

Medical Care Act

(Act No. 205 of July 30, 1948)

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Chapter I General Provisions

Article 1 The purpose of this Act is to contribute to the protection of the health of the nation by safeguarding the interests of medical care recipients and ensuring a system that efficiently delivers high quality and well-suited medical care, by means of providing for the necessary particulars to support well-suited choices about medical care by the recipients thereof, the necessary particulars to ensure the safety of medical care, the necessary particulars concerning the establishment and management of hospitals, clinics, and birthing centers, and the necessary particulars to develop such facilities and promote the sharing of functions and cooperation between medical institutions.

Article 1-2 (1) Medical care is to be provided in accordance with the physical and mental state of the medical care recipient, based on a relationship of trust between the physician, dentist, pharmacist, nurse, or other medical care

professional and the medical care recipient, in a way which respects life and ensures the dignity of the individual, and not only the medical treatment, but including measures to prevent illness and rehabilitation measures must also be of high quality and well-suited.

- (2) Medical care must be provided as a basis for efforts to ensure and improve the health of the nation, fully respecting the wishes of the medical care recipients, and seeking efficiency and organic coordination among associated services such as welfare services, in accordance with the functions of the medical institutions (hereinafter referred to as "medical institutions"), in hospitals, clinics, long-term care health facilities, integrated facilities for medical and long-term care, dispensing pharmacies, and other facilities that provide medical care, and in the homes of medical care recipients (meaning a home and other place specified by an Order of the Ministry of Health, Labour and Welfare; the same applies hereinafter).

Article 1-3 The national and local governments must endeavor to ensure a system that will efficiently provide high quality and well-suited medical care to the people based on the concepts provided in the preceding Article.

Article 1-4 (1) Physicians, dentists, pharmacists, nurses, and other medical care professionals must endeavor to deliver high quality and well-suited medical care to medical care recipients, based on the concepts provided for in Article 1-2.

- (2) In providing medical care, a physician, dentist, pharmacist, nurse or other medical care professional must give proper explanations and endeavor to foster understanding in medical care recipients.
- (3) Physicians and dentists practicing at a medical institution, when necessary, must refer medical care recipients to other medical institutions, provide information concerning diagnoses or prescriptions as required for the treatment of medical care recipients to physicians, dentists, or pharmacists engaged in diagnoses or prescriptions at other medical institutions, and must undertake other measures as required to contribute to a sharing of functions and cooperation among medical institutions.
- (4) In the case that a patient leaving a hospital or clinic continues to require medical treatment, the administrator of the relevant hospital or clinic must seek cooperation with providers of health and medical services or welfare services, and have the consideration to enable the relevant patient to continue receiving medical treatment in an appropriate environment.
- (5) The organizers and administrators of a medical institution must have consideration to allow physicians, dentists, pharmacists, nurses, and other medical care professionals who do not work at the relevant medical institution

to use the buildings or equipment thereof in order to carry out their practices, research, or training, to foster the dissemination of medical care techniques, and to efficiently provide medical care.

Article 1-5 (1) The term "hospital" as used in this Act means a facility for the hospitalization of not less than 20 patients, where physicians or dentists carry out medical practices or dental practices for the public or other specific groups of people. A hospital must be organized and operated primarily for offering facilities that enable the scientific and proper treatment of the sick and injured.

(2) The term "clinic" as used in this Act means a facility with no in-patient capacity, or a facility for the hospitalization of no more than 19 patients, where physicians or dentists carry out medical practices or dental practices for the public or other specific groups of people.

Article 1-6 (1) The term "long-term care health facility" as used in this Act means a long-term care health facility pursuant to the provisions of the Long-Term Care Insurance Act (Act No. 123 of 1997).

(2) The term "integrated facility for medical and long-term care" as used in this Act means an integrated facility for medical and long-term care pursuant to the provisions of the Long-Term Care Insurance Act.

Article 2 (1) The term "birthing center" as used in this Act means a place where midwives perform services (excluding those carried out in a hospital or clinic) for the public or other specific groups of people.

(2) A birthing center is not to have in-patient facilities for more than 10 pregnant women, women in labor, or women resting after childbirth.

Article 3 (1) No place that carries out the medical treatment of illnesses (including birthing assistance) and that is not a hospital or clinic is to bear a name that includes the term "hospital", "branch hospital", "maternity hospital", "sanatorium", "clinic", "dispensary", "doctor's office", or any other name that may cause it to be mistaken for a hospital or clinic.

(2) No clinic is to bear a name that includes the term "hospital", "branch hospital", "maternity hospital", or any other name that may cause it to be mistaken for a hospital.

(3) A facility which is not a birthing center is not bear a name that includes the term "birthing center" or any other name that may cause it to be mistaken for a place where midwives perform services.

Article 4 (1) A hospital established by the national government, a prefecture, municipality, a social medical corporation as provided for in Article 42-2,

paragraph (1), or any other party as prescribed by the Minister of Health, Labour and Welfare, and that meets the following conditions concerning the necessary support to ensure community medical care, may bear a name that includes the term "regional medical care support hospital" for its area, with the approval of the prefectural governor:

- (i) medical care is provided to patients who have been referred from other hospitals or clinics, and a system is in place that allows physicians, dentists, pharmacists, nurses, and other medical care professionals (hereinafter simply referred to as "medical care professionals"), who do not work at the relevant hospital to use all or part of its buildings, equipment, instruments, or tools for their practices, research, or training;
 - (ii) having the ability of providing emergency medical care;
 - (iii) having the capability of carrying out training to enhance the quality of community medical care professionals;
 - (iv) having facilities to hospitalize more patients than prescribed by an Order of the Ministry of Health, Labour and Welfare;
 - (v) having facilities provided for in Article 21, paragraph (1), items (ii) through (viii) and (x) through (xii), and Article 22, items (i), and (iv) through (ix); and
 - (vi) the buildings and equipment of the facility meet the requirements prescribed by the Order of the Ministry of Health, Labour and Welfare set forth in Article 21, paragraph (1) and Article 22 and Prefectural Order set forth therein.
- (2) In granting approval as set forth in the preceding paragraph, the prefectural governor must hear the opinions of the Prefectural Council on Medical Service Facilities in advance.
- (3) A facility that is not a regional medical care support hospital is not to bear a name that includes the term "regional medical care support hospital" or a name that may cause it to be mistaken for such.

Article 4-2 (1) A hospital that meets the following requirements may bear the name "advanced treatment hospital", with the approval of the Minister of Health, Labour and Welfare:

- (i) having the ability of providing advanced medical care;
- (ii) having the capability of carrying out the development and evaluation of advanced medical care techniques;
- (iii) having the capability of carrying out training on advanced medical care;
- (iv) having the capability of ensuring a high level of medical safety;
- (v) amongst its clinical departments, having the names of clinical departments as prescribed by an Order of the Ministry of Health, Labour and Welfare, pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare;

- (vi) having facilities to hospitalize more patients than prescribed by an Order of the Ministry of Health, Labour and Welfare;
 - (vii) the personnel meet the requirements prescribed by the Order of the Ministry of Health, Labour and Welfare set forth in Article 22-2;
 - (viii) having the facilities provided for in Article 21, paragraph (1) items (ii) through (viii) and (x) through (xii), and Article 22-2, items (ii), and (v) through (vi); and
 - (ix) the buildings and equipment of the facility meet the requirements prescribed by the Order of the Ministry of Health, Labour and Welfare set forth in Article 21, paragraph (1) and Article 22-2 and Prefectural Ordinances set forth therein.
- (2) In granting approval as set forth in the preceding paragraph, the Minister of Health, Labour and Welfare must hear the opinions of the Social Security Council in advance.
- (3) A facility that is not an advanced treatment hospital is not to bear the name "advanced treatment hospital" or a name that may cause it to be mistaken for such.

Article 4-3 (1) A hospital that meets the following requirements for playing a central role in the implementation of clinical research may bear the name "core hospital for clinical research", with the approval of the Minister of Health, Labour and Welfare:

- (i) having the capability of planning and implementing a project on specified clinical research (meaning clinical research conducted in accordance with the standards specified by an Order of the Ministry of Health, Labour and Welfare; the same applies hereinafter);
- (ii) having the capability of playing a leading role in the implementation of the specified clinical research, in the case where specified clinical research is to be implemented jointly with other hospitals or clinic;
- (iii) having the capability of providing consultation, necessary information, advice and other assistance to other hospitals or clinics concerning the implementation of specified clinical research;
- (iv) having the capability of providing training on specified clinical research;
- (v) having the names of clinical departments amongst its clinical departments, as prescribed by an Order of the Ministry of Health, Labour and Welfare;
- (vi) having facilities to hospitalize more patients than prescribed by an Order of the Ministry of Health, Labour and Welfare;
- (vii) the personnel meet the requirements prescribed by the Order of the Ministry of Health, Labour and Welfare set forth in Article 22-3;
- (viii) having facilities provided for in Article 21, paragraph (1), items (ii) through (viii) and (x) through (xii), and Article 22-3, items (ii), (v) and (vi);

- (ix) the buildings and equipment of the facility meet the requirements prescribed by the Order of the Ministry of Health, Labour and Welfare set forth in Article 21, paragraph (1) and Article 22-3 and Prefectural Ordinances set forth therein; and
 - (x) beyond what is listed in each of the preceding items, the requirements specified by an Order of the Ministry of Health, Labour and Welfare concerning the implementation of specified clinical research are met.
- (2) In granting approval as set forth in the preceding paragraph, the Minister of Health, Labour and Welfare must hear the opinions of the Social Security Council in advance.
- (3) A facility that is not a core hospital for clinical research is not to bear the name "core hospital for clinical research" or a name that may cause it to be mistaken for such.

Article 5 (1) For a physician or dentist who practices solely through house calls for the public or other specific groups of people, or a midwife who engages in services solely through house calls is to consider each such address as a clinic or birthing center with regards to the applicability of the provisions set forth in Article 6-4-2, Article 6-5, or Article 6-7, Article 8 and Article 9.

- (2) A prefectural governor, a mayor of a city as prescribed by the Cabinet Order as set forth in Article 5, paragraph (1) of the Community Health Act (Act No. 101 of 1947) (hereinafter referred to as a "city with a public health center"), or a mayor of a special ward of Tokyo may, when they find it necessary, order a physician, dentist, or midwife as provided for in the preceding paragraph to report as required, or may order the submission of medical records, birth records, accounting books and documents, and other articles for inspection.

Article 5-2 (1) The Minister of Health, Labour and Welfare may, based on an application from a clinically trained physician prescribed in Article 7, paragraph (1), certify the relevant physician that has the experience necessary having knowledge concerning the provision of medical care in an acute physician shortage area (meaning an area prescribed in Article 30-4, paragraph (6) and other areas specified by an Order of the Ministry of Health, Labour and Welfare; the same applies hereinafter) and other experience specified by an Order of the Ministry of Health, Labour and Welfare.

- (2) The Minister of Health, Labour and Welfare who has granted certification under the preceding paragraph is to issue a certificate.
- (3) The Minister of Health, Labour and Welfare may rescind the certification when a physician who has obtained the certification under paragraph (1) falls under any of the following items:
- (i) when the physician has had their license revoked or has been ordered to

- suspend their medical practice;
 - (ii) when it is found that the certification under paragraph (1) was obtained by deception or other wrongful means; or
 - (iii) when the physician was sentenced to a fine or severer punishment.
- (4) Necessary particulars concerning the certification set forth in paragraph (1) and the rescission of such certification is provided for by Cabinet Order.

Article 6 The applicability of the provisions of this Act to hospitals, clinics, and birthing centers established by the national government may be prescribed separately by Cabinet Order.

Chapter II Supporting Choices in Medical Care

Section 1 Providing Information on Medical Care

- Article 6-2 (1) National government and local governments must endeavor to undertake the necessary measures to enable medical care recipients to easily acquire the necessary information for choosing a hospital, clinic, or birthing center.
- (2) Organizers and administrators of medical institutions must endeavor to provide accurate and well-suited information on the medical care provided thereby, and to appropriately respond to queries from patients or their families, to enable medical care recipients to choose appropriate health and medical services.
- (3) In order to contribute to the efficient provision of high-quality and appropriate medical care, citizens must endeavor to deepen their understanding of the importance of the sharing of functions and the coordination of operations among medical institutions, and to choose and receive medical care appropriately according to the functions of medical institutions.

- Article 6-3 (1) The administrator of a hospital, clinic, or birthing center (hereinafter referred to as "hospital, etc." in this Article) must report the particulars prescribed by an Order of the Ministry of Health, Labour and Welfare as necessary information for enabling medical care recipients to choose an appropriate hospital, etc. to the prefectural governor of the location of the relevant hospital, etc., pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare, and must make documents describing such particulars available for inspection within the relevant hospital, etc.
- (2) If a change arises with regard to particulars reported pursuant to the provisions of the preceding paragraph, the administrator of a hospital, etc. must promptly promptly to the prefectural governor of the location of the

relevant hospital, etc., and amend the details of the documents provided for in the preceding paragraph, pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare.

- (3) In lieu of making documents pursuant to the provisions of paragraph (1) available for inspection, the administrator of a hospital, etc., pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare, may provide the particulars that should be stated in the relevant documents by electronic or magnetic means (which means a method using an electronic data processing system or other information communication technology; the same applies in paragraph (2) of the following Article and Article 6-4-2, paragraph (2)) specified by an Order of the Ministry of Health, Labour and Welfare.
- (4) If a prefectural governor finds it necessary in order to confirm the details of a report pursuant to the provisions of paragraph (1) or paragraph (2), the governor may request the necessary information concerning a hospital, etc. situated within the boundaries of the relevant prefecture from a municipality or other public agency.
- (5) A prefectural governor is to make public the particulars reported thereto pursuant to the provisions of paragraph (1) and paragraph (2), pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare.
- (6) If the administrator of a hospital, etc. fails to report pursuant to the provisions of paragraph (1) or paragraph (2) or has made a false report, the prefectural governor may order the organizer of the relevant hospital, etc. to have the relevant administrator give the relevant report or correct the details of the relevant report within a period that the governor prescribes.

Article 6-4 (1) When a patient has been admitted, the administrator of a hospital or clinic must have the physician or dentist responsible for their treatment prepare documents describing the following information, deliver them to the relevant patient or their family, and give an appropriate explanation thereof, pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare; provided, however, that this does not apply where the patient is expected to be discharged from the hospital in a short period of time or where prescribed by an Order of the Ministry of Health, Labour and Welfare:

- (i) the name, date of birth, and gender of the patient;
- (ii) the name of the physician or dentist primarily responsible for the relevant patient's treatment;
- (iii) the name of the illness and major symptoms leading to hospitalization;
- (iv) a plan for examinations, surgeries, medication, and other treatments to be undertaken during hospitalization (including nursing and dietary management during hospitalization); and
- (v) other particulars as prescribed by an Order of the Ministry of Health,

Labour and Welfare.

- (2) In lieu of delivering the documents as set forth in the preceding paragraph, the administrator of a hospital or clinic, pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare, may provide the particulars that should be stated in the relevant documents by electronic or magnetic means specified by an Order of the Ministry of Health, Labour and Welfare, with the consent of the patient or their family.
- (3) When a patient is being discharged from the hospital, the administrator of the relevant hospital or clinic must endeavor to have documents that describe the particulars related to health and medical services or welfare services that will be necessary for their treatment after being discharged from the hospital prepared, delivered, and appropriately explained.
- (4) In preparing the documents as set forth in paragraph (1), the administrator of a hospital or clinic must endeavor to properly reflect the opinions of the physicians, dentists, pharmacists, nurses, and other employees who work at the relevant hospital or clinic, and to appropriately provide medical care during hospitalization through organic coordination between these parties, based on the contents of the relevant documents.
- (5) In preparing the documents set forth in paragraph (3), the administrator of a hospital or clinic must endeavor to seek cooperation with providers of the health and medical services or welfare services that are necessary for the relevant patient's treatment after the patient is discharged from the hospital.

Article 6-4-2 (1) The administrator of a birthing center (or in the case of a midwife who only does house calls, the relevant midwife; the same applies in the following paragraph), when the administrator has promised to provide midwifery services to a pregnant woman or a woman in labor (hereinafter referred to as "pregnant woman, etc." in this Article and Article 19, paragraph (2)), must ensure, pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare that the midwife in charge of providing midwifery services to the relevant pregnant woman, etc. delivers a document stating the following information and provides appropriate explanation to the relevant pregnant woman, etc. or her family;

- (i) the name and date of birth of the pregnant woman, etc.;
- (ii) the name of the midwife who is in charge of providing midwifery services to the relevant pregnant woman, etc.;
- (iii) policies concerning midwifery and health guidance for the relevant pregnant woman, etc.;
- (iv) the name, address and contact information of the relevant birthing center.;
- (v) the name, address and contact information of the hospital or clinic that responds to the abnormality of the relevant pregnant woman, etc.; and

- (vi) other particulars specified by an Order of the Ministry of Health, Labour and Welfare.
- (2) In lieu of delivering the documents as set forth in the preceding paragraph, the administrator of a birthing center, pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare, provide the particulars that should be stated in the relevant documents by electronic or magnetic means specified by an Order of the Ministry of Health, Labour and Welfare, with the consent of the pregnant woman, etc. or her family.

Section 2 Advertisement of Medical Practices, Dental Practices, or Midwifery Services

- Article 6-5 (1) No party, when placing any advertisement or making any other representation as a means of inducing medical care recipients (hereinafter simply referred to as "advertisement" in this Section) with regard to medical practice or dental practice, or hospitals or clinics, are to run false advertisements, regardless of whether it is made in writing or by any other means.
- (2) In the case prescribed in the preceding paragraph, the contents and methods of the advertisement must conform to the following standards so as not to hinder appropriate selection of medical care by medical care recipients:
- (i) no advertisement is to be placed to the effect that the hospital or clinic is superior to other hospitals or clinics;
 - (ii) no exaggerated advertisement is to be placed;
 - (iii) no advertisement that undermines public order or corrupt good morals are to be placed; and
 - (iv) other standards specified by an Order of the Ministry of Health, Labour and Welfare as necessary for appropriate selection of medical care.
- (3) In the case prescribed in paragraph (1), advertisement of particulars other than those listed below must not be placed, except in cases specified by an Order of the Ministry of Health, Labour and Welfare as cases where there is little risk of hindering appropriate selection of medical care by medical care recipients even if advertisement of particulars other than those listed below is placed:
- (i) that the person is a physician or dentist;
 - (ii) the clinical department name;
 - (iii) the name, telephone number, information that indicates the location of the relevant hospital or clinic, and the name of the administrator of the relevant hospital or clinic;
 - (iv) the days and hours of practice, or whether an appointment can be booked;
 - (v) for a hospital, clinic, physician, or dentist that is designated to undertake

- standard medical care as set forth in the provisions of laws and regulations, a statement to that effect;
- (vi) in the case of a physician who has obtained the certification under Article 5-2, paragraph (1), a statement to that effect;
 - (vii) in the case of a participating hospital, etc. (meaning a participating hospital, etc. prescribed in Article 70-2, paragraph (2), item (ii)) of a regional medical coordination promotion corporation (meaning a regional medical coordination promotion corporation prescribed in Article 70-5, paragraph (1); the same applies in Article 30-4, paragraph (12)), a statement to that effect;
 - (viii) whether there are in-patient facilities, the number of each type of bed provided for in Article 7, paragraph (2), the number of physicians, dentists, pharmacists, nurses, and other employees, and other particulars related to the facilities, equipment, or employees at the relevant hospital or clinic;
 - (ix) The names, ages, genders, positions, and brief personal records of medical care professionals practicing at the relevant hospital or clinic, and other particulars related to the relevant medical care professionals that are prescribed by the Minister of Health, Labour and Welfare as particulars that contribute to recipients of medical care making appropriate choices with regard to their medical care;
 - (x) measures for responding to queries concerning medical care from patients or their families, measures to ensure the safety of medical care, measures to ensure the appropriate handling of personal information, and other particulars related to the management or operation of the relevant hospital or clinic;
 - (xi) particulars related to cooperation with other hospitals, clinics, or health and medical service or welfare service providers, such as the names of the hospitals, clinics, or other health and medical service or welfare service providers to which patients may be referred, or the shared use of facilities, equipment, or tools between such parties and the relevant hospital or clinic;
 - (xii) particulars concerning the provision of information in medical records and other records related to treatment, delivery of documents provided for in Article 6-4, paragraph (3), and provision of other information on medical care at the relevant hospital or clinic;
 - (xiii) particulars related to the details of medical care provided at the relevant hospital or clinic (limited to the details of examinations, surgery, and other medical treatment methods that are prescribed by the Minister of Health, Labour and Welfare as particulars that contribute to recipients of medical care making appropriate choices with regard to their medical care);
 - (xiv) particulars related to the average number of days of hospitalization, average out-patient or in-patient numbers, and other particulars related to the results of the medical care that is provided at the relevant hospital or

clinic and that are prescribed by the Minister of Health, Labour and Welfare as particulars that contribute to recipients of medical care making appropriate choices with regard to their medical care; and
(xv) other particulars prescribed by the Minister of Health, Labour and Welfare is to be dealt with in the same manner as particulars listed in each of the previous items.

(4) When the Minister of Health, Labour and Welfare intends to plan the enactment, revision or abolition of an Order of the Ministry of Health, Labour and Welfare set forth in item (iv) of paragraph (2) or the preceding paragraph, or to prepare a draft of the particulars listed in item (viii) or items (xii) through (xiv) of the preceding paragraph, the minister must hear the opinions of groups of persons with the relevant knowledge and experience in medical practice in order to plan or prepare based on expert scientific opinions on medical care.

Article 6-6 (1) Clinical department names pursuant to the provisions of paragraph (3), item (ii) of the preceding Article are to be the clinical department names of medical practices and dental practices prescribed by a Cabinet Order, or clinical department names other than such clinical department names in which the practicing physician or dentist has been given permission by the Minister of Health, Labour and Welfare.

(2) The Minister of Health, Labour and Welfare must hear the opinions of academic societies of medicine and medical science and the Medical Ethics Council, when planning to enact, amend, or abolish the Cabinet Order set forth in the preceding paragraph.

(3) In granting the permission set forth in paragraph (1), the Minister of Health, Labour and Welfare must hear the opinions of the Medical Ethics Council in advance.

(4) If an advertisement of a clinical department name that is related to the permission under the provisions of paragraph (1) is placed, the name of the physician or dentist who received that permission must be advertised alongside the relevant clinical department name.

Article 6-7 (1) No party, when placing any advertisement with regard to midwifery services or birthing centers, is to run false advertisement, regardless of whether it is made in writing or by any other means.

