathogens, etc. transfers Class II Pathogens, etc. pertaining to the permission to another Permitted Holder of Class II Pathogens, etc. or receives the same from another Permitted Holder of Class II Pathogens, etc. or a Person Obligated to Sterilize and Transfer Class II Pathogens, etc.; or
- (ii) when a Person Obligated to Sterilize and Transfer Class II Pathogens, etc. transfers Class II Pathogens, etc. to a Permitted Holder of Class II Pathogens, etc. 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, etc.)

Article 56-16 (1) A person possessing Class III Pathogens, etc. must notify the Minister of Health, Labour and Welfare of the types of those Class III Pathogens, etc. and other matters specified by Order of the Ministry of Health, Labour and Welfare within seven days from the date of commencement of the possession thereof, pursuant to the provisions of Cabinet Order; provided, however, that this does not apply in the following cases:

- (i) when a hospital or clinic or an institution engaged in examination of Pathogens, etc. possesses Class III Pathogens, etc. until the person completes the Sterilization and Transfer thereof, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, and they come into its possession in the course of performing its business or services;
  - (ii) when a person undertaking the transportation entrusted by a person possessing Class III Pathogens, etc. possesses the entrusted Class III Pathogens, etc. for the purpose of completing the transportation thereof; or
  - (iii) when an employee of a person possessing Class III Pathogens, etc. possesses Class III Pathogens, etc. in the course of duties.
- (2) If a person possessing Class III Pathogens, etc. that has filed a notification under the main clause of the preceding paragraph changes any matter stated in the notification, the person must notify the Minister of Health, Labour and Welfare to that effect 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, etc. pertaining to the notification.

(Notification of Importing Class III Pathogens, etc.)

Article 56-17 A person having imported Class III Pathogens, etc. must notify the Minister of Health, Labour and Welfare of the following matters within seven days from the date of the import of those Class III Pathogens, etc., 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) types of Class III Pathogens, etc. imported (or the types and quantities if they are Toxins);
- (iii) purpose of import;
- (iv) the exporter's personal name or entity name and address;
- (v) date of import;
- (vi) means of transportation; and
- (vii) name of the port of import.

#### **Section 4 Duties of Holders**

(Establishment of Rules for the Prevention of Outbreaks of Infectious Diseases)

Article 56-18 (1) Holders of Specified Class I Pathogens, etc. and Permitted Holders of Class II Pathogen, etc. must establish their own rules for prevention of outbreaks of Infectious Diseases and file the established rules with the Minister of Health, Labour and Welfare before commencement of their possession of the relevant Pathogens, etc., pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, for the purpose of preventing the outbreak or spread of an Infectious Disease caused by the relevant Pathogens, etc.

- (2) If the Holder of Specified Class I Pathogens, etc. or the Permitted Holder of Class II Pathogens, etc. revises the rules for prevention of outbreaks of Infectious Diseases, they must notify the Minister of Health, Labour and Welfare within 30 days from the date of the revision.

(Appointment of Chief Supervisors for Handling Pathogens)

Article 56-19 (1) Holders of Specified Class I Pathogens, etc. and Permitted Holders of Class II Pathogens, etc. must appoint a chief supervisor for handling Pathogens, etc. to assign them the duty of supervising the prevention of the outbreak or spread of any Infectious Disease caused by the relevant Pathogens, etc., 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 in handling relevant Pathogens, etc.

- (2) When the Holder of Specified Class I Pathogens, etc. or the Permitted Holder

of Class II Pathogens, etc. has appointed a chief supervisor for handling Pathogens, etc., it must notify the Minister of Health, Labour and Welfare to that effect within 30 days from the date 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, etc. must execute the assigned duties in good faith.

(2) Any person who enters a laboratory for the storage, use and Sterilization, etc. of Specified Class I Pathogens, etc. (hereinafter referred to as "Laboratory for Handling Class I Pathogens, etc.") or a Laboratory for Handling Class II Pathogens, etc. must follow instructions given by the chief supervisor for handling Pathogens, etc., for the purpose of ensuring the enforcement of this Act or any order or the rules for prevention of outbreaks of Infectious Diseases based on this Act.

(3) In connection with the prevention of the outbreak or spread of an Infectious Disease caused by Pathogens, etc., Holders of Specified Class I Pathogens, etc. and Permitted Holders of Class II Pathogens, etc. must respect opinions of their chief supervisor for handling Pathogens, etc.