(2) In the case prescribed in the preceding paragraph, the contents and methods of the advertisement must conform to the following standards so as not to hinder appropriate selection of medical care by medical care recipients:

(i) no advertisement is to be placed to the effect that the birthing center is superior to other birthing centers;

- (ii) no exaggerated advertisement is to be placed;
 - (iii) no advertisement that undermines public order or corrupt good morals is to be placed; and
 - (iv) other standards specified by an Order of the Ministry of Health, Labour and Welfare as necessary for appropriate selection of medical care.
- (3) In the case prescribed in paragraph (1), no advertisement of particulars other than those listed below are to be placed, except in cases specified by an Order of the Ministry of Health, Labour and Welfare as cases where there is little risk of hindering appropriate selection of medical care by medical care recipients even if advertisement of particulars other than those listed below is placed:
- (i) that the person is a midwife;
 - (ii) the name, telephone number, information that indicates the location of the birthing center, and the name of the administrator of the birthing center;
 - (iii) business days and hours or whether services can be booked;
 - (iv) whether there are in-patient facilities, the admission capacity, number of midwives and other employees, and other particulars related to the facilities, equipment or employees of the relevant birthing center;
 - (v) the names, ages, positions, and brief personal records of the midwives engaged in services at the relevant birthing center, and other particulars related to midwives, as prescribed by the Minister of Health, Labour and Welfare as particulars that contribute to recipients of medical care making appropriate choices with regard to their medical care;
 - (vi) measures for responding to queries on medical care from patients or their families, measures to ensure the safety of medical care, measures to ensure the appropriate handling of personal information, and other particulars related to the management or operation of the relevant birthing center;
 - (vii) particulars related to cooperation with the services of the relevant birthing center, such as the names of the contract physicians provided for in Article 19, paragraph (1), or the names of hospitals or clinics;
 - (viii) particulars related to the provision of information on birth records and the provision of information on medical care at the relevant birthing center; and
 - (ix) other particulars prescribed by the Minister of Health, Labour and Welfare as equivalent to the particulars listed in each of the previous items.

Article 6-8 (1) If a prefectural governor, a mayor of a city with a public health center, or a mayor of a special ward of Tokyo finds that the advertisement related to a medical practice, a dental practice, or midwifery services, or to a hospital, clinic, or birthing center violates the provisions of Article 6-5, paragraphs (1) through (3) or the preceding Article, the governor or mayor may

order the party that placed the relevant advertisement to report as required, or may have the relevant official enter the offices of the party that placed the relevant advertisement, and inspect documents or other articles related to the relevant advertisement.

- (2) If a prefectural governor, a mayor of a city with a public health center, or a mayor of a special ward of Tokyo finds that the advertisement related to a medical practice, a dental practice, or midwifery services, or to a hospital, clinic or birthing center violates the provisions of Article 6-5, paragraph (2) or (3), or paragraph (2) or (3) of the preceding Article, the governor or mayor may order the party that placed the relevant advertisement to discontinue the relevant advertisement or correct its contents by a set deadline.
- (3) An official who enters and inspects pursuant to the provisions of paragraph (1) must carry a certificate for identification and present it when requested by the concerned parties.
- (4) The authority granted pursuant to the provisions of paragraph (1) is not be construed as being approved for a criminal investigation.

Chapter III Ensuring Safety in Medical Care

Section 1 Measures for Ensuring Safety in Medical Care

Article 6-9 The national government, prefectures, cities with public health centers and special wards of Tokyo must endeavor to undertake the necessary measures to ensure safety in medical care, including the provision of information on safety in medical care, training, and raising awareness on compliance.

Article 6-10 (1) The administrator of a hospital, clinic, or birthing center (hereinafter referred to as "hospital, etc." in this Chapter), when a medical accident (meaning a death or stillbirth caused or suspected to be caused by medical care provided by medical care professionals working in the relevant hospital, etc. and determined by an Order of the Ministry of Health, Labour and Welfare as a death or stillbirth which the relevant administrator did not expect; the same applies hereinafter in this Chapter) has occurred, the administrator must immediately report the date, time, place and circumstances of the relevant medical accident and other particulars specified by an Order of the Ministry of Health, Labour and Welfare to the medical accident investigation and support center set forth in Article 6-15, paragraph (1), pursuant to an Order of the Ministry of Health, Labour and Welfare.

- (2) Prior to the submission of a report pursuant to the provision of the preceding paragraph, the administrator of the hospital, etc. must explain to the bereaved family of the deceased pertaining to the medical accident or the parents of the

stillborn baby pertaining to the medical accident and other persons specified by an Order of the Ministry of Health, Labour and Welfare (hereinafter simply referred to as "bereaved family" in this Chapter) about the particulars specified by an Order of the Ministry of Health, Labour and Welfare; provided, however, that this does not apply when there is no bereaved family or the whereabouts of the bereaved family are unknown.

Article 6-11 (1) In the event of a medical accident, the administrator of a hospital, etc., pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare, must immediately conduct an investigation necessary to clarify the cause of the accident (hereinafter referred to as "medical accident investigation" in this Chapter).

(2) The administrator of a hospital, etc. is to seek the support necessary for conducting medical accident investigations from an academic organization related to medicine and medical science or any other organization specified by the Minister of Health, Labour and Welfare (in the case of an organization that is not a corporation, it is to be limited to an organization with a designated representative or administrator; referred to as "medical accident investigation support organization" in the following paragraph and Article 6-22).

(3) When a medical accident investigation support organization is requested to provide support in accordance with the provisions of the preceding paragraph, it is to provide the necessary support for medical accident investigation.

(4) When the administrator of a hospital, etc. has completed a medical accident investigation, the administrator must immediately report the results to the medical accident investigation and support center set forth in Article 6-15, paragraph (1), pursuant to an Order of the Ministry of Health, Labour and Welfare.

(5) Prior to the submission of a report pursuant to the provisions of the preceding paragraph, the administrator of the hospital, etc. must explain to the bereaved family about the particulars specified by an Order of the Ministry of Health, Labour and Welfare; provided, however, that this does not apply when there is no bereaved family or the whereabouts of the bereaved family are unknown.

Article 6-12 Beyond what is provided for in the preceding two Articles, the administrator of a hospital, etc., pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare, must take measures to ensure the safety of medical care in the relevant hospital, etc., such as formulating guidelines to ensure the safety of medical care and providing training for employees.

Article 6-13 (1) Prefectures, cities with public health centers, and special wards

(hereinafter referred to as "prefectures, etc." in this Article and the following Article) must endeavor to provide facilities (hereinafter such a facility is referred to as a "medical care safety support center") for the implementation of the following operations, in order to undertake the measures provided for in Article 6-9:

- (i) handling complaints and responding to queries from patients or their families concerning medical care at the hospitals, etc. situated within the boundaries of the relevant prefecture, etc., and giving advice as required to the relevant patients or their families and the administrators of the relevant hospitals, etc.;
 - (ii) providing information as required to ensure safety in medical care to the organizers, administrators, and employees of the hospitals, etc. situated within the boundaries of the relevant prefecture, etc., patients or their families, or citizens;
 - (iii) implementing training on safety in medical care for the administrators and employees of the hospitals, etc. situated within the boundaries of the relevant prefecture, etc.; or
 - (iv) providing support beyond that listed in the preceding three items as required to ensure safety in medical care within the boundaries of the relevant prefecture, etc.
- (2) When a medical care safety support center has been established pursuant to the provisions of the preceding paragraph, the prefecture, etc. must provide public notice of its name and location.
- (3) A prefecture, etc. may entrust the operations of a medical care safety support center to a general incorporated association, general incorporated foundation, or to another party prescribed by an Order of the Ministry of Health, Labour and Welfare.
- (4) Personnel (including parties to whom operations have been entrusted pursuant to the provisions of the preceding paragraph (and their officers in the case that such a party is a corporation) and their personnel) who are or have been engaged in the operations of a medical care safety support center must not divulge any secret acquired in relation to the relevant operations without justifiable grounds.

Article 6-14 The national government, beyond providing information on safety in medical care, provide advice and other support on the management of medical care safety support centers to prefectures, etc., to contribute to the appropriate implementation of operations in medical care safety support centers.

Section 2 Medical Accident Investigation and Support Center

Article 6-15 (1) The Minister of Health, Labour and Welfare, upon application, may designate as a medical accident investigation and support center a general incorporated association or general incorporated foundation whose purpose is to contribute to ensuring the safety of medical care by conducting medical accident investigations and providing support for medical accident investigations conducted by the administrators of hospitals, etc. in which medical accidents have occurred, and which is found to be capable of appropriately and reliably performing the services prescribed in the following Article.

(2) When the Minister of Health, Labor and Welfare has made a designation under the provisions of the preceding paragraph, the minister must make public the name, address, and office location of the relevant medical accident investigation and support center.

(3) When a medical accident investigation and support center intends to change its name, address, or the location of its office, the center must notify the Minister of Health, Labour and Welfare to that effect in advance.

(4) When the Minister of Health, Labour and Welfare has received a notification under the preceding paragraph, the minister must make public the particulars pertaining to the relevant notification.

Article 6-16 The medical accident investigation and support center are to perform the following services:

(i) organize and analyze the information collected through the report under the provisions of Article 6-11, paragraph (4):

(ii) report the results of the organization and analysis of the information under the preceding item to the administrators of hospitals, etc. that have made a report under the provisions of Article 6-11, paragraph (4):

(iii) conduct the investigation set forth in paragraph (1) of the following Article and report the results to the administrator and the bereaved family set forth in the same paragraph:

(iv) provide training on knowledge and skills pertaining to medical accident investigation to those engaged in medical accident investigation:

(v) provide consultation on the implementation of medical accident investigation and provide necessary information and support:

(vi) promote dissemination of information and awareness-raising about prevention of recurrence of medical accidents: and

(vii) beyond what is listed in each of the preceding items, to perform services necessary to ensure the safety of medical care.

Article 6-17 (1) The medical accident investigation and support center may conduct necessary investigations when the administrator of a hospital, etc.

where a medical accident has occurred or a bereaved family requests an investigation of the relevant medical accident.

- (2) When the medical accident investigation and support center finds it necessary to conduct the investigation set forth in the preceding paragraph, it may request the administrator set forth in the same paragraph to provide written or oral explanations or submit materials or other forms of necessary cooperation.
- (3) The administrator prescribed in paragraph (1) must not refuse a request made by the medical accident investigation and support center pursuant to the preceding paragraph.
- (4) When the administrator prescribed in paragraph (1) refuses a request under the provisions of paragraph (2), the medical accident investigation and support center may make a public announcement to that effect.
- (5) When the medical accident investigation and support center has completed the investigation under paragraph (1), it must report the results of the investigation to the administrator and the bereaved family prescribed in the same paragraph.

Article 6-18 (1) When the medical accident investigation and support center performs the services listed in each item of Article 6-16 (hereinafter referred to as "investigation services, etc."), prior to performance of such services, the center must establish rules for investigation services, etc. covering particulars concerning the implementation method of investigation services, etc. and other particulars specified by an Order of the Ministry of Health, Labour and Welfare (referred to as the "service rules" in the following paragraph and Article 6-26, paragraph (1), item (iii)), and obtain approval from the Minister of Health, Labour and Welfare. The same applies when the medical accident investigation and support center intends to change the relevant rules.

- (2) When the Minister of Health, Labour and Welfare finds that the service rules approved under the preceding paragraph have become inappropriate for the proper and reliable implementation of the investigation services, etc., the minister may order that the relevant service rules be changed.

Article 6-19 (1) Each business year, the medical accident investigation and support center, pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare, must prepare a business plan and a budget for income and expenditure with respect to the investigation services, etc. and obtain the approval from the Minister of Health, Labour and Welfare. The same applies when the medical accident investigation and support center intends to change the relevant business plan and budget.

- (2) The medical accident investigation and support center, pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare, must

prepare and submit to the Minister of Health, Labour and Welfare a business report and a statement of income and expenditure with respect to the investigation services, etc. after the end of each business year.

Article 6-20 The medical accident investigation and support center must not suspend or abolish all or part of the investigation services, etc. without obtaining approval from the Minister of Health, Labour and Welfare.

Article 6-21 No officer or employee of the medical accident investigation and support center, or any former officer or employee thereof must divulge any secret obtained in connection with the investigation services, etc. without justifiable grounds.

Article 6-22 (1) The medical accident investigation and support center may entrust a part of the investigation services, etc. to a medical accident investigation support organization.

(2) An officer or employee of a medical accident investigation support organization entrusted with the investigation services, etc. under the preceding paragraph, or a person who used to be such an officer or employee must not divulge any secret obtained in connection with the relevant investigation services, etc. entrusted to them without justifiable grounds.

Article 6-23 The medical accident investigation and support center, pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare, must keep books, describe particulars specified by an Order of the Ministry of Health, Labour and Welfare concerning the investigation services, etc. therein, and store them.

Article 6-24 (1) When the Minister of Health, Labour and Welfare finds it necessary in order to ensure the proper operation of investigation services, etc., the minister may order the medical accident investigation and support center to make necessary reports on the status of the investigation services, etc. or assets, or have the relevant officials enter the office of the medical accident investigation and support center and inspect the status of the investigation services, etc. or books, documents or other objects.

(2) The official who enters and inspects under the provisions of the preceding paragraph must carry a certificate for identification and present it to the persons concerned.

(3) The authority under the provisions of paragraph (1) must not be construed as being granted for the purpose of criminal investigation.

Article 6-25 The Minister of Health, Labour and Welfare, to the extent necessary to enforce the provisions of this Section, may issue to the medical accident investigation and support center orders necessary for the supervision of the investigation services, etc.

Article 6-26 (1) When the medical accident investigation and support center falls under any of the following items, the Minister of Health, Labour and Welfare may rescind the designation under the provisions of Article 6-15, paragraph (1) (hereinafter referred to as "designation" in this Article):

- (i) when the medical accident investigation and support center is found to be unable to perform investigation services, etc. appropriately and reliably;
- (ii) when there has been a wrongful act with regard to the designation; or
- (iii) when the medical accident investigation and support center has violated the provisions of this Section or an order or disposition thereunder, or has performed investigation services, etc. without complying with the service rules approved under Article 6-18, paragraph (1).

(2) When the Minister of Health, Labour and Welfare has rescinded a designation pursuant to the provisions of the preceding paragraph, the minister must make a public announcement to that effect.

Article 6-27 Beyond what is provided for in this Section, necessary particulars concerning the medical accident investigation and support center are to be specified by an Order of the Ministry of Health, Labour and Welfare.

Chapter IV Hospitals, Clinics, and Birthing Centers

Section 1 Foundation

Article 7 (1) When a person wishes to establish a hospital, when a person who is neither a person registered pursuant to the provisions of Article 16-6, paragraph (1) of the Medical Practitioners Act (Act No. 201 of 1948) (limited to persons registered pursuant to the provisions of paragraph (2) of the same Article who have been issued an order by the Minister of Health, Labour and Welfare pursuant to the provisions of Article 7-2, paragraph (1) of the same Act; hereinafter referred to as a "clinically trained physician") nor a person registered pursuant to the provisions of Article 16-4, paragraph (1) of the Dentists Act (Act No. 202 of 1948) (limited to persons registered pursuant to the provisions of paragraph (2) of the same Article who have been issued an order by the Minister of Health, Labour and Welfare pursuant to the provisions of Article 7-2, paragraph (1) of the same Act; hereinafter referred to as a "clinically trained dentist") wishes to establish a clinic, and when a person who is not a midwife (limited to persons who have been issued an order by the

Minister of Health, Labour and Welfare pursuant to the provisions Article 15-2, paragraph (1) of the Act on Public Health Nurses, Midwives and Nurses (Act No. 203 of 1948) and who are registered pursuant to the provisions of paragraph (3) of the same Article; hereinafter the same applies in this Article, Article 8 and Article 11) wishes to establish a birthing center, the person must first acquire permission to do so from the prefectural governor for the location of the relevant facility (the mayor of a city with a public health center or the mayor of a special ward in the case that the location of the relevant clinic or birthing center is within such a city with a public health center or a special ward; the same applies in Article 8 through Article 9, Article 12, Article 15, Article 18, Article 24, Article 24-2, Article 27, and Article 28 through Article 30).

(2) When a person who has established a hospital wishes to alter the number of beds, the classification of beds described in each of the following items (hereinafter referred to as "bed classifications"), or other particulars prescribed by an Order of the Ministry of Health, Labour and Welfare, when a person who is neither a clinically trained physician nor a clinically trained dentist but has established a clinic or a person who is not a midwife but has established a birthing center, wishes to alter the number of beds or other particulars prescribed by an Order of the Ministry of Health, Labour and Welfare, the same applies as in the preceding paragraph, except where prescribed by an Order of the Ministry of Health, Labour and Welfare:

(i) psychiatric hospital beds (meaning hospital beds for the hospitalization of persons with psychiatric disorders; the same applies hereinafter):

(ii) infectious disease hospital beds (meaning hospital beds for the hospitalization of patients (including persons regarded as patients with Class I infectious diseases, Class II infectious diseases, infectious diseases including novel influenza A, and designated infections pursuant to the provisions of Article 8 of the Act on the Prevention of Infectious Diseases and Medical Care for Patients Suffering from Infectious Diseases (Act No. 114 of 1998) (including where Article 7 of the same Act applies *mutatis mutandis*)) with Class I infectious diseases provided for in Article 6, paragraph (2) of the same Act, Class II infectious diseases provided for in paragraph (3) of the same Article (except tuberculosis), infections including novel influenza A provided for in paragraph (7) of the same Article, and designated infections provided for in paragraph (8) of the same Article (limited to those infections to which the provisions of Article 19 or Article 20 of the same Act apply *mutatis mutandis* under the provisions of Article 7 of the same Act), and persons found to have new infectious diseases provided for in Article 6, paragraph (9) of the same Act; the same applies hereinafter):

(iii) tuberculosis hospital beds (meaning hospital beds for the hospitalization of

- tuberculosis patients; the same applies hereinafter):
- (iv) long-term care beds (meaning hospital or clinic beds other than those described in the above three items that are primarily for the hospitalization of patients requiring long-term recuperation; the same applies hereinafter):
or
 - (v) general beds (meaning hospital or clinic beds other than those described in each of the above items; the same applies hereinafter).
- (3) When a person wishes to provide beds in a clinic, or when the person wishes to alter the number of beds in a clinic, the bed classifications, or other particulars prescribed by an Order of the Ministry of Health, Labour and Welfare, the person must first acquire permission to do so from the prefectural governor of the area in which the relevant clinic is situated, except where prescribed by an Order of the Ministry of Health, Labour and Welfare.
- (4) Where there has been an application for permission as set forth in the preceding three paragraphs, the prefectural governor, mayor of a city with a public health center or mayor of a special ward must grant permission as set forth in the preceding three paragraphs if the buildings, equipment, and personnel of the facility pertaining to the relevant application comply with the requirements prescribed by the Order of the Ministry of Health, Labour and Welfare set forth in Article 21 and Article 23 and the Prefectural Ordinance set forth in Article 21.
- (5) When a prefectural governor grants permission for an application for permission to establish a hospital, or permission to increase the number of beds or alter bed classifications in a hospital, or permission to set up new beds in a clinic, or permission to increase the number of beds or alter bed classifications in a clinic, the governor, if with regard to the beds pertaining to the relevant application, out of the functional classification of beds prescribed in Article 30-13, paragraph (1) (hereinafter referred to as "functional classification of beds" in this paragraph), the number of existing beds according to the functional classification of beds in the vision area (meaning the "vision area" prescribed in Article 30-4, paragraph (2), item(vii), which is specified in a medical care plan prescribed in Article 30-4, paragraph (1) (hereinafter referred to as "medical care plan" in this paragraph, the following Article and Article 7-3, paragraph (1)); the same applies in Article 7-3, paragraph (1)) including the location of the hospital or clinic pertaining to the relevant application has not reached the future requirements for the number of beds prescribed in (a) of the same item in the relevant vision area specified in the medical care plan, may attach conditions specified by an Order of the Ministry of Health, Labour and Welfare as necessary for the provision of medical care pertaining to such a case and for the promotion of the achievement of the other regional medical care vision prescribed in the same item specified in the

medical care plan.

- (6) Notwithstanding the provisions of paragraph (4), the permission set forth in paragraph (1) may be refused to a person who wishes to establish a hospital, clinic or birthing center for profit.

Article 7-2 (1) Where the following persons have applied for permission to establish a hospital, to increase the number of beds, or to alter bed classifications in a hospital, notwithstanding the provisions of paragraph (4) of the preceding Article, the prefectural governor may refuse the permission set forth in paragraph (1) or paragraph (2) of the same Article when, in the area that includes the hospital to which the relevant application relates (where the beds to which the relevant application relates are recuperation or general beds only (hereinafter referred to as "long-term care beds, etc." in this Article and paragraph (1) of the following Article), this may be the area provided for in Article 30-4, paragraph (2), item (xiv) as prescribed by the medical care plan; where the beds to which the relevant application relates are psychiatric beds, infectious disease beds, or tuberculosis beds only (hereinafter referred to as "psychiatric beds, etc." in this paragraph), this is to be the prefectural area; and where the beds to which the relevant application relates are long-term care beds, etc. and psychiatric beds, etc., this is to be the area provided for in Article 30-4, paragraph (2), item (xiv) and the prefectural area), the number of hospital or clinic beds that correspond to the classifications of the beds that the relevant application relates to (or the number of long-term care beds and general beds in the relevant area, where the beds that the relevant application relates to are long-term care beds, etc. only) has already reached the target number of beds for the relevant area, as prescribed in a medical care plan that is in accordance with the requirements prescribed by the Order of the Ministry of Health, Labour and Welfare set forth in paragraph (8) of the same Article, or if it is considered that establishing a hospital, increasing the number of beds, or altering the bed classifications as per the relevant application would exceed the relevant target:

- (i) a person as provided for in Article 31;
- (ii) mutual aid associations and federations thereof formed under the provisions of the National Public Officers Mutual Aid Association Act (Act No. 128 of 1958);
- (iii) mutual aid associations formed under the provisions of the Local Public Officers Mutual Aid Association Act (Act No. 152 of 1962);
- (iv) beyond what is listed in the preceding two items, mutual aid associations and federations thereof formed under laws and regulations prescribed by Cabinet Order;
- (v) the Promotion and Mutual Aid Corporation for Private Schools of Japan

- which administers the private school mutual aid system pursuant to the provisions of the Private School Personnel Mutual Aid Association Act (Act No. 245 of 1953);
- (vi) the National Federation of Health Insurance Societies and its federations formed under the provisions of the Health Insurance Act (Act No. 70 of 1922);
 - (vii) the National Health Insurance Association and national health insurance organizations formed under the provisions of the National Health Insurance Act (Act No. 192 of 1958); or
 - (viii) Japan Community Health Care Organization.
- (2) Where a person listed in any of the items of the preceding paragraph has applied for permission to establish beds in a clinic or to increase the number of beds in a clinic, the prefectural governor may, notwithstanding the provisions of paragraph (4) of the preceding Article, refuse the permission set forth in paragraph (3) of the same Article, when, in the area that includes the clinic to which the relevant application relates (an area provided for in Article 30-4, paragraph (2), item (xiv) as prescribed by the medical care plan) the number of long-term care beds and general beds has already reached the target number of long-term care beds and general beds for the relevant area as prescribed in a medical care plan that is in accordance with the requirements prescribed by the Order of the Ministry of Health, Labour and Welfare as set forth in paragraph (8) of the same Article, or if it is considered that establishing beds or increasing the number of beds as per the relevant application would exceed the relevant target.
- (3) Where the number of long-term care beds and general beds in the area (an area provided for in Article 30-4, paragraph (2), item (xiv) as prescribed by a medical care plan) in which a hospital (limited to those with long-term care beds, etc.) or clinic (limited to those with beds permitted as set forth in paragraph (3) of the preceding Article) established by a person listed in any of the items of paragraph (1) has already reached the target number for long-term care beds and general beds in the relevant area as specified in a medical care plan that is in accordance with the requirements prescribed by the Order of the Ministry of Health, Labour and Welfare, as set forth in paragraph (8) of the same Article, when the relevant hospital or clinic is not engaging in all or some of the services related to long-term care beds, etc. under the permission set forth in paragraph (1) or paragraph (2) of the preceding Article or beds for which the permission set forth in paragraph (3) of the same Article has been received, without justifiable grounds, the prefectural governor may order the organizer or administrator of the relevant hospital or clinic to adopt measures to amend such permission so as to reduce the number of beds, up to and including the number of beds which are not used for the relevant services.
- (4) In the cases set forth in the preceding three paragraphs, in calculating the

number of existing beds in the relevant area and the number of beds to which the relevant application relates, the prefectural governor must carry out any necessary adjustments in consideration of the function and nature of the hospital or clinic, pursuant to the provisions of the Prefectural Ordinance in accordance with the requirements prescribed by the Order of the Ministry of Health, Labour and Welfare set forth in Article 30-4, paragraph (8).