(Education and Training)

Article 56-21 Holders of Specified Class I Pathogens, etc. and Permitted Holders of Class II Pathogens, etc. must familiarize the persons who enter the Laboratory for Handling Class I Pathogens, etc. or the Laboratory for Handling Class II Pathogens, etc. with the rules for prevention of outbreaks of Infectious Diseases, and provide necessary education and training to those persons to prevent the outbreak or spread of an Infectious Disease caused by the relevant Pathogens, etc., pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Sterilization)

Article 56-22 (1) When a person set forth in either of the following items falls under the case prescribed in the respective item, the person must sterilize, detoxify or transfer the Class I Pathogens, etc. or Class II Pathogens, etc. in its possession:

(i) Holders of Specified Class I Pathogens, etc. or Permitted Holders of Class II Pathogens, etc.: when it no longer needs to possess Specified Class I Pathogens, etc. or Class II Pathogens, etc., 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 rescinded or suspended;

- (ii) hospitals or clinics, or institutions engaged in the examination of Pathogens, etc.: when it has come into possession of Class I Pathogens, etc. or Class II Pathogens, etc. in the course of performing its business.
- (2) When a person required to perform the Sterilization and Transfer of Class I Pathogens, etc. or Class II Pathogens, etc. pursuant to the provisions of the preceding paragraph intends to perform the Sterilization and Transfer of the relevant Pathogens, etc., the person must notify the Minister of Health, Labour and Welfare of the types of the relevant Pathogens, etc., the methods of the 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, etc. or a Permitted Holder of Class II Pathogens, etc. files a notification under the provisions of the preceding paragraph, and it no longer needs to possess the Pathogens, etc. then in its possession, 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) Holders of Specified Class I Pathogens, etc., Permitted Holders of Class II Pathogens, etc., and persons possessing Class III Pathogens, etc. (excluding employees prescribed in Article 56-16, paragraph (1), item (iii); hereinafter referred to as "Holder of Class III Pathogens, etc.") must keep books and record the matters concerning the storage, use and Sterilization, etc. of the relevant Pathogens, etc. and other necessary matters concerning the prevention of the outbreak or spread of an Infectious Disease caused by the relevant Pathogens, etc., 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 Holders of Specified Class I Pathogens, etc., Permitted Holders of Class II Pathogens, etc., Holders of Class III Pathogens, etc., and persons possessing Class IV Pathogens, etc. (excluding those who are employees of a person possessing Class IV Pathogens, etc. and who possess those Class IV Pathogens, etc. in the course of their duties; hereinafter referred to as "Holders of Class IV Pathogens, etc.") must maintain the laboratories for the storage, use or Sterilization, etc. of such Specified Pathogens, etc. in such a way that their location, structure and facilities conform to the technical standards specified by Order of the Ministry of Health, Labour and Welfare.

(Standards for Storage)

Article 56-25 In the storage, use or transportation (excluding transportation by vessels or aircrafts; hereinafter the same applies except in paragraph (4) of the following Article), or Sterilization, etc. of Specified Pathogens, etc., the Holders of Specified Class I Pathogens, etc., Permitted Holders of Class II Pathogens, etc., the persons undertaking the transportation entrusted by those Holders, Holders of Class III Pathogens, etc., and Holders of Class IV Pathogens, etc. (hereinafter referred to as "Holder of Specified Pathogens, etc.") must implement necessary measures to prevent the outbreak or spread of an Infectious Disease caused by Specified Pathogens, etc. 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 set forth 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 set forth 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 or clinic or an institution engaged in examination of Pathogens, etc. possesses Class IV Pathogens, etc. until it completes the Sterilization and Transfer thereof, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, if they have come into its possession in the course of conducting business.
- (4) The provisions of Article 56-24 and Article 56-32, paragraph (1) do not apply when a person undertaking the transportation entrusted by a Holder of Class IV Pathogens, etc. possesses the entrusted Class IV Pathogens, etc. for the purpose of completing the transportation thereof.

(Notification of Transportation)

Article 56-27 (1) When a Holder of Specified Class I Pathogens, etc., a Person Obligated to Sterilize and Transfer Class I Pathogens, etc., a Permitted Holder of Class II Pathogens, etc., a Person Obligated to Sterilize and Transfer Class II Pathogens, etc., a person undertaking the transportation entrusted by those Holders or persons, or a Holder of Class III Pathogens, etc. transports Class I Pathogens, etc., Class II Pathogens, etc., or Class III Pathogens, etc. outside its place of business (excluding transportation by vessels or aircrafts), it must notify the Prefectural Public Safety Commission to that effect and obtain a document certifying the notification issued by the commission (hereinafter referred to as "Transportation Certificate"), pursuant to the provisions of the

Rules of the National Public Safety Commission.

- (2) Upon receipt of 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 deemed necessary for preventing those Class I Pathogens, etc., Class II Pathogens, etc., or Class III Pathogens, etc. 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 such instructions in the Transportation Certificate.
- (4) After obtaining a Transportation Certificate issued in the case prescribed in paragraph (1), Holders of Specified Class I Pathogens, etc., Persons Obligated to Sterilize and Transfer Class I Pathogens, etc., Permitted Holders of Class II Pathogens, etc., Persons Obligated to Sterilize and Transfer Class II Pathogens, etc., persons undertaking the transportation entrusted by those Holders or persons, and Holders of Class III Pathogens, etc. 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 deems it particularly necessary for the purpose of preventing Class I Pathogens, etc., Class II Pathogens, etc., or Class III Pathogens, etc. under transportation by 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 them to present the Transportation Certificate, or check 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 other appropriate measures to the extent necessary for the enforcement of the provisions of paragraph (1), paragraph (2) and the preceding paragraph for the purpose of preventing the relevant Pathogens, etc. from being stolen, lost, or involved in other accidents.
- (6) The authority prescribed in the preceding paragraph must not be construed as having been granted for criminal investigation.
- (7) The renewal or reissuance of a Transportation Certificate, or return thereof when it is no longer necessary, and the necessary liaison between or among the Prefectural Public Safety Commissions pertaining to the notifications referred to in paragraph (1), the instructions referred to in paragraph (2) and the issuance, renewal, reissuance and return of the Transportation Certificates when the transportation involves two or more prefectures, are specified by

Cabinet Order.

(Notification of Accidents)

Article 56-28 A Holder of Specified Pathogens, etc., a Person Obligated to Sterilize and Transfer Class I Pathogens, etc., or a Person Obligated to Sterilize and Transfer Class II Pathogens, etc. must make a report to a police officer or a coast guard officer without delay if any Specified Pathogens, etc. in its possession are stolen, lost or involved in other accident.

(Emergency Measures in Times of Disaster)

Article 56-29 (1) A Holder of Specified Pathogens, etc., a Person Obligated to Sterilize and Transfer Class I Pathogens, etc., or a Person Obligated to Sterilize and Transfer Class II Pathogens, etc. 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 the Specified Pathogens, etc. in its possession has broken out or spread, or is likely to break out or spread, as a result of occurrence of an earthquake, fire, or other 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 to that effect.

(3) If a situation referred to in paragraph (1) occurs, the Holder of Specified Pathogens, etc., Person Obligated to Sterilize and Transfer Class I Pathogens, etc., or Person Obligated to Sterilize and Transfer Class II Pathogens, etc. must notify the Minister of Health, Labour and Welfare to that effect 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 Holders of Specified Pathogens, etc., persons who have imported Class III Pathogens, etc., persons who have imported Class IV Pathogens, etc., Persons Obligated to Sterilize and Transfer Class I Pathogens, etc., and Persons Obligated to Sterilize and Transfer Class II Pathogens, etc. (hereinafter referred to as "Holders, etc. of Specified Pathogens, etc.") 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 case of a 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 case of a Prefectural Public Safety Commission), direct relevant officials (or police officials, in the case of a Prefectural Public Safety Commission) to enter the offices or places of business of any Holders, etc. of Specified Pathogens, etc., to inspect their books, documents and other necessary objects, to question relevant persons, or to forcibly collect Specified Pathogens, etc. or objects contaminated thereby, 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, etc. of Specified Pathogens, etc. do not conform to the technical standards referred to in Article 56-24, the Minister may order the Holder of Specified Class I Pathogens, etc., the Permitted Holder of Class II Pathogens, etc., the Holder of Class III Pathogens, etc., or the Holder of Class IV Pathogens, etc. to repair or alter the laboratory or to implement other necessary measures for the prevention of the outbreak or spread of an Infectious Disease caused by Specified Pathogens, etc.