- (5) The prefectural governor must hear the opinions of the Prefectural Council on Medical Service Facilities in advance, when the governor wishes to refuse permission as set forth in paragraph (1) through paragraph (3) of the preceding Article pursuant to the provisions of paragraph (1) or paragraph (2) or if the governor wishes to issue an order pursuant to the provisions of paragraph (3).
- (6) When a prefectural governor has issued an order as prescribed in paragraph (3) and the organizer or administrator of the hospital or clinic that has received the relevant order fails to comply with it, the prefectural governor may make a public announcement to that effect.
- (7) When an incorporated administrative agency (an incorporated administrative agency as provided for in Article 2, paragraph (1) of the Act on General Rules for Independent Administrative Agencies (Act No. 103 of 1999)) that has been specified by a Cabinet Order wishes to establish a hospital, increase bed numbers, or alter bed classifications at a hospital it has established, or where it wishes to establish beds in a clinic or increase bed numbers or alter bed classifications at a clinic, the agency must consult (or give notice where specially prescribed by Cabinet Order) with the Minister of Health, Labour and Welfare in advance regarding such plans. The same applies when it wishes to amend such plans.

Article 7-3 (1) Where a prefectural governor has received an application for permission to establish a hospital or permission to increase the number of beds in a hospital (limited to those related to long-term care beds, etc.), if the governor finds that the total number of long-term care beds and general beds in the vision area including the location of the hospital pertaining to the relevant application has already reached the total number of beds required in the future prescribed in Article 30-4, paragraph (2), item (vii),(a) in the relevant vision area as specified in the medical care plan, or will exceed the total number of beds required due to the establishment of the hospital or the increase in the number of beds in the hospital pertaining to the relevant application, the governor may request the person who has filed the relevant application (hereinafter referred to as the "applicant" in this Article) to submit a document stating the reason why it is necessary to establish a hospital or increase the number of beds in the hospital in the relevant vision area and other particulars specified by an Order of the Ministry of Health, Labour and

Welfare (hereinafter referred to as the "reasons, etc." in this Article).

- (2) When the prefectural governor finds that the reasons, etc. are not sufficient, the governor may request the applicant to participate in the consultation at the place of consultation prescribed in Article 30-14, paragraph (1).
- (3) The applicant, when requested by the prefectural governor pursuant to the provisions of the preceding paragraph, must endeavor to respond to the request.
- (4) The prefectural governor, when an agreement is not reached through the consultation at the place of consultation set forth in paragraph (2) or when otherwise specified by an Order of the Ministry of Health, Labour and Welfare, may request the applicant to attend a meeting of the Prefectural Council on Medical Service Facilities and explain the reasons, etc.
- (5) The applicant, when requested by the prefectural governor pursuant to the provisions of the preceding paragraph, must endeavor to attend the meeting of the Prefectural Council on Medical Service Facilities and explain the reasons, etc.
- (6) Notwithstanding the provisions of Article 7, paragraph (4), the prefectural governor, if the reasons, etc. are not found to be unavoidable based on the content of the consultation at the place of consultation set forth in paragraph (2) and the content of the explanation set forth in paragraph (4), may decide not to grant the permission set forth in paragraph (1) or (2) of the same Article to the applicant (limited to those listed in the items of paragraph (1) of the preceding Article).
- (7) When the prefectural governor decides not to grant the permission set forth in paragraph (1) or (2) of Article 7 under the provisions of the preceding paragraph, the governor must hear the opinions of the Prefectural Council on Medical Service Facilities in advance.
- (8) The provisions of the preceding paragraphs apply *mutatis mutandis* to an application for permission to set up new beds in a clinic or permission to increase the number of beds in a clinic. In this case, the term "paragraph (1) or (2) of the same Article" in paragraph (6) is to be replaced with "paragraph (3) of the same Article", and the term "paragraph (1) or (2) of Article 7" in the preceding paragraph is to be replaced with "paragraph (3) of Article 7".

Article 8 When a clinically trained physician, a clinically trained dentist, or a midwife establishes a clinic or birthing center, the physician must notify the prefectural governor of the area in which the clinic or birthing center is situated within ten days of its establishment.

Article 8-2 (1) The organizer of a hospital, clinic, or birthing center must not suspend the operation of the relevant hospital, clinic or birthing center for more than one year without justifiable grounds; provided, however, that this

does not apply to the organizer of a clinic or birthing center of which the prefectural governor was notified and that was established pursuant to the provisions of the preceding Article.

- (2) When the organizer of a hospital, clinic, or birthing center suspends the operation of the relevant hospital, clinic, or birthing center, the organizer must notify the prefectural governor within ten days. The same applies when a hospital, clinic, or birthing center whose operation was suspended is re-opened.

Article 9 (1) When the organizer of a hospital, clinic, or birthing center discontinues the operation of the relevant hospital, clinic, or birthing center, the organizer must notify the prefectural governor within ten days.

- (2) When the organizer of a hospital, clinic, or birthing center has died or has become the subject of an adjudication of disappearance, the person who is obligated to submit a notification of such person's death or disappearance pursuant to the provisions of the Family Register Act (Act No. 224 of 1947) must notify the prefectural governor of their area of the same within ten days.

Section 2 Management

Article 10 (1) The organizer of a hospital (excluding hospitals specified by an Order of the Ministry of Health, Labour and Welfare set forth in paragraph (3); the same applies in the following paragraph) or clinic is to have it managed by a clinically trained physician where a medical practice is operated at the relevant hospital or clinic, or must have it managed by a clinically trained dentist where a dental practice is operated at the relevant hospital or clinic.

- (2) Where both a medical practice and dental practice are operated at a hospital or clinic, the organizer of the relevant hospital or clinic is to have it managed by a clinically trained physician where it is primarily for the operation of a medical practice, or must have it managed by a clinically trained dentist where it is primarily for the operation of a dental practice.
- (3) The organizer of a hospital that provides necessary support for securing medical care in an acute physician shortage area or other hospitals specified by an Order of the Ministry of Health, Labour and Welfare, in the case that the hospital is engaged in medical practice or in the case that the hospital is engaged in both medical practice and dental practice and mainly engages in medical practice, may have it managed by a clinically trained physician certified under Article 5-2, paragraph (1); provided, however, that in the case that affects the provision of medical care in the region or in other cases specified by an Order of the Ministry of Health, Labour and Welfare, the hospital may be managed by a clinically trained physician who has not been certified under Article 5-2, paragraph (1).

Article 10-2 (1) The organizer of an advanced treatment hospital who intends to have it managed in accordance with the provisions of the preceding Article, pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare, must appoint as its administrator a person who has the necessary ability and experience to perform the particulars listed in each item of Article 16-3, paragraph (1) and other tasks related to the management and operation of the advanced treatment hospital.

(2) The appointment of an administrator of an advanced treatment hospital under the provisions of the preceding paragraph, pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare, must be made based on the results of the examination by a council for selecting a candidate for administrator, which consists of the organizer of the advanced treatment hospital and persons other than those who have a special relationship as specified by an Order of the Ministry of Health, Labour and Welfare.

Article 11 An organizer of a birthing center must have the relevant birthing center managed by a midwife.

Article 12 (1) The organizer of a hospital, clinic, or birthing center must manage the relevant hospital, clinic, or birthing center themselves if they are a person capable of being the administrator of a hospital, clinic, or birthing center; provided, however, that it is permissible for the organizer to have another party manage where permitted by the prefectural governor of the area in which the hospital, clinic, or birthing center is situated.

(2) The physician, dentist, or midwife who manages a hospital, clinic, or birthing center must be a person who does not manage any other hospital, clinic, or birthing center, except where permitted by the prefectural governor of the area in which the relevant hospital, clinic, or birthing center is situated as falling under any of the following items:

- (i) when intending to manage a clinic established in an acute physician shortage area;
- (ii) when intending to manage a clinic established in a long-term care health facility or other facilities specified by an Order of the Ministry of Health, Labour and Welfare;
- (iii) when intending to manage a clinic established in an office or other places of business for employees, etc;
- (iv) when intending to manage a clinic established to secure the medical care delivery system prescribed in Article 30-3, paragraph (1) on holidays or at night in the region; or
- (v) other cases specified by an Order of the Ministry of Health, Labour and

Welfare.

Article 12-2 (1) The organizer of a regional medical care support hospital must submit reports concerning its operation to the prefectural governor pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare.

(2) The prefectural governor must make public the details of the reports set forth in the preceding paragraph pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare.

Article 12-3 (1) The organizer of an advanced treatment hospital must submit reports concerning its operation to the Minister of Health, Labour and Welfare pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare.

(2) The Minister of Health, Labour and Welfare must make public the details of the reports set forth in the preceding paragraph pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare.

Article 12-4 (1) The organizer of a core hospital for clinical research must submit a report on its operations to the Minister of Health, Labor and Welfare pursuant to the provisions of an Order of the Ministry of Health, Labor and Welfare.

(2) The Minister of Health, Labor and Welfare is to make public the content of the report prescribed in the preceding paragraph pursuant to the provisions of an Order of the Ministry of Health, Labor and Welfare.

Article 13 The administrator of a clinic with facilities for the hospitalization of patients is to endeavor to ensure a system for the relevant clinic's physicians to make prompt diagnoses that enable appropriate medical treatment to be provided, even where the symptoms of a hospitalized patient change suddenly, and must ensure close cooperation with other hospitals or clinics.

Article 14 The administrator of a birthing center is not to allow ten or more pregnant women, women in labor, or women resting after childbirth to be admitted at the same time; provided, however, that this does not apply to temporary and emergency admissions in the case that there are no other appropriate facilities for hospitalization or admission.

Article 14-2 (1) The administrator of a hospital or clinic must post the following information concerning the relevant hospital or clinic in a visible location within the relevant hospital or clinic, pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare:

- (i) the name of the administrator;
 - (ii) the names of practicing physicians or dentists;
 - (iii) the days and hours of the physicians' or dentists' practices; and
 - (iv) beyond those listed in the preceding three items, the particulars prescribed by an Order of the Ministry of Health, Labour and Welfare.
- (2) The administrator of a birthing center must post the following information concerning the relevant birthing center in a visible location within the relevant birthing center, pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare:
- (i) the name of the administrator;
 - (ii) the names of midwives engaging in services;
 - (iii) the midwives' working days and hours; and
 - (iv) beyond what is listed in the preceding three items, the particulars prescribed by an Order of the Ministry of Health, Labour and Welfare.

Article 15 (1) The administrator of a hospital or clinic must supervise the physicians, dentists, pharmacists, and other employees working at the relevant hospital or clinic, and must take other necessary precautions for the management and operation of the relevant hospital or clinic, so that they can fulfill their responsibilities prescribed in this Act.

(2) The administrator of a birthing center must supervise the midwives and other employees working at the relevant birthing center, and must take other necessary precautions for the management and operation of the relevant birthing center, so that they can fulfill their responsibilities prescribed in this Act.

(3) The administrator of a hospital or clinic must notify the prefectural governor of the area in which the hospital or clinic is situated, pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare, where the relevant hospital or clinic has an x-ray unit for medical treatment, or in other cases prescribed by an Order of the Ministry of Health, Labour and Welfare.

Article 15-2 The administrator of a hospital, clinic or birthing center, when performing specimen testing prescribed in Article 2 of the Act on Clinical Laboratory Technicians (Act No. 76 of 1958) (hereinafter referred to as "specimen testing" in this Article and paragraph (1) of the following Article) in the relevant hospital, clinic or birthing center, must ensure that the buildings and equipment of the facilities where specimen testing is performed, management organization, methods for ensuring the accuracy of specimen testing and other particulars conform to the standards specified by an Order of the Ministry of Health, Labour and Welfare as necessary for the proper

performance of specimen testing.

Article 15-3 (1) When the administrator of a hospital, clinic or birthing center wishes to entrust specimen testing, the administrator must do so to the following persons:

- (i) an organizer of a sanitary laboratory registered under Article 20-3, paragraph (1) of the Act on Clinical Laboratory Technicians.; and
 - (ii) a person who performs specimen testing in a hospital, clinic or other places specified by an Order of the Ministry of Health, Labour and Welfare, and the buildings and equipment of the facilities where the person performs specimen testing, management organization, methods for ensuring the accuracy of specimen testing and other particulars conform to the standards specified by an Order of the Ministry of Health, Labour and Welfare as necessary for the proper performance of specimen testing.
- (2) Beyond what is provided for in the preceding paragraph, when the administrator of a hospital, clinic, or birthing center wishes to entrust the operation of the hospital, clinic, or birthing center that are prescribed by Cabinet Order as having a significant influence on physicians' or dentists' diagnoses, on the services of midwives, or on the hospitalization or admission of patients, pregnant women, women in labor, or women resting after childbirth, the administrator must entrust the relevant operations to a party who conforms to the requirements prescribed by an Order of the Ministry of Health, Labour and Welfare as a party with the ability to properly undertake its operation, in accordance with the type of operation undertaken at the relevant hospital, clinic, or birthing center.

Article 16 The administrator of a hospital that carries out a medical practice must have a physician on night duty in the hospital; provided, however, that this does not apply to the case where the physicians of the relevant hospital stand by at a place adjacent to the relevant hospital or other cases specified by an Order of the Ministry of Health, Labour and Welfare as those where a system is in place which ensures that the physicians of the relevant hospital promptly provide medical treatment in the event of a sudden change in the medical condition of an inpatient of the relevant hospital.

Article 16-2 (1) The administrator of a regional medical care support hospital must undertake the following particulars, pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare:

- (i) allowing all or part of the buildings, equipment, instruments, or tools of the relevant hospital to be used by medical care professionals who do not work at the relevant hospital for their practices, research, or training;

- (ii) providing emergency medical care;
 - (iii) carrying out training to enhance the quality of community medical care professionals;
 - (iv) systematically managing records as listed in Article 22, items (ii) and (iii);
 - (v) when a request to view records listed in Article 22, item (ii) or (iii) has been received from a physician who wishes to refer a patient to the relevant regional medical care support hospital or from other persons as prescribed by an Order of the Ministry of Health, Labour and Welfare, making available for inspection the records which are prescribed by an Order of the Ministry of Health, Labour and Welfare as having no risk of harming patient confidentiality, except where there are justifiable grounds for not doing so;
 - (vi) providing medical care to patients referred from other hospitals or clinics; and
 - (vii) other particulars as prescribed by an Order of the Ministry of Health, Labour and Welfare.
- (2) The administrator of a regional medical care support hospital must provide necessary support concerning the promotion of in-home medical care provision by medical institutions providing in-home medical care, designated in-home service providers pursuant to the provisions of Article 41, paragraph (1) of the Long-Term Care Insurance Act who undertake in-home nursing under Article 8, paragraph (4) of the same Act, and other persons providing in-home medical care (hereinafter referred to as "in-home medical care providers, etc." in this paragraph), such as supporting close coordination with in-home medical care providers, etc., and providing information concerning in-home medical care providers, etc. to recipients of medical care or medical institutions in the area.

Article 16-3 (1) The administrator of an advanced treatment hospital must undertake the following particulars pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare:

- (i) providing advanced medical care;
- (ii) carrying out development and evaluation of advanced medical care techniques;
- (iii) carrying out training in advanced medical care;
- (iv) ensuring a high level of medical safety;
- (v) systematically managing the records listed under Article 22-2, items (iii) and (iv);
- (vi) when a request to view the records listed in Article 22-2, item (iii) or (iv) has been received from a physician who wishes to refer a patient to the relevant advanced treatment hospital or from other persons as prescribed by an Order of the Ministry of Health, Labour and Welfare, making available for inspection the records that are prescribed by an Order of the Ministry of

Health, Labour and Welfare as having no risk of harming patient confidentiality, except where there are justifiable grounds for not doing so;
(vii) providing medical care to patients referred from other hospitals or clinics;
and
(viii) other particulars as prescribed by an Order of the Ministry of Health, Labour and Welfare.

(2) The administrator of an advanced treatment hospital, when carrying out particulars specified by an Order of the Ministry of Health, Labour and Welfare as important particulars concerning the management and operation of the advanced treatment hospital, must do so based on a resolution of a council composed of the relevant administrator and physicians, dentists, pharmacists, nurses and other persons working in the relevant advanced treatment hospital, pursuant to an Order of the Ministry of Health, Labour and Welfare.

(3) The administrator of an advanced treatment hospital must make arrangements so that a medical care coordination system as provided for in Article 30-4, paragraph (2), item (ii) is properly constructed.

Article 16-4 The administrator of a core hospital for clinical research, pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare, must carry out the following particulars:

- (i) to develop and implement a plan concerning specified clinical research;
- (ii) when conducting specified clinical research jointly with other hospitals or clinics, to play a leading role in the implementation of specified clinical research;
- (iii) to provide consultation, necessary information, advice and other assistance to other hospitals or clinics concerning the implementation of specified clinical research;
- (iv) to provide training on specified clinical research;
- (v) to systematically manage the various records listed in items (iii) and (iv) of Article 22-3; and
- (vi) other particulars specified by an Order of the Ministry of Health, Labour and Welfare.

Article 17 Beyond the provisions of Article 6-10 through Article 6-12 and Article 13 through the preceding Article, particulars that should be observed by the administrator of a hospital, clinic, or birthing center in the management of their buildings and equipment, medical supplies, and other articles, and in the hospitalization or admission of patients, pregnant women, women in labor, and women resting after childbirth, are to be as prescribed by an Order of the Ministry of Health, Labour and Welfare.

Article 18 The organizer of a hospital or clinic must provide an exclusive pharmacist in the relevant hospital or clinic in accordance with the standards specified by an Order of the Ministry of Health, Labour and Welfare and in accordance with Ordinances of the Prefecture (or, in the case of a clinic situated in a city or special ward with a public health center, the relevant city or special ward with a public health center); provided, however, that this does not apply where permitted by the prefectural governor of the area in which the hospital or clinic is situated.

Article 19 (1) The organizer of a birthing center must provide for contract physicians and hospitals or clinics pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare.

(2) When a midwife who only does house calls enters into a contract which provides that she will give midwifery services to a pregnant woman, etc., she must specify the hospital or clinic that responds to the abnormality of the relevant pregnant woman, etc., pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare.

Article 19-2 The organizer of an advanced treatment hospital, pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare, must take the following measures to ensure that the administrator of the relevant advanced treatment hospital properly executes the management and operation of the relevant advanced treatment hospital:

- (i) to clarify the authority that the relevant administrator has for the management and operation of the relevant advanced treatment hospital;
- (ii) to set up an audit committee for ensuring the safety of medical care.;
- (iii) to establish a system to ensure that the execution of the duties of the relevant administrator complies with laws and regulations, a system pertaining to the supervision of the business of the relevant advanced treatment hospital by the relevant organizer, and other systems specified by an Order of the Ministry of Health, Labour and Welfare as necessary to ensure the appropriateness of the business of the relevant advanced treatment hospital: and
- (iv) other measures specified by an Order of the Ministry of Health, Labour and Welfare as necessary for the proper execution of the management and operation of the relevant advanced treatment hospital by the relevant administrator.

Article 20 A hospital, clinic, or birthing center is to be maintained in a clean state, and its buildings and equipment must be recognizable as being safe in terms of sanitation, fire safety, and security.

Article 21 (1) A hospital is to have the following personnel and facilities and must prepare the following records, pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare (in the case of employees listed in item (i) (excluding physicians and dentists) and facilities listed in item (xii), Prefectural Ordinances):

- (i) beyond physicians, dentists in the numbers prescribed by an Order of the Ministry of Health, Labour and Welfare, nurses, and other employees in the numbers prescribed by prefectural ordinances, in accordance with the classifications of the beds at the relevant hospital;
- (ii) a consultation room for each clinical department;
- (iii) an operating room;
- (iv) treatment rooms;
- (v) a diagnostic laboratory;
- (vi) an X-ray unit;
- (vii) a dispensary;
- (viii) food service facilities;
- (ix) records concerning medical treatment;
- (x) delivery rooms and neonatal bathing facilities in hospitals that have a gynecology and obstetrics department or an obstetrics department;
- (xi) functional training rooms in hospitals that have long-term care beds; and
- (xii) other facilities as prescribed by prefectural ordinances.

(2) A clinic with long-term care beds must have the following personnel and facilities, pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare (in the case of employees listed in item (i) (excluding physicians and dentists) and facilities listed in item (iii), Prefectural Ordinances):

- (i) beyond physicians, dentists in the numbers prescribed by an Order of the Ministry of Health, Labour and Welfare, nurses, and other employees, including those engaged in nursing support, in the numbers prescribed by Prefectural Ordinances;
- (ii) functional training rooms; and
- (iii) other facilities as prescribed by Prefectural Ordinances.

(3) When formulating the ordinances set forth in the preceding two paragraphs, prefectures is to determine the employees and the number of employees of hospitals and clinics with long-term care beds (limited to those specified by an Order of the Ministry of Health, Labour and Welfare) in accordance with the standards specified by an Order of the Ministry of Health, Labour and Welfare, and other particulars with reference to the standards specified by an Order of the Ministry of Health, Labour and Welfare.

Article 22 Beyond the provisions of paragraph (1) of the preceding Article (excluding item (ix)), a regional medical care support hospital is to have the following facilities and must prepare the following records, pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare:

- (i) an intensive care unit;
- (ii) records concerning medical treatment;
- (iii) records concerning the management and operation of the hospital;
- (iv) chemical, bacteriological, and pathological inspection facilities;
- (v) an autopsy room;
- (vi) a laboratory;
- (vii) a lecture room;
- (viii) a library; and
- (ix) other facilities as prescribed by an Order of the Ministry of Health, Labour and Welfare.

Article 22-2 Beyond the provisions of Article 21, paragraph (1) (excluding items (i) and (ix)), an advanced treatment hospital is to have the following personnel and facilities and must prepare the following records, pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare:

- (i) physicians, dentists, pharmacists, nurses, and other employees in the numbers prescribed by an Order of the Ministry of Health, Labour and Welfare;
- (ii) an intensive care unit;
- (iii) records concerning medical treatment;
- (iv) records concerning the management and operation of the hospital;
- (v) the facilities listed in item (iv) through item (viii) of the preceding Article; and
- (vi) other facilities as prescribed by an Order of the Ministry of Health, Labour and Welfare.