(2) When the Minister of Health, Labour and Welfare finds that the measures concerning the storage, use, transportation, or Sterilization, etc. of Specified Pathogens, etc. do not conform to the technical standards referred to in Article 56-25, the Minister may order the Holder of Specified Pathogens, etc. to change the methods for the storage, use, transportation, or Sterilization, etc. or to implement other necessary measures to prevent the outbreak or spread of an Infectious Disease caused by Specified Pathogens, etc.

(Order to Change the Rules for Prevention of Outbreaks of Infectious Diseases)

Article 56-33 When the Minister of Health, Labour and Welfare deems it necessary for the purpose of preventing the outbreak or spread of an Infectious Disease caused by Specified Class I Pathogens, etc. or Class II Pathogens, etc., the Minister may order the Holder of Specified Class I Pathogens, etc. or the Permitted Holder of Class II Pathogens, etc. to change its rules for prevention of outbreaks of Infectious Diseases.

(Order of Dismissal)

Article 56-34 When a chief supervisor for handling Pathogens, etc. violates any provisions of this Act or any order based on this Act, the Minister of Health, Labour and Welfare may order the Holder of Specified Class I Pathogens, etc. or the Permitted Holder of Class II Pathogens, etc. to dismiss the chief supervisor for handling Pathogens, etc.

(Rescission of a Designation)

Article 56-35 (1) If a Holder of Specified Class I Pathogens, etc. falls under any of the following items, the Minister of Health, Labour and Welfare may rescind 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 it 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, etc. do not conform to the technical standards specified by Order of the Ministry of Health, Labour and Welfare; or
- (iii) if it is deemed to be incapable of possessing Specified Class I Pathogens, etc. properly.

(2) If a Permitted Holder of Class II Pathogens, etc. falls under any of the following items, the Minister of Health, Labour and Welfare may rescind 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 it falls under any item of Article 56-7;
- (ii) if it 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, etc. do not conform to the technical standards referred to in Article 56-8, item (ii); or
- (iv) if it has violated any condition 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 deems it necessary, the Minister may order a person required to perform the Sterilization and Transfer of Class I Pathogens, etc. or Class II Pathogens, etc. pursuant to the provisions of Article 56-22, paragraph (1) to change the methods of the Sterilization and Transfer of the relevant Pathogens, etc. or to implement other necessary measures for the prevention of the outbreak or spread of an Infectious Diseases caused by the relevant Pathogens, etc., 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 deems it particularly necessary for the purpose of preventing the outbreak or spread of an Infectious Disease caused by Specified Pathogens, etc. in the case referred to in Article 56-29, paragraph (1), the Minister may order a Holder of Specified Pathogens, etc., a Person Obligated to Sterilize and Transfer Class I Pathogens, etc., or a Person Obligated to Sterilize and Transfer Class II Pathogens, etc. to change the location for storage of Specified Pathogens, etc., to perform the Sterilization, etc. of Specified Pathogens, etc., or to implement other necessary measures for the prevention of the outbreak or spread of an Infectious Disease caused by Specified Pathogens, etc.

(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 deemed particularly necessary for the purpose of maintaining public safety or maritime safety, the Commissioner General of the National Police Agency or the Commandant of the Japan Coast Guard may respectively express 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 any Holders of Specified Pathogens, etc., Persons Obligated to Sterilize and Transfer Class I Pathogens, etc., or Persons Obligated to Sterilize and Transfer Class II Pathogens, etc., to inspect their books, documents and other necessary items, or to question 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 the same 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 filed 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 to 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) Upon receipt of 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 to that effect without delay.

(6) When it is deemed necessary for the purpose of preventing the outbreak or spread of an Infectious Disease caused by Specified Pathogens, etc., the Minister of Health, Labour and Welfare may ask the minister who has jurisdiction over the business or services operated by enterprises handling those Specified Pathogens, etc. to implement necessary measures for ensuring that those enterprises will properly handle Specified Pathogens, etc.

(7) When the Minister of Health, Labour and Welfare deems it particularly necessary for the purpose of protecting the lives and person of the public, the Minister may request prefectural governors to dispatch an employee of an Infectious Diseases Research Institute or to provide other necessary cooperation to prevent the outbreak or spread of an Infectious Disease caused by Specified Pathogens, etc.