Article 22-3 Beyond the provisions of Article 21, paragraph (1) (excluding items (i) and (ix)), a core hospital for clinical research is to have the following personnel and facilities and must prepare the following records, pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare:

- (i) physicians, dentists, pharmacists, nurses, and other employees involved in clinical research in the numbers prescribed by an Order of the Ministry of Health, Labour and Welfare;
- (ii) an intensive care unit;
- (iii) records concerning medical treatment and clinical research;
- (iv) records concerning the management and operation of the hospital;
- (v) the facilities listed in item (iv) through item (viii) of Article 22; and

(vi) other facilities as prescribed by an Order of the Ministry of Health, Labour and Welfare.

Article 23 (1) Beyond the provisions of Article 21 through the preceding Article, the necessary standards for ensuring satisfactory ventilation, lighting, illumination, damp proofing, security, emergency evacuation, cleanliness, and other sanitary conditions with regard to the buildings and equipment of a hospital, clinic or birthing center, is to be prescribed by an Order of the Ministry of Health, Labour and Welfare.

(2) Regulations may be established by Cabinet Order to sentence persons who have violated the provisions of the Order of the Ministry of Health, Labour and Welfare as set forth in the provisions of the preceding paragraph to a fine of up to 200,000 yen.

Section 3 Supervision

Article 23-2 When the distribution of personnel in a hospital or in a clinic with long-term care beds is significantly lacking in terms of the standards prescribed by the Order of the Ministry of Health, Labour and Welfare or prefectural ordinances set forth in Article 21, paragraph (1) (limited to the parts pertaining to item (i)) or paragraph (2) (limited to the part pertaining to item (i)), and falls under cases prescribed by an Order of the Ministry of Health, Labour and Welfare as cases that cause a significant impediment to the suitable provision of medical care, the prefectural governor may order the organizer to increase the number of personnel by a set deadline, or may suspend all or a part of its operations for a period that the governor prescribes.

Article 24 (1) When a hospital, clinic, or birthing center is lacking in cleanliness, or when its buildings and equipment violate the provisions of Article 21, paragraph (1) or (2), or Article 22, or violate the provisions of an Order of the Ministry of Health, Labour and Welfare that is based on the provisions set forth in Article 23, paragraph (1), or are found to be a sanitation hazard or safety risk, the prefectural governor may prescribe a period of time and order the organizer to fully or partially limit or prohibit the use thereof, or may order repairs or reconstruction to be carried out by a set deadline.

(2) When the buildings and equipment of an advanced treatment hospital or core hospital for clinical research (hereinafter referred to as "advanced treatment hospital, etc." in this Section) violate the provisions of Article 22-2 or Article 22-3, the Minister of Health, Labour and Welfare may order their repair or reconstruction to be carried out by the organizer of the relevant advanced treatment hospital, etc. by a set deadline.

Article 24-2 (1) When a prefectural governor finds that the business of a hospital, clinic or birthing center violates laws and regulations or dispositions under laws and regulations, or that the operation of a hospital, clinic or birthing center is extremely inappropriate (excluding the cases prescribed in Article 23-2 or paragraph (1) of the preceding Article), the governor may, to the extent necessary for the enforcement of this Act, order the organizer of the relevant hospital, clinic or birthing center to take necessary measures by a set deadline.

(2) In the event that the organizer set forth in the preceding paragraph does not comply with the order as prescribed in the same paragraph, the prefectural governor may order the relevant organizer to suspend all or part of the business of the relevant organizer's hospital, clinic or birthing center for a specified period of time.

Article 25 (1) When a prefectural governor, the mayor of a city with a public health center, or the mayor of a special ward of Tokyo finds it necessary, the governor or mayor may order the organizer or administrator of a hospital, clinic, or birthing center to report as necessary, and may have the relevant officials enter the relevant hospital, clinic, or birthing center and inspect the personnel or the state of cleanliness, its buildings, and equipment, its medical records, birth records, books and documents, and other articles.

(2) When a prefectural governor, the mayor of a city with a public health center, or the mayor of a special ward of Tokyo suspects that the operation of a hospital, clinic or birthing center is in violation of laws and regulations or a disposition based on laws and regulations, or suspects that the management thereof is significantly unsuitable, the governor or mayor may order the organizer or administrator of the relevant hospital, clinic, or birthing center to submit medical records, birth records, books and documents, and other articles, or have the relevant officials enter the office of the organizer of the relevant hospital, clinic or birthing center or other places related to the operation of the relevant hospital, clinic or birthing center and inspect books and documents, and other articles to the extent necessary for the enforcement of this Act.

(3) When the Minister of Health, Labour and Welfare finds it necessary, the minister may order the organizer or administrator of an advanced treatment hospital, etc. to report as necessary, and may have the relevant officials enter the advanced treatment hospital, etc. and inspect the personnel or the state of cleanliness, its buildings and equipment, medical records, birth records, books and documents, and other articles.

(4) When the Minister of Health, Labour and Welfare suspects that the operation of an advanced treatment hospital, etc. is in violation of laws and regulations or a disposition based on laws and regulations, or suspects that the

management thereof is significantly unsuitable, the minister may order the organizer or administrator of the relevant advanced treatment hospital, etc. to submit medical records, birth records, books and documents, or other articles.

(5) The provisions set forth in Article 6-8, paragraph (3) apply mutatis mutandis pursuant to entry and inspection as set forth in paragraph (1) through paragraph (3), and the provisions set forth in paragraph (4) of the same Article apply mutatis mutandis pursuant to the authority set forth in each of the preceding paragraphs.

Article 25-2 Mayor of cities with public health centers and mayors of special wards of Tokyo must give notice of the particulars as prescribed by an Order of the Ministry of Health, Labour and Welfare concerning clinics and birthing centers, to the prefectural governor, pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare.

Article 26 (1) The Minister of Health, Labour and Welfare, prefectural governors, mayors of cities with public health centers, and mayors of special wards of Tokyo are to appoint medical care inspectors from among the officials of the Ministry of Health, Labour and Welfare, prefecture, city with the public health center, or special ward of Tokyo, to be entrusted with the authority of the relevant officials provided for in Article 25, paragraphs (1) and (3).

(2) Beyond the provisions of the preceding paragraph, necessary particulars concerning medical care inspectors are to be as prescribed by an Order of the Ministry of Health, Labour and Welfare.

Article 27 A hospital, clinic with in-patient facilities, or birthing center with admission facilities must not use its buildings and equipment without first undergoing inspection by the prefectural governor with jurisdiction over their location and receiving a license.

Article 27-2 (1) When the organizer or administrator of a hospital or clinic fails to comply with the conditions attached to the permission granted under the provisions of Article 7, paragraph (5) without justifiable grounds, the prefectural governor may recommend that the relevant organizer or administrator comply with the relevant conditions by a set deadline, after hearing the opinions of the Prefectural Council on Medical Service Facilities.

(2) When the organizer or administrator of a hospital or clinic who has received a recommendation pursuant to the provisions of the preceding paragraph fails to take measures pertaining to the relevant recommendation without justifiable grounds, the prefectural governor may order the relevant organizer or administrator to take measures pertaining to the relevant recommendation by

a set deadline, after hearing the opinions of the Prefectural Council on Medical Service Facilities.

- (3) If a prefectural governor has issued an order under the preceding paragraph, and the organizer or administrator of a hospital or clinic who has received the relevant order fails to comply with it, the prefectural governor may make a public announcement to that effect.

Article 28 When the prefectural governor finds the administrator of a hospital, clinic, or birthing center to have committed a criminal act, to have committed an unlawful act related to medical practice, or to be unfit to manage, the governor may order the organizer of the relevant hospital, clinic, or birthing center to replace the the relevant administrator by a set deadline.

- Article 29 (1) The prefectural governor may rescind permission for establishment of a hospital, clinic, or birthing center, or may order the organizer to close the hospital, clinic, or birthing center by a period that the governor prescribes, if it falls under any of the following items:
- (i) when operation has not commenced six months or more after permission was received for its establishment, without justifiable grounds;
 - (ii) when the operation of a hospital, clinic (excluding where notification and establishment have taken place as set forth in Article 8), or a birthing center (excluding where notification and establishment have taken place as set forth in the same Article) has not re-commenced one year or more after it was suspended, without justifiable grounds;
 - (iii) when the organizer has violated an order or disposition based on the provisions of Article 6-3, paragraph (6), Article 24, paragraph (1), Article 24-2, paragraph (2), or the preceding Article; or
 - (iv) when the organizer has committed a criminal act or an unlawful act related to medical practice.
- (2) The prefectural governor may, when operation related to the permission pursuant to the provisions of Article 7, paragraph (2) or (3) has not commenced six months or more after the relevant permission was received without justifiable grounds, rescind the relevant permission.
- (3) The prefectural governor may rescind the approval for a regional medical care support hospital if it falls under any of the following items:
- (i) when the regional medical care support hospital has failed to meet the requirements listed in each item of Article 4, paragraph (1);
 - (ii) when the organizer of the regional medical care support hospital has violated provisions of Article 12-2, paragraph (1);
 - (iii) when the organizer of the regional medical care support hospital has violated an order based on the provisions of Article 24, paragraph (1) or

- Article 30-13, paragraph (5);
- (iv) when the administrator of a regional medical care support hospital has violated the provisions of Article 16-2, paragraph (1);
 - (v) when the organizer or administrator of the regional medical care support hospital has violated an order under the provisions of Article 7-2, paragraph (3), Article 27-2, paragraph (2), or Article 30-15, paragraph (6);
 - (vi) when the organizer or administrator of the regional medical care support hospital fails to comply with a recommendation under the provisions of Article 30-12, paragraph (2) or Article, paragraph 30-17; or
 - (vii) when the organizer or administrator of the regional medical care support hospital fails to comply with an instruction under the provisions of Article 30-16, paragraph (1).
- (4) The Minister of Health, Labour and Welfare may rescind their approval for an advanced treatment hospital, if it falls under any of the following items:
- (i) when the advanced treatment hospital has failed to meet the requirements listed in each of the items of Article 4-2, paragraph (1);
 - (ii) when the organizer of the advanced treatment hospital has violated the provisions of Article 10-2, Article 12-3, paragraph (1), or Article 19-2;
 - (iii) when the organizer of the advanced treatment hospital has violated an order based on the provisions of Article 24, paragraph (2) or Article 30-13, paragraph (5);
 - (iv) when the administrator of the advanced treatment hospital has violated the provisions of paragraph (1) or (2) of Article 16-3;
 - (v) when the organizer or administrator of the advanced treatment hospital has violated an order under the provisions of Article 7-2, paragraph (3), Article 27-2, paragraph (2), or Article 30-15, paragraph (6);
 - (vi) when the organizer or administrator of the advanced treatment hospital fails to comply with a recommendation under the provisions of Article 30-12, paragraph (2) or Article 30-17; or
 - (vii) when the organizer or administrator of the advanced treatment hospital fails to comply with an instruction under the provisions of Article 30-16, paragraph (1).
- (5) The Minister of Health, Labour and Welfare may revoke the approval for a core hospital for clinical research, if it falls under any of the following items:
- (i) when the core hospital for clinical research has failed to meet the requirements listed in each of the items of Article 4-3, paragraph (1);
 - (ii) when the organizer of the core hospital for clinical research has violated the provisions of Article 12-4, paragraph (1);
 - (iii) when the organizer of the core hospital for clinical research has violated an order under the provisions of Article 24, paragraph (2); or
 - (iv) when the administrator of the core hospital for clinical research has

violated the provisions of Article 16-4.

- (6) In revoking the approval for a regional medical care support hospital pursuant to the provisions of paragraph (3), the prefectural governor must hear the opinions of the Prefectural Council on Medical Service Facilities in advance.
- (7) In revoking the approval for an advanced treatment hospital, etc. pursuant to the provisions of paragraph (4) or (5), the Minister of Health, Labour and Welfare must hear the opinions of the Social Security Council in advance.

Article 29-2 If the Minister of Health, Labour and Welfare finds an urgent necessity to protect the health of the citizens, the minister may instruct a prefectural governor to render a disposition pursuant to the provisions of Article 28, and paragraph (1) and paragraph (2) of the preceding Article.

Article 30 When a disposition has been rendered pursuant to the provisions of Article 23-2, Article 24, paragraph (1), Article 24-2, Article 28, or Article 29, paragraph (1) or (3) in advance of an opportunity for explanation being granted or a hearing being undertaken pursuant to Article 13, paragraph (2), item (i) of the Administrative Procedure Act (Act No. 88 of 1993), the prefectural governor must grant an opportunity for explanation to parties subject to the relevant disposition within three days of the relevant disposition.

Section 4 Miscellaneous Provisions

Article 30-2 Beyond those provided for in this Chapter, the necessary particulars concerning the establishment and management of hospitals, clinics, and birthing centers are to be as specified by Cabinet Order.

Chapter V Ensuring the Medical Care Delivery System

Section 1 Basic Policy

Article 30-3 (1) The Minister of Health, Labour and Welfare, in accordance with the comprehensive securing policy prescribed in Article 3, paragraph (1) of the Act for Promoting Comprehensive Measures for Securing Regional Medical and Nursing Care (Act No. 64 of 1989), is to set forth a basic policy (hereinafter referred to as "basic policy") for ensuring the presence of a system that efficiently delivers good quality and appropriate medical care (hereinafter referred to as the "medical care delivery system").

(2) The basic policy is to prescribe the following particulars:

- (i) particulars that should form the basis of any measures to be undertaken for ensuring the medical care delivery system;
- (ii) basic particulars related to investigation and research into ensuring the

- medical care delivery system;
- (iii) particulars related to targets for ensuring the medical care delivery system;
 - (iv) basic particulars related to the sharing of functions and cooperation between medical institutions, and to promoting the provision of information that concerns medical care functions to recipients of medical care;
 - (v) basic particulars related to the regional medical care vision prescribed in Article 30-4, paragraph (2) item (vii);
 - (vi) basic particulars related to the promotion of the differentiation and coordination of bed functions (meaning the contents of medical care provided in hospital or clinic beds in accordance with the medical conditions of patients; the same applies hereinafter) in the region and the provision of information about bed functions to medical care recipients;
 - (vii) basic particulars related to ensuring the medical care delivery system for outpatient medical care;
 - (viii) basic particulars related to ensuring the availability of physicians;
 - (ix) basic particulars related to ensuring the availability of medical care professionals (excluding physicians);
 - (x) basic particulars related to the preparation of the medical care plans provided for in Article 30-4, paragraph (1), and to evaluating the status of implementation of activities under medical care plans; and
 - (xi) other important particulars related to ensuring the medical care delivery system.
- (3) When the Minister of Health, Labour and Welfare has set forth or amended the basic policy, the minister is to provide a public notice thereof without delay.

Article 30-3-2 When the Minister of Health, Labour and Welfare finds it necessary in order to set down or change the particulars listed in item (v) or (vi) of paragraph (2) of the preceding Article, the minister may request the prefectural governor or the organizer or administrator of a hospital, etc. subject to a report on the bed functions prescribed in Article 30-13, paragraph (1) to provide the content of the report provided for in the same paragraph and other necessary information, pursuant to an Order of the Ministry of Health, Labour and Welfare.

Section 2 Medical Care Plans

Article 30-4 (1) The prefecture, with regard to basic policy, is to provide a plan (hereinafter referred to as "medical care plan") for ensuring the medical care delivery system in the relevant prefecture, in accordance with the actual conditions in the area.

- (2) The following particulars are to be stipulated in the medical care plan:
- (i) particulars related to the activities set forth in item (iv) and item (v) and ensuring in-home medical care that should be achieved in the prefecture;
 - (ii) particulars related to the medical care coordination system (meaning the system to ensure the sharing of functions between medical institutions and the coordination of operations; the same applies hereinafter) pertaining to activities as set forth in item (iv) and item (v) and ensuring in-home medical care;
 - (iii) particulars related to promoting the provision of information on functions of medical institutions under the medical care coordination system;
 - (iv) particulars related to activities connected with treatment or prevention of illnesses prescribed by an Order of the Ministry of Health, Labour and Welfare as lifestyle diseases or other illnesses that are recognized as specifically requiring the provision of extensive and continuous medical care in order to ensure the health of the citizens;
 - (v) particulars related to activities that are necessary for ensuring the following medical care (hereinafter referred to as "activities to ensure emergency medical care") (limited to where it is necessary to ensure this in the case of medical care listed in (c));
 - (a) emergency medical care;
 - (b) medical care in times of disaster;
 - (c) medical care in remote areas;
 - (d) perinatal medical care;
 - (e) pediatric medical care (including pediatric emergency medical care);
 - (f) beyond what is listed in (a) through (e), particulars that are recognized by the prefectural governor as being specifically necessary in the light of outbreaks of illness in the relevant prefecture;
 - (vi) particulars related to ensuring in-home medical care;
 - (vii) particulars related to the vision of the future medical care delivery system including the following particulars (hereinafter referred to as "regional medical care vision") in the area specified in accordance with the standards set down by an Order of the Ministry of Health, Labour and Welfare as the standards for promoting the differentiation and coordination of bed functions in the region (hereinafter referred to as "vision area");
 - (a) the future requirements for the number of beds for each functional classification of beds prescribed in Article 30-13, paragraph (1) (hereinafter simply referred to as the "future requirements for the number of beds") in the vision area calculated pursuant to an Order of the Ministry of Health, Labour and Welfare; and
 - (b) beyond what is listed in (a), particulars specified by an Order of the Ministry of Health, Labour and Welfare as necessary for promoting the

- differentiation and coordination of the bed functions in the vision area;
 - (viii) particulars related to the promotion of the differentiation and coordination of bed functions to achieve the regional medical care vision;
 - (ix) particulars related to the promotion of the provision of information on bed functions;
 - (x) particulars related to ensuring the medical care delivery system for outpatient medical care;
 - (xi) the following particulars related to ensuring the availability of physicians:
 - (a) policies for ensuring the availability of physicians in the areas prescribed in items (xiv) and (xv);
 - (b) the target of the number of physicians to be secured in the area prescribed in item (xiv) to be determined based on the indicator concerning the number of physicians in the relevant area calculated by the method specified by an Order of the Ministry of Health, Labour and Welfare;
 - (c) the target number of physicians to be secured in the area prescribed in item (xv) to be determined based on the indicator concerning the number of physicians in the relevant area calculated by the method specified by an Order of the Ministry of Health, Labour and Welfare; and
 - (d) measures to dispatch physicians to achieve the targets listed in (b) and (c) and other measures for ensuring the availability of physicians;
 - (xii) particulars related to ensuring the availability of medical care professionals (excluding physicians);
 - (xiii) particulars related to ensuring safety in medical care;
 - (xiv) particulars related to the establishment of an area to be classified as a regional unit for the development of mainly beds in hospitals (excluding beds prescribed in the following item, psychiatric beds, infectious disease beds and tuberculosis beds) and beds in clinics;
 - (xv) particulars related to the establishment of an area that combines two or more areas prescribed in the preceding item as a regional unit for the development of mainly long-term care beds in hospitals that provide special medical care or general beds used for special medical care as specified by an Order of the Ministry of Health, Labour and Welfare;
 - (xvi) in the event of the establishment of areas prescribed in paragraphs (6) and (7), particulars related to the establishment of the relevant areas; and
 - (xvii) particulars related to the target number of beds for long-term care beds and general beds, the target number of beds for psychiatric beds, the target number of beds for infectious disease beds, and the target number of beds for tuberculosis beds.
- (3) Beyond the particulars listed in each item of the preceding paragraph, efforts is to be made so that medical care plans stipulate the following particulars:
- (i) particulars related to targets for the development of regional medical care

- support hospitals and targets for the development of other medical institutions in consideration of the functions of such institutions; and
- (ii) beyond what is listed in the preceding item, particulars necessary for securing the medical care delivery system.
- (4) The prefecture must consider the following particulars when stipulating particulars listed in paragraph (2) item (ii):
- (i) specific measures for the establishment of a medical care coordination system are to be specified for each disease prescribed by an Order of the Ministry of Health, Labour and Welfare set forth in item (iv) of paragraph (2) or medical care listed in (a) through (f) of item (v) of the same paragraph or in-home medical care;
 - (ii) the details of the establishment of the medical care coordination system are to ensure that patients can receive appropriate medical care continuously even after being discharged from the hospital;
 - (iii) the details of the establishment of the medical care coordination system are to include the coordination between health and medical services and welfare services provided in medical institutions and in homes; and
 - (iv) the medical care coordination system is to be established through consultation among medical care professionals, long-term care service providers provided for in the Long-Term Care Insurance Act, citizens, and other related parties in the community.
- (5) The prefecture, in stipulating particulars concerning the regional medical care vision, is to take into consideration the contents of reports under Article 30-13, paragraph (1), the prospects for changes in the demographic structure and other trends in demand for medical care, the prospects for the arrangement of medical care professionals and medical institutions, and other circumstances.
- (6) In stipulating the particulars listed in paragraph (2), item (xi), the prefecture, for each type of medical care to be provided that is specified by an Order of the Ministry of Health, Labour and Welfare, may establish, in accordance with the standard specified by an Order of the Ministry of Health, Labour and Welfare concerning the indicator prescribed in paragraph (2) item (xi), (b), the area prescribed in item (xiv) of the same paragraph where the number of physicians is recognized to be small.
- (7) In stipulating the particulars listed in paragraph (2), item (xi), the prefecture, for each type of medical care to be provided that is specified by an Order of the Ministry of Health, Labour and Welfare, may establish, in accordance with the standard specified by an Order of the Ministry of Health, Labour and Welfare concerning the indicator prescribed in paragraph (2) item (xi), (b), the area prescribed in item (xiv) of the same paragraph where the number of physicians is recognized to be large.

- (8) Standards related to the establishment of areas provided for in paragraph (2), items (xiv) and (xv), and the target number of beds provided for in item (xvii) of the same paragraph (for standards related to the target number of long-term care beds and general beds, standards based on the total number calculated according to each type of bed) are to be as prescribed by an Order of the Ministry of Health, Labour and Welfare.
- (9) The prefecture, where it wishes to stipulate the target number of beds provided for in paragraph (2) item (xvii), when a sudden increase in population is expected or when there are other circumstances as provided by a Cabinet Order, may disregard the standards set forth in the preceding paragraph with regard to the required number of beds provided for in the same item, pursuant to the provisions of a Cabinet Order.
- (10) After providing public notice of the medical care plan for a prefecture pursuant to provisions in paragraph (18), the relevant prefecture, when a sudden increase in population is expected or when there are other circumstances as provided by a Cabinet Order, may regard the target number of beds provided for in paragraph (2), item (xvii) as the number calculated pursuant to the provisions of a Cabinet Order, in areas as provided by Cabinet Order, and may engage in activities related to granting permission for applications for permission to establish hospitals and granting permission for other applications as prescribed by Cabinet Order.
- (11) After providing public notice of the medical care plan for the prefecture pursuant to the provisions of paragraph (18), the relevant prefecture, where there has been an application for permission to establish a hospital that includes beds as prescribed by an Order of the Ministry of Health, Labour and Welfare, or where there has been another application as prescribed by a Cabinet Order, may regard the target number of beds provided for in paragraph (2), item (xvii) as the number calculated pursuant to the provisions of a Cabinet Order, in areas as provided by Cabinet Order, and may engage in activities related to granting permission for the relevant application.
- (12) After providing public notice of the medical care plan for the prefecture pursuant to the provisions of paragraph (18), the relevant prefecture, where an application for permission to establish a hospital or any other application specified by a Cabinet Order has been filed by a participating corporation (meaning a participating corporation prescribed in Article 70, paragraph (1)) of a regional medical coordination promotion corporation and where it is found that the relevant application is necessary for promoting the achievement of the regional medical care vision specified in the relevant medical care plan and other requirements specified by an Order of the Ministry of Health, Labour and Welfare are met, may regard the number obtained by adding the number calculated pursuant to the provisions of a Cabinet Order to the target number

of beds provided for in paragraph (2), item (xvii) in the relevant medical care plan pertaining to the relevant application as the relevant target number of beds, and may engage in activities related to granting permission for the relevant application.

- (13) In preparing medical care plans, prefectures must ensure consistency with the prefectural plans prescribed in Article 4, paragraph (1) of the Act for Promoting Comprehensive Measures for Securing Regional Medical and Nursing Care and the prefectural long-term care insurance business support plans prescribed in Article 118, paragraph (1) of the Long-Term Care Insurance Act.
- (14) In preparing medical care plans, prefectures are to endeavor to ensure that harmony is maintained with plans prepared pursuant to the provisions of other laws and regulations and with particulars that concern ensuring medical care, and must endeavor to seek coordination among public health, pharmacy, social welfare, and other measures which are closely related to medical care.
- (15) In preparing medical care plans, prefectures are to undertake liaison and coordination with related prefectures, when it is considered necessary in the light of the supply and demand of medical care in areas near the boundaries of the relevant prefectures.
- (16) The prefecture must hear the opinions of groups of persons with the relevant knowledge and experience in diagnoses or prescriptions, in order to prepare a draft medical care plan based on expert scientific opinions on medical care.
- (17) The prefecture must hear the opinions of the Prefectural Council on Medical Service Facilities, municipalities (including a part of the administrative associations and cross-regional federations set forth in Article 284, paragraph (1) of the Local Autonomy Act (Act No. 67 of 1947) that handle first aid services), and the Council of Insurers set forth in Article 157-2, paragraph (1) of the Act on Assurance of Medical Care for Elderly People (Act No. 80 of 1982) in advance, when stipulating the medical care plan or revising the medical care plan pursuant to the provisions of Article 30-6.
- (18) When a prefecture has established a medical care plan or revised a medical care plan pursuant to the provisions of Article 30-6, it must submit the relevant plan to the Minister of Health, Labour and Welfare without delay and provide public notice of the details thereof.

Article 30-5 A prefecture, if it finds it necessary for the preparation of the medical care plan or for the execution of activities based on the medical care plan, may request the delivery of any necessary information from the municipalities and their public agencies, medical insurers provided for in Article 7, paragraph (7) of the Long-Term Care Insurance Act (referred to as "medical insurers" in Article 30-14, paragraph (1) and Article 30-18-2,

paragraph (1)), or organizers or administrators of medical institutions, including information concerning the functions of medical institutions within the boundaries of the relevant prefecture.

Article 30-6 (1) The prefecture, every three years, must inspect, analyze and evaluate the particulars listed in Article 30-4 (2), items (vi) and (xi), the particulars listed in Article 30-4, paragraph (2) items (vi) and (xi) out of the particulars listed in the following items, and other particulars specified by an Order of the Ministry of Health, Labour and Welfare (referred to as "specified particulars" in the following paragraph) and is to revise the medical care plan of the relevant prefecture when it finds it necessary:

(i) particulars listed in each item of Article 30-4, paragraph (2) (excluding items (vi) and (xi)); and

(ii) if the medical care plan stipulates the particulars listed in each item of Article 30-4, paragraph (3), particulars listed in the relevant items.

(2) The prefecture, every six years, inspect, is to analyze and evaluate the particulars listed in each item of the preceding paragraph (excluding specified particulars), and is to revise the medical care plan of the relevant prefecture when it finds it necessary.

Article 30-7 (1) Organizers and administrators of medical institutions are to endeavor to cooperate as necessary in the construction of the medical care coordination system, in order to contribute to the implementation of the medical care plan.

(2) Organizers and administrators of medical institutions listed in the following items, when providing the necessary cooperation set forth in the preceding paragraph, are to endeavor to fulfill the roles prescribed in the respective items, while coordinating their operations with those of other medical institutions, in order to efficiently provide high-quality and appropriate medical care:

(i) hospitals: To secure necessary medical care in the community by cooperating in the promotion of differentiation and coordination of the bed functions in the community, according to the bed functions; and

(ii) clinics with beds: To provide the following medical care and ensure other necessary medical care in the community so that patients can lead their daily lives in their familiar communities, according to the content of the medical care they provide;

(a) to provide medical care necessary for patients discharged from hospitals to make a smooth transition to in-home medical treatment;

(b) to provide necessary in-home medical care; and

(c) to hospitalize patients and provide them with necessary medical care

when their condition suddenly changes or otherwise when hospitalization is necessary.

- (3) Organizers and administrators of hospitals are to provide in-home medical care, and are to seek cooperation with welfare services and endeavor to give the necessary support for the provision of in-home medical care, in order to contribute to the implementation of the medical care plan.
- (4) Organizers and administrators of hospitals are to endeavor to allow the use of all or parts of the hospital's buildings, equipment, instruments, and tools by physicians, dentists, or pharmacists who do not work at the relevant hospital in their practice, research, or training, provided there is no hindrance to the medical care services of the relevant hospital, in order to contribute to the implementation of the medical care plan.

Article 30-8 The Minister of Health, Labour and Welfare may provide the necessary advice to the prefectures regarding the method of preparing medical care plans and other key practical particulars regarding the preparation of medical care plans.

Article 30-9 The national government may provide subsidies to prefectures for part of the costs required for activities based on medical care plans, within the extent of the budget, in order to promote the fulfillment of medical care plans.

Article 30-10 (1) National government and local governments are to endeavor to undertake any necessary measures, including improving hospitals or clinics in areas with insufficient hospitals or clinics, promoting the differentiation and coordination of the bed functions in the community and ensuring the availability of physicians, in order to promote the fulfillment of medical care plans.

(2) Beyond what is set forth in the preceding paragraph, the national government is to endeavor to improve the system for providing medical care as necessary on a cross-regional level which extends beyond prefectural boundaries.

Article 30-11 The prefectural governor, where it is specifically necessary in order to promote the fulfillment of the medical care plan, may hear the opinions of the Prefectural Council on Medical Service Facilities, and recommend that a person who wishes to establish a hospital or clinic, or an organizer or administrator of a hospital or clinic, establish a hospital, increase a hospital's number of beds, or change its bed classifications, or recommend that such a person establish beds in a clinic or increase the number of beds in a clinic.

Article 30-12 (1) The provisions of Article 7-2, paragraphs (3) through (5) apply

mutatis mutandis to hospitals established by persons other than those listed in each item of paragraph (1) of the same Article (limited to those having long-term care beds or general beds) or clinics (limited to those setting up beds with permission under Article 7, paragraph (3)), when it is especially necessary for promoting the achievement of the medical care plan. In this case, the term "order" in Article 7-2, paragraph (3) is replaced with "request", the term "preceding three paragraphs" in paragraph (4) of the same Article is replaced with "preceding paragraph", the term "the number of beds, and the number of beds to which the relevant application relates" is replaced with "the number of beds", the terms "refuse permission as set forth in paragraphs (1) through (3) of the preceding Article pursuant to the provisions of paragraph (1) or (2), or paragraph (3)" in paragraph (5) of the same Article is replaced with "paragraph (3)", and the term "wishes to issue an order" is replaced with "wishes to issue a request".

- (2) When a prefectural governor finds that the organizer or administrator of a hospital or clinic that has received a request under Article 7-2, paragraph (3) as applied mutatis mutandis by replacing the terms in accordance with the preceding paragraph has not taken measures pertaining to the relevant request without justifiable grounds, the prefectural governor may recommend that the relevant organizer or administrator of the hospital or clinic should take the relevant measures, after hearing the opinions of the Prefectural Council on Medical Service Facilities.
- (3) In the case where a prefectural governor has made a recommendation under the preceding paragraph, the governor, if the organizer or administrator of a hospital or clinic that has received the relevant recommendation fails to comply with it, may make a public announcement to that effect.

Section 3 Promotion of differentiation and coordination of the bed functions in the community

Article 30-13 (1) In order to promote the differentiation and coordination of the bed functions in the community, the administrator of a hospital or clinic with general beds or long-term care beds (hereinafter referred to as a "hospital, etc. subject to a report on the bed functions"), pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare, must report the following particulars in accordance with the classification specified by an Order of the Ministry of Health, Labour and Welfare according to the bed functions (hereinafter referred to as "functional classification of beds") of the relevant hospital, etc. subject to a report on the bed functions to the governor of the prefecture where the relevant hospital, etc. subject to a report on the bed functions is situated:

- (i) the bed functions on the date specified by an Order of the Ministry of Health, Labour and Welfare (referred to as the "reference date" in the following item) (hereinafter referred to as the "reference date bed functions");
 - (ii) the bed functions expected on the day when the period specified by an Order of the Ministry of Health, Labour and Welfare from the reference date has elapsed (hereinafter referred to as the "bed functions after the reference date");
 - (iii) details of medical care to be provided to patients hospitalized in the relevant hospital, etc. subject to a report on the bed functions; and
 - (iv) other particulars specified by an Order of the Ministry of Health, Labour and Welfare.
- (2) The administrator of a hospital, etc. subject to a report on the bed functions, when the bed functions after the reference date reported under the provisions of the preceding paragraph are deemed to have changed, as specified by an Order of the Ministry of Health, Labour and Welfare, must immediately report to the governor of the prefecture where the relevant hospital, etc. subject to a report on the bed functions is situated, pursuant to an Order of the Ministry of Health, Labour and Welfare.
- (3) When the prefectural governor finds it necessary in order to confirm the contents of the report prescribed in the preceding two paragraphs, the governor may request municipalities and other public offices to provide necessary information concerning hospitals, etc. subject to a report on the bed functions located within the area of the relevant prefecture.
- (4) The prefectural governor, pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare, must publicize the particulars reported in accordance with the provisions of paragraphs (1) and (2).
- (5) When the administrator of a hospital, etc. subject to a report on the bed functions has failed to make a report pursuant to the provisions of paragraph (1) or (2) or has made a false report, the prefectural governor may order the organizer of the relevant hospital, etc. subject to a report on the bed functions to have the relevant administrator make a report or correct the contents of the report, by setting a period of time.
- (6) If the prefectural governor has issued an order pursuant to the provisions of the preceding paragraph, if the organizer of a hospital, etc. subject to a report on the bed functions who has received the relevant order fails to comply with it, the prefectural governor may make a public announcement to that effect.

Article 30-14 (1) The prefecture is to establish a place of consultation (hereinafter referred to as the "place of consultation" except for Article 30-18-2, paragraphs (1) and (2) and Article 30-23, paragraph (1)) for consultation with organizations of academic experts on medical treatment, other medical experts,

medical insurers, and other related parties (hereinafter referred to as "related parties" in this Article) in each of the vision areas and other areas that the governor of the relevant prefecture deems appropriate (referred to as the "vision area, etc." in Article 30-16, paragraph (1) and Article 30-18-2, paragraph (3)), and in cooperation with related parties, are to hold consultations on measures to achieve the future requirements for the number of beds specified in the medical care plan and other particulars necessary to promote the achievement of the regional medical care vision.

- (2) When related parties are requested by the prefecture to participate in a consultation conducted by the prefecture pursuant to the provisions of the preceding paragraph, they is to endeavor to cooperate by participating in it, and must also endeavor to cooperate in the implementation of particulars which related parties have agreed upon at the place of such consultation.
- (3) In order to promote the achievement of the regional medical care vision specified in the medical care plan, a person who has filed an application prescribed in Article 7, paragraph (5) must endeavor to respond to a request made by the prefectural governor to participate in a consultation at the place of consultation, with regard to the establishment of a hospital or an increase in the number of beds or a change in the type of beds in a hospital, or the establishment of beds in a clinic or an increase in the number of beds or a change in the type of beds in a clinic pertaining to the relevant application.

Article 30-15 (1) In the case where the reference date bed functions and the bed functions after the reference date pertaining to a report under the provisions of Article 30-13, paragraph (1) are different, or in other cases specified by an Order of the Ministry of Health, Labour and Welfare, the prefectural governor, if the number of beds according to the functional classification of beds pertaining to the bed functions after the reference date pertaining to the relevant report of beds at a hospital subject to a report on the bed functions in the vision area including the location of a hospital, etc. subject to a report on the bed functions having filed the relevant report (hereinafter referred to as a "reporting hospital, etc." in this Article and the following Article) has already reached the future requirements for the number of beds according to the functional classification of beds pertaining to the bed functions after the reference date pertaining to the relevant report in the relevant vision area as specified in the medical care plan, may request the organizer or administrator of a reporting hospital, etc. to submit a document stating the reasons why the reference date bed functions and the bed functions after the reference date pertaining to the relevant report are different, and other particulars specified by an Order of the Ministry of Health, Labour and Welfare (hereinafter referred to as "reasons, etc." in this Article).

- (2) When the prefectural governor finds that the reasons, etc. stated in the document set forth in the preceding paragraph are not sufficient, the governor may request the organizer or administrator of the relevant reporting hospital, etc. to participate in the consultation at the place of consultation.
- (3) The organizer or administrator of a reporting hospital, etc., when requested by the prefectural governor under the preceding paragraph, must endeavor to respond to the request.
- (4) When no agreement is reached through the consultation at the place of consultation set forth in paragraph (2), or when otherwise specified by an Order of the Ministry of Health, Labour and Welfare, the prefectural governor may request the organizer or administrator of the relevant reporting hospital, etc. to attend a meeting of the Prefectural Council on Medical Service Facilities and explain the relevant reasons, etc.
- (5) The organizer or administrator of a reporting hospital, etc., when requested by the prefectural governor under the preceding paragraph, must endeavor to attend a meeting of the Prefectural Council on Medical Service Facilities and explain the relevant reasons, etc.
- (6) If the relevant reasons, etc. are not found to be unavoidable based on the content of the consultation at the place of consultation set forth in paragraph (2) and the content of the explanation set forth in paragraph (4), the prefectural governor may order the organizer or administrator of the reporting hospital, etc. (limited to those established by the persons listed in the items of Article 7-2, paragraph (1)) not to change the reference date bed functions pertaining to a report under the provisions of Article 30-13, paragraph (1) to the bed functions after the reference date pertaining to the relevant report and to take other necessary measures, after hearing the opinions of the Prefectural Council on Medical Service Facilities.
- (7) The provisions of the preceding paragraph apply mutatis mutandis to a reporting hospital, etc. established by a person other than those listed in the items of Article 7-2, paragraph (1), when it is especially necessary for promoting the achievement of the regional medical care vision specified in the medical care plan. In this case, the term "order" in the preceding paragraph is replaced with "request".

Article 30-16 (1) The prefectural governor, when no agreement is reached through consultation at the place of consultation on particulars necessary to promote the achievement of the regional medical care vision specified in the medical care plan, or when otherwise specified by an Order of the Ministry of Health, Labour and Welfare, may instruct the organizer or administrator of a hospital, etc. subject to a report on the bed functions (limited to those established by the persons listed in the items of Article 7-2, paragraph (1)) in

the vision area, etc. to provide medical care pertaining to the case where, out of the functional classification of beds, the number of existing beds according to the functional classification of beds in the vision area pertaining to the relevant vision area, etc. has not reached the future requirements for the number of beds in the relevant vision area specified in the medical care plan and take other necessary measures, after hearing the opinions of the Prefectural Council on Medical Service Facilities.

- (2) The provisions of the preceding paragraph apply mutatis mutandis to a hospital, etc. subject to a report on the bed functions established by a person other than those listed in the items of Article 7-2, paragraph (1), when it is especially necessary for promoting the achievement of the regional medical care vision specified in the medical care plan. In this case, the term "instruct" in the preceding paragraph is replaced with "request".

Article 30-17 When the prefectural governor finds that the organizer or administrator of a hospital, etc. subject to a report on the bed functions who has received a request under Article 30-15, paragraph (6) as applied mutatis mutandis by replacing the terms in accordance with paragraph (7) of the same Article, or under paragraph (1) of the preceding Article as applied mutatis mutandis by replacing the terms in accordance with paragraph (2) of the same Article has not taken measures pertaining to the relevant request without justifiable grounds, the governor may recommend that the relevant organizer or administrator of a hospital, etc. subject to a report on the bed functions should take the relevant measures, after hearing the opinions of the Prefectural Council on Medical Service Facilities.

Article 30-18 In the event that a prefectural governor has issued an order under the provisions of Article 30-15, paragraph (6), an instruction under the provisions of Article 30-16, paragraph (1), or a recommendation under the provisions of the preceding Article, and the organizer or administrator of a hospital, etc. subject to a report on the bed functions who has received the relevant order, instruction or recommendation fails to comply with it, the prefectural governor may make a public announcement to that effect.

Section 4 Securing the Medical Care Delivery System for Outpatient Medical Care in the Region

Article 30-18-2 (1) The prefecture is to establish a place of consultation for consultation with organizations of academic experts on medical treatment, other medical experts, medical insurers, and other related parties (hereinafter referred to as "related parties" in this paragraph and the following paragraph)

in each of the areas set forth in Article 30-4, paragraph (2), item (xiv) and other areas that the governor of the relevant prefecture deems appropriate (referred to as the "target area" in paragraph (3)), and, in cooperation with related parties, are to hold consultations on the following particulars (with regard to the particulars listed in items (ii) through (iv), limited to those related to securing the medical care delivery system for outpatient medical care; the same applies in paragraph (3)), and summarize and publicize the results thereof:

- (i) particulars concerning the status of the medical care delivery system for outpatient medical care, based on the information on the number of physicians indicated by the indicator prescribed in Article 30-4, paragraph (2) item (xi), (b);
 - (ii) particulars concerning the promotion of functional differentiation and coordination of hospitals and clinics;
 - (iii) particulars concerning the promotion of medical treatment provided by multiple physicians in cooperation;
 - (iv) particulars concerning the efficient utilization of all or part of buildings, equipment, instruments and appliances of medical institutions; and
 - (v) other particulars necessary for securing the medical care delivery system for outpatient medical care.
- (2) When related parties are requested by the prefecture to participate in a consultation conducted by the prefecture pursuant to the provisions of the preceding paragraph, they are to endeavor to cooperate by participating in it, and must also endeavor to cooperate in the implementation of particulars which related parties have agreed upon at the place of such consultation.
- (3) When the target area coincides with the vision area, etc., the prefecture, in lieu of the consultation set forth in paragraph (1) in the relevant target area, may hold consultations on the particulars listed in the items of the same paragraph at the place of consultation in the relevant vision area, etc.
- (4) In the case prescribed in the preceding paragraph, related parties as prescribed in Article 30-14, paragraph (1), when requested by the prefecture to participate in a consultation conducted by the prefecture pursuant to the provisions of the preceding paragraph, are to endeavor to cooperate by participating in it, and must also endeavor to cooperate in the implementation of particulars which related parties have agreed upon at the place of such consultation.

Section 5 Measures to Ensure the Availability of Medical Care Professionals, etc.

Article 30-19 The administrator of a hospital or clinic must endeavor to take

measures to improve the working environment of medical care professionals working in the relevant hospital or clinic and other measures that contribute to ensuring the availability of medical care professionals.

Article 30-20 The Minister of Health, Labour and Welfare is to establish and publicize particulars that should serve as guidelines for the appropriate and effective implementation of measures to be taken by administrators of hospitals and clinics in accordance with the provisions of the preceding Article.

Article 30-21 (1) The prefecture is to endeavor to implement the following particulars in order to promote the improvement of the working environment of medical care professionals:

(i) providing consultation, necessary information, advice and other assistance concerning the improvement of the working environment of medical care professionals working in hospitals or clinics;

(ii) conducting surveys and awareness-raising activities concerning the improvement of the working environment of medical care professionals working in hospitals or clinics; and

(iii) beyond what is listed in the preceding two items, providing support necessary for improving the working environment of medical care professionals.

(2) The prefecture may entrust all or part of the affairs listed in the items of the preceding paragraph to a person specified by an Order of the Ministry of Health, Labour and Welfare.

(3) A person entrusted pursuant to the provisions of the preceding paragraph, when implementing the affairs listed in each item of paragraph (1) or the particulars pertaining to the relevant entrustment, is to pay special attention to the following particulars:

(i) importance of improving the working environment in a hospital or clinic in an acute physician shortage area where physicians will be staffed; and

(ii) importance of securing the function as a center to promote the improvement of the working environment of medical care professionals.

(4) The prefecture or a person entrusted pursuant to the provisions of paragraph (2), when implementing the affairs listed in each item of paragraph (1) or the affairs pertaining to the relevant entrustment, must mutually cooperate with a person who implements the affairs to support regional medical care prescribed in Article 30-25, paragraph (3) or the affairs pertaining to the entrustment set forth in the same paragraph.

(5) A person entrusted pursuant to the provisions of paragraph (2), or an officer or employee thereof, or a person who used to be such a person must not divulge any secret that has come to their knowledge concerning the affairs pertaining

to the relevant entrustment without justifiable grounds.

Article 30-22 In order to contribute to appropriate implementation of the affairs listed in each item of paragraph (1) of the preceding Article, the national government is to provide necessary information and other forms of cooperation to prefectures.