## **Chapter XII Surveys and Research on Infectious Diseases and Pathogens, etc., and Research and Development of Medicines**

(Promotion of Surveys and Research on Infectious Diseases and Pathogens, etc., 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, etc., which form the basis for ensuring high-quality and appropriate medical care for patients with Infectious Diseases by seeking cooperation, such as the provisions of information and samples obtained from 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 such 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 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, etc., physicians, and other relevant persons, using an appropriate method.
- (3) The Minister of Health, Labour and Welfare may entrust the affairs pertaining 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) In the provisions of 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 Appropriate Medical Care for Patients)

Article 56-40 The Minister of Health, Labour and Welfare, in order to contribute to ensuring high-quality and appropriate medical care for patients, 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 (hereinafter referred to as "Infectious Disease-related information").

(Use or Provisions of Anonymous Infectious Diseases-related Information for the Improvement of National Health)

Article 56-41 (1) In order to contribute to the improvement of the national health, the Minister of Health, Labour and Welfare may use anonymous Infectious Disease-related information (refers to Infectious Disease-related Information 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 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 and to restore the information related to Infectious Diseases used in the preparation thereof.; The same applies hereinafter), or, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, provide it to those carrying out the operations set forth in each of the

following items by those specified in the relevant item as operations that are found to have a considerable public interest in receiving Infectious Disease-related information:

- (i) other national administrative organs and local governments: surveys concerning the planning and drafting of policies that contribute to the provisions of appropriate 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 health; and
  - (iii) private business operators and other persons specified by Order of the Ministry of Health, Labour and Welfare: Analysis 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) The Minister of Health, Labour and Welfare may, when using or providing anonymous Infectious Disease-related information pursuant to the provisions of the preceding paragraph, use the anonymous Infectious Disease-related information 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 Infectious Disease-related information 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 After receiving Infectious Disease-related information pursuant to the provisions of paragraph (1) of the preceding Article, when handling anonymous Infectious Disease-related information, the person who uses the information (hereinafter referred to as "user of anonymous Infectious Disease-related information") must not, in order to identify the persons in question pertaining to the Infectious Disease-related information used in the preparation of the anonymous Infectious Disease-related information, obtain information on the processing methods used to create the anonymous Infectious Disease-related information, 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 Infectious Disease-related information, or collate the anonymous Infectious Disease-related information with other information.

(Deleted)

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

(Safety Management Measures)

Article 56-44 A user of anonymous Infectious Disease-related information must take measures specified by Order of the Ministry of Health, Labour and Welfare as necessary and appropriate for the prevention of leakage, loss or damage of anonymous Infectious Disease-related information and for the safe management of such information.

(Obligations of Users)

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

(Entry and Inspections, etc.)

Article 56-46 (1) The Minister of Health, Labour and Welfare may, within the limit necessary for the enforcement of the provisions of this Chapter (excluding Article 56-39 and Article 56-40), order a user of anonymous Infectious Disease-related information (excluding other administrative organs of the national government; the same applies hereinafter in this paragraph and the following Article) to report, submit or present books and documents, have the official ask questions to the person concerned, enter the office or other place of business of a user of anonymous Infectious Disease-related information, and inspect books, documents and other items of a user of anonymous Infectious Disease-related information.

(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 Infectious Disease-related information 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 the Reimbursement Services, etc.)

Article 56-48 The Minister of Health, Labour and Welfare may entrust the whole or part of the affairs pertaining to the survey and research prescribed in Article 56-40 and the use or provisions of anonymous Infectious Disease-related information 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 "the Reimbursement Services, etc." 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 Infectious Disease-related information must pay a fee specified by a Cabinet Order in consideration of actual costs to the national government (in cases where the Health Insurance Claims Review and the Reimbursement Services, etc. performs all of the affairs pertaining to the provisions of anonymous infectious diseases-related information 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, the Reimbursement Services, etc.).

(2) When the persons who intend to pay the fees in the preceding paragraph are prefectural governments or other person specified by a Cabinet Order as a person who plays a particularly important role for the improvement of national 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 the Reimbursement Services, etc. pursuant to the provisions of paragraph (1) is deemed the income of the Reimbursement Services, etc.

### **Chapter XIII Payment of Expenses**

(Expenses Paid by Municipal Governments)

Article 57 Municipal governments must pay the following expenses:

- (i) expenses required 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 required 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 required 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 required for supplying water for daily life, 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 required 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 required 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 required 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 the same 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 required for medical examinations conducted under the provisions of Article 17 or 45;
- (iii) expenses required 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 required 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 required for receipt or forcible collection of 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 required for receipt or collection of specimens under the provisions of Article 26-4, paragraph (1) or (3) (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 26-4, paragraphs (5) through (8) (including cases where they are applied mutatis mutandis in Article 50, paragraph (3));
  - (v) expenses required 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 required 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 required 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 required for measures implemented pertaining to 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 required 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 required 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 borne 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 borne pursuant to the provisions of Article 37, paragraph (1);
  - (xii) expenses borne pursuant to the provisions of Article 37-2, paragraph (1);
  - (xiii) expenses required for the payment of medical treatment expenses under the provisions of Article 42, paragraph (1);
  - (xiv) expenses borne pursuant to the provisions of Article 44-3-2, paragraph (1) and Article 50-3, paragraph (1);
  - (xv) expenses required 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 borne 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 required 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 required 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 required 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 required for periodical medical examinations provided by the heads of schools or Specified Institutions pursuant to the provisions of Article 53-2, paragraph (1).

(Expenses Shared by Prefectural Governments)

Article 59 Prefectural governments will bear 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 required 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 required to the establisher of a public medical institution, etc. that has taken the measures set forth in the items of Article 36-2, paragraph (1), regional medical care support hospital, and advanced treatment hospital, and a medical institution that has concluded a medical care agreement or an organization, etc. engaged in the examination of Pathogens, etc. that has concluded an examination, etc. measures agreement for the establishment of these medical institutions or organizations, etc.

engaged in the examination of Pathogens, etc.

(Expenses Shared by the National Government)

- Article 61 (1) The national government must bear the expenses required 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 the same Article, which are to be paid by the prefectural government pursuant to the provisions of Article 58), and the expenses required for the import quarantine pursuant to the provisions of Article 55 (excluding the expenses for the raising and management of Designated Animals during import quarantine).
- (2) The national government will bear three-fourths of the expenses referred to in Article 58, item (xi), the expenses referred to in item (xiii) of the same 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 bear 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 the same 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 required 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 of a Class I Infectious Disease, a Class II Infectious Disease, a Class III Infectious Disease, a Class IV Infectious Disease or a Novel Influenza Infection, etc. stay or stayed, or where there are or were the corpses of persons who had died of the relevant Infectious Disease, and other places contaminated or suspected to have been contaminated with pathogens of the relevant Infectious Disease pursuant to the provisions of Article 27, paragraph (2) (including cases where such disinfection is performed pursuant to the provisions of Article 50, paragraph (1)), the mayor of a municipality 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 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 such 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 drink, clothing, bedding, or other physical items contaminated or suspected to have been contaminated with pathogens of a Class I Infectious Disease, a Class II Infectious Disease, a Class III Infectious Disease, a Class IV Infectious Disease or a Novel Influenza Infection, etc. pursuant to the provisions of Article 29, paragraph (2) (including such disinfection is performed pursuant to the provisions of Article 50, paragraph (1)), the mayor of a municipality may collect the amounts of actual costs required for the disinfection from the Holders of the food or drink, clothing, bedding, or 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), extermination of rodents, insects or the like prescribed in Article 28, paragraph (2), or 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 deems it

particularly necessary for the purpose of preventing the outbreak or 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; hereinafter the same applies in the following paragraph) or pursuant to the provisions of any Cabinet Order based on this Act.

- (2) In addition to the provisions set forth in the preceding paragraph, the Minister of Health, Labour and Welfare may, in cases where a prefectural governor has violated 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, when the Minister deems it particularly necessary for the purpose of preventing the outbreak or the rapid spread across the country of a Novel Influenza Infection, etc. 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)) or to prevent its rapid spread nationwide, give 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 the outbreak of Infectious Diseases or to prevent the spread of Infectious Diseases in whole or in part of the area under the jurisdiction of the prefectural governor, the mayor of a municipality, medical institution, Infectious Diseases Research Institute, or other relevant persons (hereinafter referred to as "relevant organizations, etc." 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 the outbreak or spread of Infectious Diseases pertaining to all or part of the area implemented by the relevant organizations, etc.

- (2) The mayor of a city, etc. having a public health center may, when the mayor finds it necessary, request the prefectural governor to carry out comprehensive coordination pursuant to the provisions of the preceding paragraph with regard to the mayor of a city, etc. having a public health center and other relevant organizations, etc. In this case, the prefectural governor must carry out comprehensive coordination pursuant to the provisions of the same paragraph when deemed necessary.