Article 30-23 (1) The prefecture must establish a place of consultation with the administrators of the following entities and other related parties (referred to as the "Council for Regional Medical Care Measures" in the following paragraph), which are to hold consultations with the cooperation of these persons on particulars necessary for the implementation of the particulars listed in each item of the same paragraph concerning ensuring the availability of physicians specified in the medical care plans, and must make a public announcement of the particulars agreed upon through the relevant consultations:

- (i) advanced treatment hospitals;
 - (ii) regional medical care support hospitals;
 - (iii) public medical institutions provided for in Article 31 (referred to as "public medical institutions" in item (v)).
 - (iv) hospitals designated by prefectural governors and provided for in Article 16-2, paragraph (1) of the Medical Practitioners' Act;
 - (v) hospitals other than public medical institutions (excluding those specified by an Order of the Ministry of Health, Labour and Welfare as being equivalent to public medical institutions);
 - (vi) groups of persons with the relevant knowledge and experience in medical practice;
 - (vii) universities prescribed in Article 1 of the School Education Act (Act No. 26 of 1947) (hereinafter simply referred to as "universities") and other organizations related to the training of medical care professionals;
 - (viii) social medical corporations provided for in Article 42-2, paragraph (1) authorized by the relevant prefectural governor; or
 - (ix) other parties as prescribed by an Order of the Ministry of Health, Labour and Welfare.
- (2) The particulars to be discussed at the Council for Regional Medical Care Measures pursuant to the provisions of the preceding paragraph are to be the following particulars:
- (i) particulars concerning plans specified by an Order of the Ministry of Health, Labour and Welfare as those aimed at contributing to ensuring the availability of physicians in acute physician shortage areas and at developing and improving the abilities of physicians to be dispatched to acute physician shortage areas;

- (ii) particulars concerning the staffing of physicians;
 - (iii) particulars concerning continuous assistance for the development and improvement of the abilities of the physicians dispatched to acute physician shortage areas in accordance with the plans prescribed in item (i);
 - (iv) particulars concerning measures to alleviate the burden on physicians dispatched to acute physician shortage areas;
 - (v) particulars concerning measures to be taken in cooperation between universities and prefectures for ensuring the availability of physicians in acute physician shortage areas that are specified by an Order of the Ministry of Education, Culture, Sports, Science and Technology and an Order of the Ministry of Health, Labour and Welfare;
 - (vi) particulars that fall under the authority as set forth in the Medical Practitioners' Act; and
 - (vii) other particulars concerning ensuring the availability of physicians specified in the medical care plan.
- (3) The prefectural governor, when holding consultations on the particulars listed in item (ii) of the preceding paragraph, must take into account the information on the number of physicians indicated by the indicator prescribed in Article 30-4, paragraph (2) item (xi), (b) and give consideration to other particulars specified by an Order of the Ministry of Health, Labour and Welfare, so that the dispatch of physicians will contribute to ensuring the availability of physicians in acute physician shortage areas.
- (4) Administrators of the entities listed in the items of paragraph (1) and other related parties must endeavor to cooperate, if requested by the prefecture, by participating in consultations carried out by the prefecture as set forth in the provisions of the same paragraph.

Article 30-24 When the prefectural governor finds it especially necessary based on the particulars agreed upon through the consultation prescribed in paragraph (1) of the preceding Article (referred to as "particulars agreed upon" in paragraph (1) of the following Article, Article 30-27 and Article 31), the governor may request the organizers and administrators of entities listed in the items of paragraph (1) of the preceding Article and other related parties to provide necessary cooperation for ensuring the availability of physicians in hospitals or clinics in acute physician shortage areas, such as dispatching physicians and developing training systems.

Article 30-25 (1) The prefecture, based on the particulars agreed upon, is to endeavor to implement the following affairs in order to secure the medical care required in the region:

- (i) to conduct surveys and analyses concerning: trends in ensuring the

- availability of physicians in hospitals and clinics located in the areas prescribed in Article 30-4, paragraph (6); factors contributing to ensuring the availability of physicians in hospitals and clinics located in the areas prescribed in Article 30-4, paragraph (7); and other particulars concerning the securing of medical care required in the region;
- (ii) to provide consultation, necessary information, advice and other assistance concerning ensuring the availability of physicians to organizers and administrators of hospitals and clinics and other related parties;
 - (iii) to provide consultation, necessary information, advice and other assistance concerning employment to physicians who wish to work, students majoring in medicine at universities and other related parties;
 - (iv) to provide physicians with consultation, necessary information, advice and other assistance concerning training on the latest knowledge and skills related to medical care and other programs for the development and improvement of their abilities;
 - (v) to formulate the plans prescribed in Article 30-23, paragraph (2), item (i);
 - (vi) to make the necessary coordination with regard to the implementation of the particulars listed in items (ii) through (iv) of Article 30-23, paragraph (2); and
 - (vii) beyond what is listed in each of the preceding items, to provide necessary support for ensuring the availability of physicians in hospitals and clinics.
- (2) Beyond the affairs listed in the items of the preceding paragraph, the prefecture may carry out free employment placement services for physicians pursuant to the provisions of Article 29, paragraph (1) of the Employment Security Act (Act No. 141 of 1947) or carry out worker dispatching services for medical practitioners by obtaining the license provided for in Article 5, paragraph (1) of the Act for Securing the Proper Operation of Worker Dispatching Businesses and Protecting Dispatched Workers (Act No. 88 of 1985).
- (3) The prefecture may entrust all or part of the affairs listed in the items of paragraph (1) and the affairs provided for in the preceding paragraph (hereinafter referred to as "affairs to support regional medical care" in this Article and the following Article) to a person specified by an Order of the Ministry of Health, Labour and Welfare.
- (4) The prefecture or a person who has been entrusted under the provisions of the preceding paragraph, when implementing the affairs to support regional medical care or the affairs pertaining to the relevant entrustment, is to endeavor to secure the functions as a center for securing the medical care required in the region.
- (5) The prefecture or a person who has been entrusted under the provisions of paragraph (3), when implementing the affairs to support regional medical care

or the affairs pertaining to the relevant entrustment, cooperate with a person who implements affairs listed in each item of Article 30-21, paragraph (1) or affairs pertaining to the entrustment under Article 30-21, paragraph (2).

- (6) A person who has been entrusted under the provisions of paragraph (3) or an officer or employee thereof, or a person who used to be such a person must not divulge any secret that has come to their knowledge with regard to the affairs pertaining to the relevant entrustment without justifiable grounds.

Article 30-26 In order to contribute to the appropriate implementation of affairs to support regional medical care, the national government is to provide necessary information and other forms of cooperation to prefectures.

Article 30-27 The persons listed in the items of Article 30-23, paragraph (1) (excluding item (iii)) and medical care professionals are to endeavor to cooperate in the implementation of particulars agreed upon and other particulars concerning the securing of medical care required in relevant prefectures. They must also, when cooperation is requested in accordance with the provisions of Article 30-24, respond to the relevant request and endeavor to cooperate in ensuring the availability of physicians.

Section 6 Public Medical Institutions

Article 31 Public medical institutions (hospitals or clinics established by a prefecture, municipality or other party as prescribed by the Minister of Health, Labour and Welfare; the same applies hereinafter in this Section) are to endeavor to cooperate in the implementation of particulars agreed upon and other particulars concerning the securing of medical care required in relevant prefectures. They must also, when cooperation is requested in accordance with the provisions of Article 30-24, respond to the relevant request and cooperate in ensuring the availability of physicians.

Articles 32 and 33 Deleted

Article 34 (1) If the Minister of Health, Labour and Welfare finds it specifically necessary for the dissemination of medical care, may order the parties provided for in Article 31 to establish a public medical institution.

- (2) In the case referred to in the preceding paragraph, the national treasury is to subsidize part of the costs required for the relevant establishment, within the extent determined by the budget.

Article 35 (1) The Minister of Health, Labour and Welfare or a prefectural

governor may order the organizer or administrator of a public medical institution to undertake the following particulars:

- (i) allow the use of all or parts of the buildings, equipment, instruments, and tools for the practice and research of physicians and dentists who do not work at the relevant public medical institution, provided that this is not a hindrance to the medical care services of the relevant hospital or clinic;
 - (ii) provide the necessary conditions for practical training pursuant to Article 11, item (ii) of the Medical Practitioners' Act or Article 11, item (ii) of the Dentists Act, or for clinical training pursuant to Article 16-2, paragraph (1) of the Medical Practitioners' Act or Article 16-2, paragraph (1) of the Dentists Act; and
 - (iii) undertake necessary measures to ensure medical care in relation to activities to ensure emergency medical care as prescribed by the medical care plan of the prefecture in which the relevant public medical institution is situated.
- (2) The Minister of Health, Labour and Welfare or a prefectural governor may instruct the organizer of a public medical institution as necessary on particulars concerning the operation thereof other than those listed in each item of the preceding paragraph.

Articles 36 through 38 Deleted

Chapter VI Medical Corporations

Section 1 General Rules

Article 39 (1) An association or foundation that wishes to establish a hospital, a clinic where a physician or dentist will work full-time, a long-term care health facility, or an integrated facility for medical and long-term care may incorporate the relevant facility pursuant to the provisions of this Act.

(2) A corporation pursuant to the provisions of the previous paragraph is to include in its name the term "medical corporation".

Article 40 An entity that is not a medical corporation must not use the term "medical corporation" in its name.

Article 40-2 A medical corporation, as well as seeking to independently strengthen its operational foundations, is to seek to improve the quality of the medical care it provides and ensure transparency in its operation, and must endeavor to actively fulfill its role as a major medical care actor in the community.

Article 41 (1) A medical corporation must possess the assets necessary for it to operate.

(2) Necessary particulars concerning the assets set forth in the preceding paragraph are to be as prescribed by an Order of the Ministry of Health, Labour and Welfare, in accordance with the scale, etc. of medical care functions established by the medical corporation.

Article 42 A medical corporation may carry out all or some of the following operations, provided there is no hindrance to the operation of the hospital, clinic, long-term care health facility, or integrated facility for medical and long-term care it has established (including a hospital, clinic, long-term care health facility, or integrated facility for medical and long-term care publically established by the relevant medical corporation and managed by a designated administrator provided for in Article 244-2, paragraph (3) of the Local Autonomy Act (hereinafter referred to as "hospital, etc. managed by a designated administrator")), pursuant to the provisions of its articles of incorporation or its act of endowment:

- (i) the training or re-training of medical personnel;
- (ii) the establishment of a research center for medicine or dentistry;
- (iii) the establishment of clinics other than clinics provided for in Article 39, paragraph (1);
- (iv) the establishment of facilities that allow people to engage in aerobic exercise for the prevention of illness (meaning physical exercise undertaken in order to maintain or rehabilitate physiological functions related to whole-body stamina, through the continuous intake of oxygen; the same applies in the following item) that are affiliated with a clinic and whose personnel, equipment, and operation comply with standards prescribed by the Minister of Health, Labour and Welfare;
- (v) the establishment of facilities that allow the use of a hot spring for the prevention of illness that has a space for aerobic exercise and whose personnel, equipment, and operation comply with standards prescribed by the Minister of Health, Labour and Welfare;
- (vi) beyond what is listed in each of the preceding items, operations related to health and hygiene;
- (vii) the establishment of the activities prescribed by the Minister of Health, Labour and Welfare, among those listed in Article 2, paragraphs (2) and (3) of the Social Welfare Act (Act No. 45 of 1951); and
- (viii) the establishment of the fee-based home care for the elderly provided for in Article 29, paragraph (1) of the Act on Social Welfare Services for the Elderly (Act No. 133 of 1963).

Article 42-2 (1) A medical corporation that has received authorization from the prefectural governor as falling under the following requirements, pursuant to the provisions of a Cabinet Order (hereinafter referred to as "social medical corporations") may undertake operations as prescribed by the Minister of Health, Labour and Welfare (hereinafter referred to as "profit-making activities"), for the purpose of allocating its proceeds to the administration of a hospital, clinic, long-term care health facility, or integrated facility for medical and long-term care established by the relevant social medical corporation, pursuant to the provisions of its articles of incorporation or act of endowment, provided that this does not hinder the operation of the hospital, clinic, long-term care health facility, or integrated facility for medical and long-term care the relevant medical corporation has established (including hospitals, etc. managed by a designated administrator):

- (i) no more than one-third of the total number of officers is composed of the officer, their spouse, their relatives within the third degree of kinship, or other persons who have a special relationship with the officer as specified by an Order of the Ministry of Health, Labour and Welfare.;
- (ii) no more than one-third of the total number of members of an associated medical corporation is composed of the member, their spouse, their relatives within the third degree of kinship, or other persons who have a special relationship with the member as specified by an Order of the Ministry of Health, Labour and Welfare;
- (iii) no more than one-third of the total number of councillors of an associated medical corporation is composed of the councillor, their spouse, their relatives within the third degree of kinship, or other persons who have a special relationship with the councillor as specified by an Order of the Ministry of Health, Labour and Welfare;
- (iv) it carries out operations related to activities to ensure emergency medical care (limited to those listed in the medical care plan prepared by the prefecture of the hospital or clinic established by the relevant medical corporation; the same applies in the following Article) in the prefecture (in the case of a medical corporation listed in (a) or (b) below, the prefecture specified in (a) or (b) respectively) in which the relevant hospital or clinic is situated;
 - (a) a medical corporation that establishes hospitals or clinics in two or more prefectures (excluding those listed in (b)): All prefectures where the relevant hospitals or clinics are located; or
 - (b) a medical corporation that establishes hospitals in one prefecture and clinics in the area prescribed in Article 30-4, paragraph (2), item (xiv) specified in the medical care plan of the prefecture other than the prefecture where the relevant hospitals are located, which is adjacent to

- the area prescribed in the same item specified in the medical care plan of the prefecture where the relevant hospitals are located, and medical care in the relevant hospitals and the relevant clinics is provided in an integrated manner in conformity with the standards specified by an Order of the Ministry of Health, Labour and Welfare: The prefecture where the relevant hospitals are located;
- (v) the operations set forth in the preceding item comply with the standards prescribed by the Minister of Health, Labour and Welfare with regard to the following particulars:
 - (a) the buildings and equipment of the hospitals or clinics engaged in the relevant operations;
 - (b) the system by which the relevant operations are undertaken; and
 - (c) the outcome of the relevant operations;
 - (vi) beyond what is listed in each of the preceding items, particulars that comply with the requirements set out by an Order of the Ministry of Health, Labour and Welfare with regard to public operations; and
 - (vii) it is stipulated in the articles of incorporation or the act of endowment that any residual assets at the time of dissolution will belong to the national government, local government, or another social medical corporation.
- (2) In granting the authorization set forth in the preceding paragraph, the prefectural governor must hear the opinions of the Prefectural Council on Medical Service Facilities in advance.
- (3) Accounting for profit-making activities are to be kept separate from accounting for the operation of a hospital, clinic, long-term care health facility, or integrated facility for medical and long-term care established by the relevant social medical corporation (including a hospital, etc. managed by a designated administrator), and from operations listed in each item of the preceding Article, and must be accounted for in a special account.

Article 42-3 (1) Out of medical corporations that have received authorization set forth in paragraph (1) of the preceding Article (hereinafter referred to as "authorization as a social medical corporation" in this paragraph and Article 64-2, paragraph (1)), those that have fallen under Article 64-2, paragraph (1), item (i) due to the fact that they no longer meet the requirements listed in paragraph (1), item (v), (c) of the preceding Article (limited to the case where the relevant failure to meet the requirements is due to reasons specified by an Order of the Ministry of Health, Labour and Welfare as reasons not attributable to the relevant medical corporations) and have their authorization as a social medical corporation rescinded pursuant to the provisions of Article 64-2, paragraph (1) (limited to those that fall under the requirements listed in each item (excluding item (v), (c)) of paragraph (1) of the preceding Article)

may prepare a plan for the continuous implementation of activities to ensure emergency medical care (hereinafter referred to as the "implementation plan" in this Article) and submit it to the prefectural governor to receive approval to the effect that the implementation plan is appropriate.

- (2) A medical corporation that has received the approval set forth in the preceding paragraph may conduct profit-making operations in accordance with the provisions of paragraphs (1) and (3) of the preceding Article.
- (3) The provisions of paragraph (2) of the preceding Article apply mutatis mutandis to the case of granting the approval set forth in paragraph (1).
- (4) Beyond what is provided for in the preceding three paragraphs, particulars necessary for the approval of an implementation plan and its revocation is specified by Cabinet Order.

Article 43 (1) A medical corporation must complete its registration pursuant to the provisions of a Cabinet Order, in the case of its establishment, the establishment of secondary offices, a relocation of its offices, a change in other registered particulars, dissolution, merger, split, the appointment or change of a liquidator, and the completion of liquidation.

- (2) Particulars which are to be registered pursuant to the provisions of the preceding paragraph may not be duly asserted against a third party after registration.

Section 2 Establishment

Article 44 (1) A medical corporation may not be established without the authorization of the prefectural governor of the location of its principal office (hereinafter referred to simply as "prefectural governor" in this Chapter (excluding paragraph (3) and Article 66-3)).

- (2) A person who wishes to establish a medical corporation must stipulate at least the following particulars in its articles of incorporation or act of endowment:
 - (i) its purpose;
 - (ii) its name;
 - (iii) the name and established location of the hospital, clinic, long-term care health facility, or integrated facility for medical and long-term care (including a publically established hospital, clinic, long-term care health facility, or integrated facility for medical and long-term care that is to be managed by a designated administrator as provided in Article 244-2, paragraph (3) of the Local Autonomy Act) to be established;
 - (iv) the location of its offices;
 - (v) provisions on assets and accounting;

- (vi) provisions on officers;
 - (vii) provisions on the board of directors;
 - (viii) for an association of medical corporations, provisions on general meetings and the acquisition or loss of member status;
 - (ix) for medical corporation foundations, provisions on the board of councillors and councillors;
 - (x) provisions on dissolution;
 - (xi) provisions on changes to the articles of incorporation or act of endowment; and
 - (xii) the method of public notice.
- (3) If a person who wishes to establish a medical corporation foundation dies without stipulating the name, location of its offices, or method of appointment and dismissal of directors, the prefectural governor must determine such particulars by the authority of the governor or at the request of an interested party.
- (4) The initial officers at the time of the establishment of a medical corporation must be stipulated in the articles of incorporation or act of endowment.
- (5) Where, among the particulars listed in paragraph (2), item (x), provisions on persons with vested rights to residual assets have been established, such persons must be selected from among the national government or local governments, or medical corporations or other persons who deliver medical care, as prescribed by an Order of the Ministry of Health, Labour and Welfare.
- (6) Beyond the provisions of this Section, any necessary particulars related to applications for authorization to establish a medical corporation is to be as prescribed by an Order of the Ministry of Health, Labour and Welfare.

Article 45 (1) Where there has been an application for authorization pursuant to the provisions of paragraph (1) of the preceding Article, the prefectural governor must reach a decision on such authorization based on an examination of whether the assets of the medical corporation to which the relevant application relates comply with the requirements set forth in Article 41, and whether the articles of incorporation or act of endowment are not in violation of laws and regulations.

(2) In granting or refusing authorization pursuant to the provisions of paragraph (1) of the preceding Article, the prefectural governor must hear the opinions of the Prefectural Council on Medical Service Facilities in advance.

Article 46 (1) A medical corporation is to be incorporated through the registration of its establishment at the location of the principal office thereof, pursuant to the provisions of a Cabinet Order.

(2) A medical corporation must prepare an inventory of assets at the time of

incorporation, and keep it in its principal office at all times.

Section 3 Organizations

Subsection 1 Establishment of Organizations

Article 46-2 (1) A medical corporation as an association must have a general meeting of members, directors, a board of directors, and auditors.

(2) A medical corporation as a foundation must have councillors, a board of councillors, directors, a board of directors, and auditors.

Subsection 2 General Meeting of Members

Article 46-3 (1) A general meeting of members may adopt resolutions on particulars provided for in this Act and particulars provided for in the articles of incorporation.

(2) Provisions in the articles of incorporation to the effect that the directors, the board of directors, or other organizations other than the general meeting of members may decide on particulars requiring a resolution of the general meeting of members under the provisions of this Act has no effect.

Article 46-3-2 (1) A medical corporation as an association must keep a list of its members and make necessary changes whenever there is a change in the members.

(2) The president of a medical corporation as an association must hold an ordinary general meeting of members at least once a year.

(3) The president may convene an extraordinary general meeting of members, whenever the president finds it necessary,

(4) When one fifth or more of the total number of members request the convening of an extraordinary general meeting of members by indicating the particulars that are the purpose of the general meeting of members, the president must convene an extraordinary general meeting of members within 20 days from the date of the request; provided, however, that the articles of incorporation may provide for a ratio of less than one fifth of the total number of members.

(5) A notice of convocation of a general meeting of members must be given at least five days prior to the date of such general meeting of members, indicating the particulars to be discussed at such general meeting of members and in accordance with the method prescribed in the articles of incorporation.

(6) At a general meeting of members, resolutions may be adopted only with respect to particulars for which advance notice has been given pursuant to the provisions of the preceding paragraph, except as otherwise provided in the articles of incorporation.

Article 46-3-3 (1) Each member is to have one voting right.

- (2) Except as otherwise provided in the articles of incorporation, no general meeting of members may be held and no resolution may be adopted unless a majority of all members are present.
- (3) Except as otherwise provided in this Act or the articles of incorporation, the agenda of a general meeting of members is to be decided by a majority of the voting rights of those present, and in case of a tie vote, the chairperson is to decide.
- (4) In the case of the preceding paragraph, the chairperson may not participate in the voting as a member.
- (5) Any member who is not present at the general meeting of members may vote in writing or by proxy, unless otherwise provided for in the articles of incorporation.
- (6) Any member who has a special interest in the resolutions of the general meeting of members may not participate in the voting.

Article 46-3-4 In the event that the directors and auditors are requested by members to explain specific particulars at a general meeting of members, they must provide necessary explanations regarding such particulars. However, this does not apply to cases where such particulars do not relate to the particulars that are the purpose of the general meeting of members or other cases specified by Order of the Ministry of Health, Labour and Welfare as cases where there are justifiable grounds.

Article 46-3-5 (1) The chairperson of a general meeting of members is to be elected at the general meeting of members.

- (2) The chairperson of a general meeting of members is to maintain order and organize the proceedings of the relevant general meeting of members.
- (3) The chairperson of a general meeting of members may dismiss any person who does not obey the chairpersons' orders or who otherwise disturbs the order of the relevant general meeting of members.

Article 46-3-6 The provisions of Article 57 of the Act on General Incorporated Associations and General Incorporated Foundations (Act No. 48 of 2006) apply mutatis mutandis to the general meeting of members of a medical corporation. In this case, the term "Ministry of Justice Order" in paragraphs (1), (3) and (4), item (ii) of the same Article is replaced with "Order of the Ministry of Health, Labour and Welfare".

Subsection 3 Councillors and Board of Councillors

Article 46-4 (1) The persons who serve as councillors are to be as follows:

- (i) persons elected as provided for in the act of endowment from among medical care professionals;
 - (ii) persons elected as provided for in the act of endowment from among persons who have knowledge and experience in the management of a hospital, clinic, long-term care health facility, or integrated facility for medical and long-term care;
 - (iii) persons elected as provided for in the act of endowment from among medical care recipients; or
 - (iv) beyond those listed in the preceding three items, persons elected as provided for in the act of endowment.
- (2) Any person who falls under any of the following items may not serve as a councillor of a medical corporation:
- (i) the corporation;
 - (ii) a person specified by an Order of the Ministry of Health, Labour and Welfare as a person who is unable to execute their duties properly due to a mental or physical disorder;
 - (iii) a person sentenced to a fine or severer punishment pursuant to the provisions of this Act, the Medical Practitioners Act, the Dental Practitioners Act or any other laws concerning medical affairs specified by a Cabinet Order, and for whom two years have not yet elapsed from the day on which the execution of the sentence was completed or the sentence became no longer applicable; or
 - (iv) except for those who fall under the preceding item, a person who has been sentenced to imprisonment without work or severer punishment and has completed the execution of the sentence or is no longer subject to the execution of the sentence.
- (3) A councillor must not concurrently serve as an officer or employee of the relevant medical corporation as a foundation.
- (4) The relationship between a medical corporation as a foundation and its councillors is to be governed by the provisions concerning delegation.

Article 46-4-2 (1) The board of councillors are to consist of a number of councillors that exceeds the fixed number of directors (in the case of a medical corporation approved under the proviso of Article 46-5, paragraph (1), three or more councillors).