- (3) In the case referred to in paragraph (1), the relevant organizations, etc. may offer their opinions to the prefectural governor concerning comprehensive coordination pursuant to the provisions of the same 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, etc. to submit reports or materials on the implementation status of measures necessary to prevent the outbreak of Infectious Diseases or to prevent the spread of Infectious Diseases affecting all or part of the area under the jurisdiction of the prefectural governor implemented by the relevant organizations, etc.

(Instructions of a Prefectural Governor)

Article 63-4 When a prefectural governor finds it necessary urgently to prevent the outbreak or spread of a Novel Influenza Infection, etc., Designated Infectious Disease, or New Infectious Disease during the period from the announcement of outbreaks, etc. pertaining to a Novel Influenza Infection, etc., until the announcement, etc. to the effect that it is no longer recognized as a Novel Influenza Infection, etc., they may give the mayor of a city, etc. having a public health center necessary instructions concerning the recommendation for hospitalization 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.

(City, etc. Having a Public Health Center)

Article 64 (1) In the case of a city, etc. having 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 pertaining to Designated Medical Institutions for Tuberculosis in the provisions of paragraphs (2), (10) and (11) of the same Article), Article 40, paragraphs (3) through (5), Article 43 (excluding the part pertaining 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 pertaining to examination, etc. measures agreements)) and Article 63-2 is deemed to be "the mayor of a city, etc. having a public health center," and "prefectural government" is deemed to

be "city, etc. having 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 (hereinafter referred to as "Designated Cities") and the core cities referred to in Article 252-22, paragraph (1) of the same Act (hereinafter referred to as "Core Cities"), the affairs which prefectural governments are supposed to conduct under this Act (limited to those pertaining to the prevention of tuberculosis) which are specified by Cabinet Order are to be conducted by the Designated Cities or Core Cities (hereinafter referred to as "Designated Cities, etc.") pursuant to the provisions of Cabinet Order. In this case, the provisions concerning prefectural governments in this Act are deemed as the provisions concerning the Designated Cities, etc., by which the Designated Cities, etc. are governed.

(Order of Statutory Liens)

Article 64-3 The statutory liens for the contribution to ensure early epidemic medical care, etc. 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 contribution to ensure early epidemic medical care, etc. 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 contribution to ensure early epidemic medical care, etc., is to have the effect of renewal of the statute of limitations.

(Computation of a Period of Time)

Article 64-5 The provisions of the Civil Code concerning the computation of a period of time apply mutatis mutandis to the computation 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 on a request for administrative review concerning any disposition imposed by the mayor of a city, etc. having 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, etc. having 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 the city or special ward or to the head of an administrative organ under the control of the 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 the same Act.

(Classification of Administrative Affairs)

Article 65-2 The affairs which prefectural governments or cities, etc. having 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 the same Article as applied mutatis mutandis in paragraph (9) thereof, paragraphs (2) and (3) of the same Article as applied mutatis mutandis in paragraph (4) of the same 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 same 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), paragraphs (1) and (2) of the same Article 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, paragraph (1) of the same Article as applied mutatis mutandis in Article 51, paragraph (4), and Article 44-5, paragraph (3) as applied mutatis mutandis in Article 51-4, paragraph (2) and paragraph (3) of the same Article), 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 abolished 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 such establishment, revision or abolition.

## **Chapter XV Penal Provisions**

Article 67 (1) A person who emits Class I Pathogens, etc. without good reason,

thereby endangering 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 the same 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 commitment 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 set forth 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, etc. in violation of the provisions of Article 56-3; or
  - (ii) when transferring or receiving Class I Pathogens, etc. 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 commitment 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 the crimes set forth in the preceding two paragraphs will be punished.

Article 70 When a person has imported Class II Pathogens, etc. 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, etc. 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, etc. 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 set forth 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 set forth 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 the same 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 making 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 failing to answer or giving a false answer to any question under the same paragraph;  
or
- (viii) when a person refuses, obstructs or avoids any entry or inspection under the provisions of Article 56-38, paragraph (2) or failing to make a statement or making a false statement to any question under the same paragraph.