- (2) Beyond expressing the opinions set forth in Article 46-4-5, paragraph (1), the board of councillors may adopt resolutions only on the particulars provided for in this Act and the particulars provided for in the act of endowment.
- (3) Provisions in the act of endowment to the effect that the directors, the board

of directors, or other organizations other than the board of councillors may decide on particulars requiring a resolution of the board of councillors under the provisions of this Act are to have no effect.

Article 46-4-3 (1) The president of a medical corporation as a foundation is to hold an ordinary meeting of the board of councillors at least once a year.

(2) The president may convene an extraordinary meeting of the board of councillors whenever the president finds it necessary.

(3) The meeting of the board of councillors are to have a chairperson.

(4) When one fifth or more of the total number of councillors request the convening of a meeting of the board of councillors by indicating the particulars that are the purpose of the meeting, the president must convene a meeting of the board of councillors within 20 days from the date of the request; provided, however, that the act of endowment may provide for a ratio of less than one fifth of the total number of councillors.

(5) Notice of a meeting of the board of councillors must be given at least five days prior to the date of the meeting, indicating the particulars that are the purpose of the meeting and in accordance with the method prescribed in the act of endowment.

(6) At a meeting of the board of councillors, resolutions may be adopted only with respect to particulars for which prior notice has been given pursuant to the preceding paragraph, except as otherwise provided in the act of endowment.

Article 46-4-4 (1) No meeting of the board of councillors may be held and no resolution may be adopted unless a majority of all councillors are present.

(2) Except as otherwise provided in this Act, the agenda of a meeting of the board of councillors is to be decided by a majority of the voting rights of those present, and in case of a tie vote, the chairperson is to decide.

(3) In the case of the preceding paragraph, the chairperson may not participate in the voting as a councillor.

(4) Any councillor who has a special interest in the resolutions of the meeting of the board of councillors may not participate in the voting.

Article 46-4-5 (1) The president must hear the opinion of the board of councillors before the medical corporation takes any of the following actions:

(i) determining or changing the budget;

(ii) borrowings (excluding temporary borrowings to be redeemed with the income of the relevant fiscal year);

(iii) disposal of important assets;

(iv) determining or changing the business plan;

(v) merger and split;

- (vi) dissolution due to any of the reasons listed in Article 55, paragraph (1), item (ii) out of those listed in Article 55, paragraph (3), item (ii); or
 - (vii) other important particulars concerning the business of the medical corporation as specified in the act of endowment.
- (2) With regard to the particulars listed in each item of the preceding paragraph, it may be provided for in the act of endowment that a resolution of the board of councillors may be required.

Article 46-4-6 The board of councillors may express its opinions to the officers, respond to their inquiries, or collect reports from them concerning the status of the business or the status of the property of the medical corporation or the status of the execution of business by the officers.

Article 46-4-7 The provisions of Article 193 of the Act on General Incorporated Associations and General Incorporated Foundations apply mutatis mutandis to the meeting of the board of councillors of a medical corporation. In this case, the term "Ministry of Justice Order" in paragraph (1), (3) and (4), item (ii) of the same Article is replaced with "Order of the Ministry of Health, Labour and Welfare".

Subsection 4 Election and Dismissal of Officers

- Article 46-5 (1) A medical corporation must have three or more directors and one or more auditors as its officers; provided, however, that if the approval of the prefectural governor has been obtained, it is sufficient to have one or two directors.
- (2) Officers of a medical corporation as an association is to be elected by a resolution of a general meeting of members.
 - (3) Officers of a medical corporation as a foundation is to be elected by a resolution of the board of councillors.
 - (4) The relationship between a medical corporation and its officers is to be governed by the provisions concerning delegation.
 - (5) The provisions of Article 46-4, paragraph (2) apply mutatis mutandis to officers of a medical corporation.
 - (6) A medical corporation must include as directors the administrators of all hospitals, clinics, long-term care health facilities or integrated facilities for medical and long-term care it has established (including hospitals, etc. it manages as a designated administrator) provided, however, that in the case where a medical corporation has established two or more hospitals, clinics, long-term care health facilities or integrated facilities for medical and long-term care and approval is obtained from the prefectural governor, it is not

obliged to include as directors some of the administrators (excluding the administrators of hospitals, etc. it manages as a designated administrator).

(7) The directors set forth in the main clause of the preceding paragraph are to lose their positions as directors when they resign from their positions as administrators.

(8) Auditors must not concurrently serve as directors or employees of the medical corporation.

(9) The term of office of an officer must not exceed two years; provided, however, that this must not preclude reappointment.

Article 46-5-2 (1) An officer of a medical corporation as an association may be dismissed at any time by a resolution of the general meeting of members.

(2) An officer who has been dismissed pursuant to the provisions of the preceding paragraph may claim compensation for damages caused by the dismissal from the medical corporation as an association unless there are justifiable grounds for such dismissal.

(3) A medical corporation as an association may not adopt a resolution at a general meeting of members set forth in paragraph (1) (limited to the case of dismissal of auditors) unless two-thirds or more of those present (or, if a higher ratio is specified in the articles of incorporation, that ratio) approve the resolution.

(4) When an officer of a medical corporation as a foundation falls under any of the following, the officer may be dismissed by a resolution of the board of councillors:

(i) when the officer has violated or neglected their duties; or

(ii) when the officer is unable to properly perform their duties due to a mental or physical disorder.

(5) A medical corporation as a foundation may not adopt a resolution at a meeting of the board of councillors set forth in the preceding paragraph (limited to the case of dismissal of auditors) unless two-thirds or more of those present (or, if a higher ratio is specified in the act of endowment, that ratio) approve the resolution.

Article 46-5-3 (1) In the event a situation arises in which the number of officers is less than the number prescribed in this Act or the articles of incorporation or act of endowment, an officer who has retired due to expiration of the term of office or resignation is to continue to have the rights and obligations as an officer until a newly elected officer (including a person who is to perform the duties of a temporary officer set forth in the following paragraph) assumes office.

(2) In the case prescribed in the preceding paragraph, if there is a risk of damage

due to delay in the business of the medical corporation, the prefectural governor must appoint a person to perform the duties of a temporary officer at the request of an interested party or by the authority of the governor.

- (3) If more than one-fifth of positions of directors or auditors are vacant, the vacancy must be filled within one month.

Article 46-5-4 The provisions of Article 72 and Article 74 (excluding paragraph (4)) of the Act on General Incorporated Associations and General Incorporated Foundations apply mutatis mutandis to the election and dismissal of officers of a medical corporation as an association and a medical corporation as a foundation. In this case, the term "and the particulars listed in Article 38, paragraph (1), item (i)" in paragraph (3) of the same Article as applied mutatis mutandis to the election and dismissal of officers of a medical corporation as an association is replaced with "and the date, time and place of the relevant general meeting of members", the term "general meeting of members" in Article 72 and Article 74, paragraphs (1) through (3) of the same Act as applied mutatis mutandis to the election and dismissal of officers of a medical corporation as a foundation is replaced with "meeting of the board of councillors", and the term "and the particulars listed in Article 38, paragraph (1), item (i)" in the same paragraphs is replaced with "and the date, time and place of the relevant meeting of the board of councillors".

Subsection 5 Directors

Article 46-6 (1) One of the directors of a medical corporation (excluding a medical corporation prescribed in the following paragraph) is the president, who is to be elected from among the directors who are physicians or dentists; provided, however, that in the case where approval has been obtained from the prefectural governor, the president may be elected from among the directors who are neither physicians nor dentists.

- (2) In the case of a medical corporation that has one director with approval under the proviso of Article 46-5, paragraph (1), the relevant director is deemed to be the president with regard to the application of the provisions of this Chapter (excluding paragraph (3) of the following Article).

Article 46-6-2 (1) The president has the authority to represent the medical corporation and to perform any and all judicial or extrajudicial acts concerning the business of the medical corporation.

- (2) The restrictions placed on the authority set forth in the preceding paragraph can not be asserted against a bona fide third party.
- (3) The provisions of Article 46-5-3, paragraphs (1) and (2) apply mutatis

mutandis to the case where the position of the president is vacant.

Article 46-6-3 A director who discovers that there is a fact that is likely to cause significant damage to the medical corporation must immediately report the relevant fact to the auditor.

Article 46-6-4 The provisions of Article 78, Article 80, Articles 82 through 84, Article 88 (excluding paragraph (2)) and Article 89 of the Act on General Incorporated Associations and General Incorporated Foundations apply mutatis mutandis to the directors of a medical corporation as an association and a medical corporation as a foundation. In this case, the term "general meeting of members" in Article 84, paragraph (1) of the same Act as applied mutatis mutandis to the relevant directors is replaced with "board of directors", the term "significant" in Article 88, paragraph (1) of the same Act is replaced with "irrecoverable", the term "articles of incorporation" in Article 83 of the same Act as applied mutatis mutandis to the directors of a medical corporation as a foundation is replaced with "act of endowment", the term "general meeting of members" is replaced with "meeting of the board of councillors", the term "members" in the heading of Article 88 of the same Act and paragraph (1) of the same Article is replaced with "councillors", the term "articles of incorporation" in the same paragraph and Article 89 of the same Act is replaced with "act of endowment", the term "general meeting of members" in the same Article is replaced with "meeting of the board of councillors", and any other necessary technical replacement of terms are to be prescribed by a Cabinet Order.

Subsection 6 Board of Directors

Article 46-7 (1) The board of directors is composed of all directors.

(2) The board of directors performs the following duties:

- (i) deciding the execution of business of the medical corporation;
- (ii) supervising the execution of the duties by the directors; and
- (iii) electing and dismissing the president.

(3) The board of directors may not delegate the following particulars and other important decisions on the execution of business to the directors:

- (i) disposal and acceptance of important assets;
- (ii) borrowing a large amount of money;
- (iii) selection and dismissal of employees with important roles;
- (iv) establishment, change and abolition of secondary offices and other important organizations;
- (v) in the case of a medical corporation as an association, exemption from

liability under Article 47, paragraph (1) based on the provisions of the articles of incorporation pursuant to the provisions of Article 114, paragraph (1) of the Act on General Incorporated Associations and General Incorporated Foundations as applied mutatis mutandis pursuant to Article 47-2, paragraph (1); or

(vi) in the case of a medical corporation as a foundation, exemption from liability under Article 47, paragraph (1) as applied mutatis mutandis pursuant to Article 47, paragraph (4) based on the provisions of the act of endowment pursuant to the provisions of Article 114, paragraph (1) of the Act on General Incorporated Associations and General Incorporated Foundations as applied mutatis mutandis pursuant to Article 47-2, paragraph (1).

Article 46-7-2 (1) The provisions of Articles 91 through 98 (excluding the items of Article 91, paragraph (1) and Article 92, paragraph (1)) of the Act on General Incorporated Associations and General Incorporated Foundations apply mutatis mutandis to the board of directors of a medical corporation as an association and a medical corporation as a foundation. In this case, the terms "the following directors" in Article 91, paragraph (1) of the same Act as applied mutatis mutandis to the relevant board of directors and "the directors listed in the items of the preceding paragraph" in paragraph (2) of the same Article is replaced with "the president", and the term "Ministry of Justice Order" in Article 95, paragraphs (3) and (4) and Article 97, paragraph (2), item (ii) of the same Act is replaced with "Order of the Ministry of Health, Labour and Welfare", while the term "articles of incorporation" in Article 91, paragraph (2), Article 93, paragraph (1), Article 94, paragraph (1), Article 95, paragraphs (1) and (3), and Article 96 of the same Act as applied mutatis mutandis to the board of directors of a medical corporation as a foundation is replaced with "act of endowment", the term "members, when necessary to exercise their rights, with the permission of the court" in Article 97, paragraph (2) of the same Act is replaced with "councillors, at any time during the business hours of the medical corporation as a foundation", and any other necessary technical replacement of terms are prescribed by a Cabinet Order.

(2) With regard to the permission set forth in Article 97, paragraphs (2) and (3) of the Act on General Incorporated Associations and General Incorporated Foundations as applied mutatis mutandis by replacing the terms under the preceding paragraph, the provisions of Article 287, paragraph (1), Article 288, Article 289 (limited to the part pertaining to item (i)), the main clause of Article 290, Article 291 (limited to the part pertaining to item (ii)), the main clause of Article 292, Article 294 and Article 295 of the same Act apply mutatis mutandis.

Subsection 7 Auditors

Article 46-8 The duties of the auditors are as follows:

- (i) to audit the business of the medical corporation;
- (ii) to audit the status of the property of the medical corporation;
- (iii) to prepare an audit report on the status of the business or property of the medical corporation for each fiscal year and submit it to the general meeting of members or the board of councillors and the board of directors within three months after the end of the relevant fiscal year;
- (iv) to report to the prefectural governor, the general meeting of members or the board of councillors, or the board of directors, if, as a result of the audit prescribed in item (i) or (ii), it is found that there is any wrongful act concerning the business or property of the medical corporation or any material fact in violation of laws and regulations, or the articles of incorporation or act of endowment;
- (v) in the case of an auditor of a medical corporation as an association, to convene a general meeting of members when it is necessary to make a report under the provisions of the preceding item;
- (vi) in the case of an auditor of a medical corporation as a foundation, to request the president to convene a meeting of the board of councillors when it is necessary to make a report under the provisions of item (iv);
- (vii) in the case of an auditor of a medical corporation as an association, to investigate proposals, documents and other items specified by an Order of the Ministry of Health, Labour and Welfare (referred to as "proposals, etc." in the following item) that the directors intend to submit to the general meeting of members. In this case, if it is found that there is a violation of laws and regulations or the articles of incorporation, or that there are extremely unjust particulars, to report the results of the investigation to the general meeting of members; and
- (viii) in the case of an auditor of a medical corporation as a foundation, to investigate proposals, etc. that the directors intend to submit to the board of councillors. In this case, if it is found that there is a violation of laws and regulations or the act of endowment, or that there are extremely unjust particulars, to report the results of the investigation to the board of councillors.

Article 46-8-2 (1) The auditor must attend the meeting of the board of directors and state their opinion when the auditor finds it necessary.

(2) In the case prescribed in item (iv) of the preceding Article, when the auditor finds it necessary, the auditor may request the directors (in the case prescribed

in the proviso of Article 93, paragraph (1) of the Act on General Incorporated Associations and General Incorporated Foundations as applied mutatis mutandis under Article 46-7-2, paragraph (1), the person with the authority to convene the meeting as prescribed in paragraph (2) of the same Article) to convene a meeting of the board of directors.

- (3) If a notice of convocation of a meeting of the board of directors is not issued within five days from the date of the request under the preceding paragraph setting the date of the meeting within two weeks from the date of the request, the auditor who made the request may convene a meeting of the board of directors.

Article 46-8-3 The provisions of Articles 103 through 106 of the Act on General Incorporated Associations and General Incorporated Foundations apply mutatis mutandis to the auditors of a medical corporation as an association and a medical corporation as a foundation. In this case, the term "articles of incorporation" in Article 103, paragraph (1) of the same Act as applied mutatis mutandis to the auditors of a medical corporation as a foundation is to be replaced with "act of endowment", the terms "articles of incorporation" and "general meeting of members" in Article 105, paragraphs (1) and (2) of the same Act is replaced with "act of endowment" and "meeting of the board of councillors", respectively, and the term "general meeting of members" in paragraph (3) of the same Article is replaced with "meeting of the board of councillors".

Subsection 8 Liability for Damages of Officers

Article 47 (1) A director or auditor of a medical corporation as an association, if they neglected their duties, are liable to compensate the relevant medical corporation for damages caused thereby.

- (2) When a director of a medical corporation as an association has conducted a transaction set forth in item (i) of Article 84, paragraph (1) of the Act on General Incorporated Associations and General Incorporated Foundations in violation of the same paragraph as applied mutatis mutandis by replacing the terms pursuant to Article 46-6-4, the amount of profit obtained by the director or a third party from the relevant transaction is presumed to be the amount of damage set forth in the preceding paragraph.
- (3) When a medical corporation as an association has suffered damage due to a transaction set forth in Article 84, paragraph (1) item (ii) or (iii) of the Act on General Incorporated Associations and General Incorporated Foundations as applied mutatis mutandis by replacing the terms pursuant to Article 46-6-4, any of the directors listed below is presumed to have neglected their duties:

- (i) a director set forth in Article 84, paragraph (1) of the Act on General Incorporated Associations and General Incorporated Foundations as applied mutatis mutandis by replacing the terms pursuant to Article 46-6-4;
 - (ii) a director who has decided that the medical corporation as an association is to conduct the relevant transaction; and
 - (iii) a director who voted in favor of the resolution for approval of the relevant transaction by the board of directors.
- (4) The provisions of the preceding three paragraphs apply mutatis mutandis to councillors or directors, or auditors of a medical corporation as a foundation.

Article 47-2 (1) The provisions of Articles 112 through 116 of the Act on General Incorporated Associations and General Incorporated Foundations apply mutatis mutandis to the liability of directors or auditors of a medical corporation as an association set forth in paragraph (1) of the preceding Article and the liability of councillors or directors or auditors of a medical corporation as a foundation set forth in paragraph (1) of the same Article as applied mutatis mutandis pursuant to paragraph (4) of the same Article. In this case, the term "Ministry of Justice Order" in Article 113, paragraph (1) item (ii) and paragraph (4) of the same Act as applied mutatis mutandis to the liability of these persons is replaced with "Order of the Ministry of Health, Labour and Welfare", the term "all members" in Article 112 of the same Act as applied mutatis mutandis to the liability of councillors or directors or auditors of a medical corporation as a foundation is replaced with "all councillors", the term "general meeting of members" in Article 113 of the same Act is replaced with "meeting of the board of councillors", the term "articles of incorporation" in the heading of Article 114 of the same Act and paragraphs (1) and (2) of the same Article is replaced with "act of endowment", the term "general meeting of members" in the same paragraph is replaced with "meeting of the board of councillors", the term "articles of incorporation" in paragraph (3) of the same Article is replaced with "act of endowment", the term "members" is replaced with "councillors", the terms "all members", "articles of incorporation" and "members" in paragraph (4) of the same Article is replaced with "all councillors", "act of endowment" and "councillors", respectively, the term "articles of incorporation" in paragraph (5) of the same Article and paragraphs (1) and (3) of Article 115 of the same Act is replaced with "act of endowment", the term "general meeting of members" in the same paragraph and paragraph (4) of the same Article is replaced with "meeting of the board of councillors", and any other necessary technical replacement of terms are prescribed by a Cabinet Order.

- (2) A medical corporation as an association may not adopt a resolution at a general meeting of members set forth in Article 113, paragraph (1) of the Act

on General Incorporated Associations and General Incorporated Foundations as applied mutatis mutandis by replacing the terms under the preceding paragraph, unless two-thirds or more (in the case where a higher ratio is specified in the articles of incorporation, that ratio) of those present approve the resolution.

- (3) A medical corporation as a foundation may not adopt a resolution at a meeting of the board of councillors set forth in Article 113, paragraph (1) of the Act on General Incorporated Associations and General Incorporated Foundations as applied mutatis mutandis by replacing the terms under paragraph (1), unless two-thirds or more (in the case where a higher ratio is specified in the act of endowment, that ratio) of those present approve the resolution.

Article 48 (1) When a councillor, director or auditor (hereinafter referred to as "officer, etc." in this paragraph, the following Article and Article 49-3) of a medical corporation acted in bad faith or were grossly negligent in performing their duties, the relevant officer, etc. is liable to compensate for any damage caused to a third party thereby.

- (2) The provisions of the preceding paragraph apply when a person listed in each of the following items commits an act specified in the respective items; provided, however, that this does not apply in the case where the person proves that they have exercised due care in committing the relevant act:

(i) director: Any of the following acts:

- (a) false statement about important particulars to be stated in documents to be prepared pursuant to the provisions of Article 51, paragraph (1);
- (b) false registration;
- (c) false public notice; and

(ii) auditor: False statement of material particulars to be stated in an audit report.

Article 49 If an officer, etc. is liable to compensate for damage caused to the medical corporation or a third party, and other officers, etc. are also liable to compensate for the relevant damage, they are to be jointly and severally liable.

Article 49-2 The provisions of Chapter VI, Section 2, Subsection 2 of the Act on General Incorporated Associations and General Incorporated Foundations apply mutatis mutandis to a medical corporation as an association. In this case, the term "Ministry of Justice Order" in Article 278, paragraph (1) of the same Act is replaced with "Order of the Ministry of Health, Labour and Welfare", and the term "members at the time of incorporation, directors at the time of incorporation, officers, etc. (meaning officers, etc. prescribed in Article 111,

paragraph (1); the same apply in paragraph (3)) or liquidators" is deemed to be replaced with "directors or auditors", the terms "members at the time of incorporation, directors at the time of incorporation, officers, etc. or liquidators" and " Ministry of Justice Order" in paragraph (3) of the same Article is replaced with "directors or auditors" and "Order of the Ministry of Health, Labour and Welfare", respectively, and the term "liquidators and these persons" in Article 280, paragraph (2) of the same Act is replaced with "directors".

Article 49-3 The provisions of Chapter VI, Section 2, Subsection 3 of the Act on General Incorporated Associations and General Incorporated Foundations apply mutatis mutandis to an action for dismissal of an officer, etc. of a medical corporation. In this case, the term "articles of incorporation" in Article 284 of the same Act is replaced with "articles of incorporation or act of endowment", and any other necessary technical replacement of terms are specified by a Cabinet Order.

Section 4 Accounting

Article 50 The accounting of a medical corporation is to be in accordance with accounting practices that are generally accepted as fair and appropriate, beyond the provisions of this Act and an Order of the Ministry of Health, Labour and Welfare under this Act.

Article 50-2 (1) A medical corporation must prepare accurate accounting books in a timely manner pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare.

(2) A medical corporation must preserve its accounting books and important materials concerning its business for ten years from the time of closure of the accounting books.

Article 51 (1) A medical corporation, within two months after the end of each fiscal year, must prepare a business report, an inventory of property, a balance sheet, a profit and loss statement, a report on the status of transactions with related business operators (meaning a person who has a special relationship with the medical corporation or its officers specified by an Order of the Ministry of Health, Labour and Welfare, such as the spouse of the president being its representative), and other documents specified by an Order of the Ministry of Health, Labour and Welfare (hereinafter referred to as "business report, etc.").

(2) A medical corporation (limited to those that meet the standards specified by

- an Order of the Ministry of Health, Labour and Welfare in consideration of the scale of their business activities and other circumstances) must prepare the balance sheet and profit and loss statement set forth in the preceding paragraph pursuant to an Order of the Ministry of Health, Labour and Welfare.
- (3) A medical corporation must preserve the balance sheet and profit and loss statement for ten years from the time of preparation of the relevant balance sheet and profit and loss statement.
 - (4) A medical corporation must have its business report, etc. audited by an auditor pursuant to an Order of the Ministry of Health, Labour and Welfare.
 - (5) A medical corporation set forth in paragraph (2) must have its inventory of property, balance sheet and profit and loss statement audited by a certified public accountant or an audit corporation, pursuant to an Order of the Ministry of Health, Labour and Welfare.
 - (6) A medical corporation must obtain the approval of the board of directors for the business report, etc. audited by the auditor or certified public accountant or audit corporation set forth in the preceding two paragraphs.