Article 73 (1) If a physician becomes aware of any secret of an individual in the course of 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; hereinafter the same applies in

paragraph (1) of Article 74) or providing medical treatment for that Infectious Disease and the physician divulges such a 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 ex-government employee who was engaged in the affairs concerning any of the following matters divulges a secret of any individual which came to their attention in the course of executing the duties for those affairs without reasonable grounds: acceptance of a notification under the provisions of Articles 12 to 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 the same Article is extended pursuant to a Cabinet Order referred to in paragraph (2) of the same Article; the same applies hereinafter) 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 the same Article is extended pursuant to a Cabinet Order referred to in paragraph (2) of the same Article; the same applies hereinafter); receipt of 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 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)); questioning 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 the cases where they are applied with the replacement of terms pursuant to the provisions of paragraph (7) of the same Article), or reporting or questioning under the provisions of paragraph (1) of the same 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 specimens or pathogens of an Infectious Disease under the provisions of Article 26-3, 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)), including cases where such receipt is performed pursuant to the provisions of Article 50, paragraph (1) or (7); forcible collection of 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 such 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 such 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 such 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, 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 the same Article is extended by the Cabinet Order under the provisions of paragraph (2) of the same Article; the same applies hereinafter 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), 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)), under the provisions of Articles 31 through 33, or under the provisions of 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 ex-government employee divulges any secret referred to in the preceding paragraph which came to their attention in the course of executing the duties for relevant affairs without reasonable grounds.

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 such a person has divulged any confidential information of any person they have come to know in relation to the affairs pertaining to the entrustment without reasonable grounds, 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 contents of the anonymous infectious disease-related information that was learned through the use of anonymous Infectious Disease-related information, or uses it for an unreasonable purpose or in violation of the provisions of Article 56-45,;
- (ii) when violating an order made under the provisions of Article 56-47.

Article 74 (1) If a person becomes aware in the course of duties that a certain individual is a patient with an Infectious Disease and the person divulges such a 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 asked by the referenced official under the provisions of the same 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 file a notification under the provisions of the main clause of Article 56-16, paragraph (1) or the provisions of Article 56-17 or filing a false notification;
- (iii) when failing to file a notification under the provisions of Article 56-22, paragraph (2) or filing a false notification;
- (iv) when violating the provisions of Article 56-24 (limited to the part pertaining to Holders of Specified Class I Pathogens, etc. or Permitted Holders of Class II Pathogen, etc.);
- (v) when failing to file a notification under the provisions of Article 56-27, paragraph (1) or filing a false notification, and transporting Class I Pathogens, etc., Class II Pathogens, etc., or Class III Pathogens, etc.;
- (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 file a notification under the provisions of Article 56-11, paragraph (2) (including cases where it is applied mutatis mutandis in Article 56-14) or filing a false notification, and making a change prescribed in the proviso of Article 56-11, paragraph (1);
- (ii) when failing to file a notification under the provisions of Article 56-16,

paragraph (2), Article 56-28, or Article 56-29, paragraph (3) or filing 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 the same 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 file a notification under the provisions of Article 12, paragraph (1) or (8) or the provisions of paragraph (1) of the same Article as applied mutatis mutandis in paragraph (10) of the same 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 pertaining to a New Infectious Disease;
- (ii) when a veterinarian fails to file a notification under the provisions of Article 13, paragraph (1) or the provisions of paragraph (1) of the same Article as applied mutatis mutandis in paragraph (7) of the same 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 asked by the referenced 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 the same Article), or refusing, obstructing or avoiding any inspection by the referenced 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, etc. having 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 falsely answering to any question asked by the referenced 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 referenced 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 the same 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 the paragraph or giving a false answer, 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 the same paragraph, they are to be punished by a fine of not more than 500 thousand yen.

Article 77-2 When failing to file 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 set forth in the same 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 (hereinafter referred to as an "association or foundation without juridical personality" in this Article); hereinafter the same applies in this Article) (including an administrator of an association or foundation without juridical personality), or an agent, employee or other staff member of a corporation or individual commits a crime referred to in Article 67 or commits a violation referred to in Articles 68 to 72, Article 73-3, Article 75, Article 76, Article 77, paragraph (1), items (x) through (xiii) or Article 77-2 in connection with the business or services operated by the corporation or individual, not only will the offender be punished but 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 criminal procedure in cases where a juridical person is the accused or a suspect is 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); hereinafter the same applies 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 the same 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 not been hospitalized by the beginning of the period they should be hospitalized without reasonable grounds, the person is to be punished by a civil fine of not more than 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 to answer the questions asked 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)) without reasonable grounds 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 the same 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 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 file 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 file 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 file a notification under the provisions of Article 56-18, paragraph (2).