Article 51-2 (1) The directors of a medical corporation as an association must submit the business report, etc. approved under paragraph (6) of the preceding Article to the general meeting of members.

- (2) Upon the notice of convocation of the general meeting of members set forth in the preceding paragraph, the directors must provide the members with the business report, etc. approved under paragraph (6) of the preceding Article pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare.
- (3) The business report, etc. (limited to the balance sheet and profit and loss statement) submitted pursuant to the provisions of paragraph (1) must be approved by the general meeting of members.
- (4) The directors must report the contents of the business report, etc. (excluding the balance sheet and profit and loss statement) submitted pursuant to the provisions of paragraph (1) to the general meeting of members.
- (5) The provisions of the preceding paragraphs apply mutatis mutandis to a medical corporation as a foundation. In this case, the term "general meeting of members" in the preceding paragraphs is replaced with "meeting of the board of councillors", and the term "members" in paragraph (2) is replaced with "councillors".

Article 51-3 A medical corporation (limited to those that meet the standards specified by an Order of the Ministry of Health, Labour and Welfare in consideration of the scale of their business activities and other circumstances), pursuant to an Order of the Ministry of Health, Labour and Welfare, must

publicize the business report, etc. (limited to the balance sheet and profit and loss statement) approved under paragraph (3) of the preceding Article (including cases where it is applied mutatis mutandis by replacing the terms pursuant to paragraph (5) of the same Article).

Article 51-4 (1) A medical corporation (excluding those prescribed in the following paragraph) must keep the following documents at its principal office and make them available for inspection upon request from its members, councillors or creditors, except in cases where there are justifiable grounds, pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare:

- (i) the business report, etc.;
- (ii) the audit report set forth in Article 46-8, item (iii) (hereinafter referred to as "auditor's audit report");and
- (iii) the articles of incorporation or act of endowment.

(2) A social medical corporation and a medical corporation set forth in Article 51, paragraph (2) (excluding social medical corporations) must keep the following documents (in the case of documents listed in item (ii), limited to medical corporations set forth in Article 51, paragraph (2)) at its principal office and make them available for inspection upon request, except in cases where there are justifiable grounds, pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare:

- (i) documents listed in each item of the preceding paragraph; and
- (ii) audit reports of certified public accountants or audit corporations (hereinafter referred to as "audit report of a certified public accountant, etc.").

(3) A medical corporation must keep the business report, etc., the auditor's audit report and the audit report of a certified public accountant, etc. at its principal office for five years from one week prior to the date of the general meeting of members set forth in Article 51-2, paragraph (1) (in the case of a medical corporation as a foundation, the date of the meeting of the board of councillors set forth in paragraph (1) of the same Article as applied mutatis mutandis by replacing the terms pursuant to paragraph (5) of the same Article).

(4) The provisions of the preceding three paragraphs apply mutatis mutandis to the keeping and inspection of documents at the secondary office of a medical corporation. In this case, the term "documents" in paragraph (1) is replaced with "copies of documents", and the term "documents (limited to" in paragraph (2) is replaced with "copies of documents (limited to", the term "five years" in the preceding paragraph is replaced with "three years", the term "business report, etc." is replaced with "copies of business report, etc.", and the term "audit report" is replaced with "copies of audit report".

Article 52 (1) A medical corporation, pursuant to an Order of the Ministry of Health, Labour and Welfare, must submit the following documents to the prefectural governor within three months after the end of each fiscal year:

- (i) the business report, etc.;
- (ii) the auditor's audit report.; and
- (iii) in the case of a medical corporation set forth in Article 51, paragraph (2), the audit report of a certified public accountant, etc.

(2) The prefectural governor, pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare, must make the articles of incorporation, act of endowment, or documents submitted under the preceding paragraph available for inspection upon request.

Article 53 The fiscal year of a medical corporation is to begin on April 1 and end on March 31 of the following year; provided, however, that this does not apply when it is otherwise specified in the articles of incorporation or act of endowment.

Article 54 A medical corporation must not distribute dividends of surplus.

Section 5 Social Medical Corporation Bonds

Article 54-2 (1) A social medical corporation may issue social medical corporation bonds (monetary claims against a social medical corporation that arise as a result of allotments carried out pursuant to the provisions of the Companies Act (Act No. 86 of 2005) as applied mutatis mutandis pursuant to Article 54-7, and which are redeemed in accordance with the provisions on the particulars listed in each item of paragraph (1) of the following Article; the same apply hereinafter) in an amount not exceeding the limit decided at a general meeting or by the board of councillors pursuant to the provisions of the act of endowment, in order to contribute to the implementation of activities to ensure emergency medical care.

(2) When a social medical corporation has issued social medical corporation bonds pursuant to the preceding paragraph, it must not transfer funds equivalent to the proceeds from the issuance of the relevant social medical corporation bonds to a special account as provided for in Article 42-2, paragraph (3).

Article 54-3 (1) A social medical corporation, whenever it wishes to solicit subscribers for social medical corporation bonds it is issuing, must specify the following particulars regarding its social medical corporation bonds for subscription (meaning social medical corporation bonds that will be allocated

to the persons who subscribe for the relevant social medical corporation bonds in response to the relevant solicitation; the same applies hereinafter):

- (i) the use of funds provided by the issuance of social medical corporation bonds for subscription;
 - (ii) the total amount of social medical corporation bonds for subscription;
 - (iii) the amount of each social medical corporation bond for subscription;
 - (iv) the coupon rate for the social medical corporation bonds for subscription;
 - (v) the method and due date for the redemption of social medical corporation bonds for subscription;
 - (vi) the method and due date for payment of interest;
 - (vii) when social medical corporation bond certificates (meaning securities that represent the social medical corporation bonds; the same applies hereinafter) will be issued, a statement to that effect;
 - (viii) when it will be arranged that the bondholder of a social medical corporation bond (hereinafter referred to as a "social medical corporation bondholder") may not make a claim, in whole or in part, pursuant to the provisions of Article 698 of the Companies Act as applied mutatis mutandis pursuant to Article 54-7, a statement to that effect;
 - (ix) when it will be arranged that a social medical corporation bond administrator may carry out the act listed in Article 706, paragraph (1), item (ii) of the Companies Act as applied mutatis mutandis pursuant to Article 54-7, in the absence of a social medical corporation bondholders meeting resolution, a statement to that effect;
 - (x) the amount to be paid in for each social medical corporation bond for subscription (meaning the amount of monies to be paid in, in exchange for each social medical corporation bond for subscription), or the minimum amount thereof, or the method for calculating such amounts;
 - (xi) the due date for payment of the monies in exchange for the social medical corporation bonds for subscription;
 - (xii) when it will be arranged that the issuance of social medical corporation bonds for subscription will not be carried out in its entirety where the persons to whom the social medical corporation bonds for subscription will be allotted have not been established for the total amount of the social medical corporation bonds by a certain day, a statement to that effect and that certain day; and
 - (xiii) beyond what is listed in each of the preceding items, the particulars prescribed by an Order of the Ministry of Health, Labour and Welfare.
- (2) The particulars listed in item (ii) of the preceding paragraph and other particulars prescribed by an Order of the Ministry of Health, Labour and Welfare as important particulars that concern the solicitation of subscribers for social medical corporation bonds are decided by a majority of the directors.

Article 54-4 A social medical corporation must prepare its social medical corporation bond registry and enter or record the following particulars in that registry, without delay after the date social medical corporation bonds are issued:

- (i) the particulars listed in paragraph (1), item (iv) through (ix) of the preceding Article, and other particulars prescribed by an Order of the Ministry of Health, Labour and Welfare as particulars that specify the features of social medical corporation bonds (hereinafter referred to as a "class");
- (ii) the total amount of social medical corporation bonds and the amount of each social medical corporation bond for each class;
- (iii) the amount of monies paid in, in exchange for each social medical corporation bond and the date of payment;
- (iv) the name and address of social medical corporation bondholders (excluding social medical corporation bondholders of social medical corporation bearer bonds (social medical corporation bonds for which social medical corporation bond certificates are issued in bearer form));
- (v) the dates when the social medical corporation bondholders set forth in the preceding item acquired each social medical corporation bond;
- (vi) when social medical corporation bond certificates have been issued, the serial numbers of the social medical corporation bond certificates, the dates of their issuance, whether the social medical corporation bond certificates are registered or in bearer form, and the number of social medical corporation bearer bond certificates; and
- (vii) beyond what is listed in each of the preceding items, the particulars prescribed by an Order of the Ministry of Health, Labour and Welfare.

Article 54-5 A social medical corporation, where it issues social medical corporation bonds, must appoint a social medical corporation bond administrator, and entrust the receipt of payments, the preservation of rights of claim on behalf of the social medical corporation bondholders, and other administration of the social medical corporation bonds to that administrator; provided, however, that this does not apply where the amount of each social medical corporation bond is 100,000,000 yen or more, and in other cases prescribed by an Order of the Ministry of Health, Labour and Welfare as cases where it is unlikely that the protection of social medical corporation bondholders will be compromised.

Article 54-6 (1) Social medical corporation bondholders are to be the framework for social medical corporation bondholders meetings for each class of social

medical corporation bonds.

- (2) A social medical corporation bondholders meeting may adopt resolutions on particulars provided for in this Act or the Companies Act as applied mutatis mutandis pursuant to the following Article, and particulars related to the interests of the social medical corporation bondholders.

Article 54-7 Where a social medical corporation issues social medical corporation bonds, the provisions set forth in Article 677 through Article 680, Article 682, Article 683, Article 684 (excluding paragraph (4) and paragraph (5)), Article 685 through Article 701, Article 703 through Article 714, Article 717 through Article 742, Part VII, Chapter II, Section 7, Article 868, paragraph (4), Article 869, Article 870, paragraph (1) (limited to the parts pertaining to item (ii) and item (xii) through item (ix)), Article 871 (limited to the parts pertaining to item (ii)), Article 872 (limited to the parts pertaining to item (iv)), Article 873, Article 874 (limited to the parts pertaining to item (i) and item (iv)), Article 875, and Article 876 of the Companies Act apply mutatis mutandis to social medical corporation bonds, social medical corporation bonds for subscription, social medical corporation bond certificates, social medical corporation bondholders, social medical corporation bond administrators, social medical corporation bondholders meetings, and social medical corporation bond registers. Where this is the case, any necessary replacement of terms are prescribed by Cabinet Order.

Article 54-8 A social medical corporation bond is deemed to be a bond in regard to the application of the Secured Bonds Trust Act (Act No. 52 of 1905) and other laws and regulations as prescribed by Cabinet Order, pursuant to the provisions of a Cabinet Order.

Section 6 Changes to Articles of Incorporation and Act of Endowment

Article 54-9 (1) In order for a medical corporation as an association to change its articles of incorporation, a resolution of the general meeting of members must be adopted.

(2) In order for a medical corporation as a foundation to change its act of endowment, it must hear the opinion of the board of councillors in advance.

(3) Changes to the articles of incorporation or act of endowment (excluding those pertaining to particulars specified by an Order of the Ministry of Health, Labour and Welfare) must not take effect unless approved by the prefectural governor.

(4) In the case where an application for approval has been filed pursuant to the provisions of the preceding paragraph, the prefectural governor must decide on

the approval after examining the particulars prescribed in Article 45, paragraph (1) and whether the procedures for the change of the articles of incorporation or act of endowment are not in violation of laws and regulations or the articles of incorporation or act of endowment.

- (5) When a medical corporation has changed its articles of incorporation or act of endowment pertaining to the particulars specified by an Order of the Ministry of Health, Labour and Welfare as set forth in paragraph (3), it must notify the prefectural governor of the changed articles of incorporation or act of endowment without delay.
- (6) The provisions of Article 44, paragraph (5) apply mutatis mutandis to the case where provisions concerning the person to whom the residual property is to belong are established or changed as a result of changing the articles of incorporation or act of endowment.

Section 7 Dissolution and Liquidation

Article 55 (1) An association of medical corporations is to be dissolved on the following grounds:

- (i) occurrence of grounds for dissolution that are specified by the articles of incorporation;
 - (ii) the inability to successfully carry out the intended operations;
 - (iii) a general meeting resolution;
 - (iv) merger with another medical corporation (limited to the case where the relevant medical corporation ceases to exist as a result of the merger; the same applies in paragraph (1) of the following Article and Article 56-3);
 - (v) a lack of members;
 - (vi) a decision to commence bankruptcy proceedings; or
 - (vii) rescission of authorization for establishment.
- (2) An association of medical corporations may not adopt a general meeting resolution as set forth in item (iii) of the preceding paragraph without the support of a three-quarters majority of all members; provided, however, that this does not apply when it is otherwise specified in the articles of incorporation.
- (3) A medical corporation foundation is to be dissolved for the following reasons:
- (i) occurrence of reasons for dissolution that are specified by the act of endowment; or
 - (ii) reasons listed in paragraph (1), item (ii), (iv), (vi), or (vii).
- (4) Where a medical corporation can no longer perform on its obligations by means of its assets, a court, in response to a petition from the directors or obligees or sua sponte, is to issue a decision for the commencement of bankruptcy procedures.

- (5) In the case prescribed in the preceding paragraph, the directors must immediately file a petition for the commencement of bankruptcy procedures.
- (6) Dissolution resulting from the grounds listed in paragraph (1), item (ii) or (iii) must not be effective without the authorization of the prefectural governor.
- (7) In granting or refusing the authorization set forth in the preceding paragraph, a prefectural governor must hear the opinions of the Prefectural Council on Medical Service Facilities in advance.
- (8) A liquidator, where a medical corporation has been dissolved based on the grounds listed in paragraph (1), items (i) or (v), or paragraph (3), item (i), must notify the prefectural governor to that effect.

Article 56 (1) The residual assets of a dissolved medical corporation are to belong to persons to whom it should belong pursuant to the provisions of the articles of incorporation or act of endowment, except in the case of dissolution due to a decision to merge or to commence bankruptcy proceedings.

(2) Assets not disposed of pursuant to the provisions of the preceding paragraph is to belong to the national treasury.

Article 56-2 A dissolved medical corporation is deemed to remain in existence until the liquidation is completed, to the extent of the purpose of liquidation.

Article 56-3 When a medical corporation has been dissolved, a director becomes its liquidator, except in the case of dissolution due to a decision to merge or to commence bankruptcy proceedings; provided, however, that this does not apply when it is otherwise specified in the articles of incorporation or act of endowment, or when a person other than a director is appointed at a general meeting.

Article 56-4 In the absence of a liquidator pursuant to the provisions of the preceding Article or when damages are likely to be incurred due to the absence of a liquidator, a court may appoint the liquidator in response to a petition by an interested party or the public prosecutor, or sua sponte.

Article 56-5 When there are material grounds for doing so, a court may dismiss a liquidator in response to a petition by an interested party or the public prosecutor, or sua sponte.

Article 56-6 A liquidator appointed during liquidation must notify the prefectural governor of their name and address.

Article 56-7 (1) A liquidator is to perform the following duties:

- (i) conclude current business;
 - (ii) collect debts and the performance of obligations; and
 - (iii) deliver residual assets.
- (2) A liquidator may engage in any and all acts that are necessary to the performance of the duties listed in each of the items of the preceding paragraph.

Article 56-8 (1) A liquidator is to provide public notice on at least three occasions, requiring obligees to submit their claims within a stated period, within two months of the date that the relevant liquidator takes office. In this case, the period for filing claims must not be less than two months.

- (2) The public notice set forth in the preceding paragraph must note that if an obligee fails to submit their claim within the stated period, their claim will be excluded from the liquidation proceedings; provided, however, that the liquidator may not exclude any known obligee.
- (3) The liquidator must notify each known obligee separately of the requirement for them to submit their claim.
- (4) The public notice set forth in paragraph (1) is to be carried out via publication in the Official Gazette.

Article 56-9 A obligee who submits their claim after the expiry of the period set forth in paragraph (1) of the preceding Article may claim only the assets which, after all debts of the medical corporation have been fully paid, have not yet been delivered to persons with vested rights.

Article 56-10 (1) When it has become clear that the assets of a medical corporation in liquidation are insufficient to perform on its obligations, the liquidator must immediately file to commence bankruptcy proceedings and provide public notice to that effect.

- (2) Where a medical corporation in liquidation is subject to a ruling for the commencement of bankruptcy proceedings, the liquidator is deemed to have completed their duties when the administration of the relevant proceedings has been transferred to the bankruptcy trustee.
- (3) In the case provided for in the preceding paragraph, when a medical corporation in liquidation has already made payment to an obligee or delivered assets to persons with vested interests, the bankruptcy trustee may retrieve such monies or assets.
- (4) Public notice pursuant to the provisions of paragraph (1) is carried out via publication in the Official Gazette.

Article 56-11 When liquidation proceedings are completed, the liquidator must

notify the prefectural governor to that effect.

Article 56-12 (1) The dissolution and liquidation of a medical corporation is to be subject to court supervision.

(2) A court may conduct the necessary investigations for the supervision set forth in the preceding paragraph at any time, sua sponte.

(3) A court supervising the dissolution and liquidation of a medical corporation may seek the opinion of the prefectural governor, or may commission an investigation thereby.

(4) The prefectural governor provided for in the preceding paragraph may state their opinion to the court provided for in the same paragraph.

Article 56-13 Cases related to the supervision of the dissolution and liquidation of a medical corporation or to the liquidator is subject to the jurisdiction of the district court with jurisdiction over the location of the principal office thereof.

Article 56-14 No appeal may be entered against a judicial decision on the appointment of the liquidators.

Article 56-15 A court, where a liquidator has been appointed pursuant to the provisions of Article 56-4, may specify the amount in fees to be paid to the relevant liquidator by the medical corporation. In this case, the court must hear the statements of the relevant liquidator and the auditor.

Article 56-16 (1) A court may appoint an inspector so as to have them carry out the necessary investigations for the supervision of the dissolution and liquidation of a medical corporation.

(2) The provisions of the preceding two Articles apply mutatis mutandis to where the court has appointed an inspector as prescribed in the preceding paragraph. In this case, the term "liquidator and the auditor" in the preceding Article is replaced with "medical corporation and the inspector".

Section 8 Merger and Split

Subsection 1 Merger

Division 1 General Rules

Article 57 A medical corporation may merge with another medical corporation. In this case, the medical corporation to be merged must conclude a merger agreement.

Division 2 Absorption-Type Merger

Article 58 When a medical corporation conducts an absorption-type merger (meaning a merger by a medical corporation with another medical corporation whereby all of the rights and obligations of the medical corporation to be dissolved as a result of the merger are to be succeeded to by the medical corporation to survive the merger; hereinafter the same applies in this Division), the absorption-type merger agreement must stipulate the names and locations of the principal offices of the medical corporation that will survive the absorption-type merger (hereinafter referred to as the "surviving medical corporation in the absorption-type merger" in this Division) and the medical corporation that will dissolve as a result of the absorption-type merger (hereinafter referred to as the "dissolving medical corporation in the absorption-type merger" in this Division), and other particulars specified by an Order of the Ministry of Health, Labour and Welfare.

Article 58-2 (1) A medical corporation as an association must obtain the consent of all members of the relevant medical corporation for an absorption-type merger agreement.

(2) A medical corporation as a foundation may conduct an absorption-type merger only when its act of endowment provides that it may do so.

(3) A medical corporation as a foundation must obtain the consent of two-thirds or more of its directors for an absorption-type merger agreement, unless otherwise provided for in its act of endowment.

(4) An absorption-type merger must not take effect unless approved by the prefectural governor (meaning the prefectural governor of the location of the principal office of the surviving medical corporation in the absorption-type merger).

(5) The provisions of Article 55, paragraph (7) apply mutatis mutandis to the approval set forth in the preceding paragraph.

Article 58-3 (1) When a medical corporation has obtained the approval set forth in paragraph (4) of the preceding Article, the corporation must prepare an inventory of property and a balance sheet within two weeks from the date of the notice of the approval.

(2) Until the merger pertaining to an absorption-type merger approved under paragraph (4) of the preceding Article is registered, a medical corporation must keep the inventory of property and balance sheet prepared pursuant to the provisions of the preceding paragraph at its principal office and make them available for inspection upon request from its creditors, pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare.

Article 58-4 (1) A medical corporation, within the period set forth in paragraph (1) of the preceding Article, is to make a public notice to its creditors to the effect that any objection, if any, should be stated within a certain period of time, and must notify each known creditor separately. However, such period is not to be less than two months.

(2) If creditors do not object to the absorption-type merger within the period set forth in the preceding paragraph, it is to be deemed that they have approved the absorption-type merger.

(3) When a creditor has made an objection, the medical corporation must pay or provide reasonable security to the creditor or place reasonable property with a trust company, etc. (meaning a trust company and a financial institution (meaning a financial institution authorized under Article 1, paragraph (1) of the Act on Engagement in Trust Business by Financial Institutions (Act No. 43 of 1943) engaged in trust business; the same applies hereinafter) for the purpose of having the creditor receive payment; provided, however, that this does not apply when the absorption-type merger is unlikely to harm the creditor.

Article 58-5 The surviving medical corporation in the absorption-type merger is to succeed to the rights and obligations of the dissolving medical corporation in the absorption-type merger (including the rights and obligations that the relevant medical corporation has based on the permission or other disposition of the administrative agency with respect to the business it conducts).

Article 58-6 An absorption-type merger becomes effective when the surviving medical corporation in the absorption-type merger registers the merger at the location of its principal office pursuant to the provisions of a Cabinet Order.

Division 3 Consolidation-Type Merger

Article 59 When two or more medical corporations conduct a consolidation-type merger (meaning a merger between two or more medical corporations in which all of the rights and obligations of the medical corporation to be dissolved as a result of the merger must be succeeded to by the medical corporation to be established as a result of the merger; hereinafter the same applies in this Division), the following information are to be stipulated in the consolidation-type merger agreement:

(i) the name and location of the principal office of the medical corporation to be dissolved as a result of the consolidation-type merger (hereinafter referred to as the "medical corporation dissolved in the consolidation-type merger" in this Division);

- (ii) the purpose, name and location of the principal office of the medical corporation to be established as a result of the consolidation-type merger (hereinafter referred to as the "medical corporation established in the consolidation-type merger" in this Division);
- (iii) particulars specified in the articles of incorporation or act of endowment of the medical corporation established in the consolidation-type merger; and
- (iv) beyond the particulars listed in the preceding three items, particulars specified by an Order of the Ministry of Health, Labour and Welfare.

Article 59-2 The provisions of Article 58-2 through Article 58-4 apply mutatis mutandis to the case where a medical corporation conducts a consolidation-type merger. In this case, the term "absorption-type merger agreement" in Article 58-2, paragraphs (1) and (3) is replaced with "consolidation-type merger agreement", and the term "surviving medical corporation in the absorption-type merger" in paragraph (4) of the same Article is replaced with "medical corporation established in the consolidation-type merger".

Article 59-3 A medical corporation established in the consolidation-type merger is to succeed to the rights and obligations of the medical corporation dissolved in the consolidation-type merger (including the rights and obligations that the relevant medical corporation has based on the permission or other disposition of the administrative agency with respect to the business it conducts).

Article 59-4 A consolidation-type merger is to become effective when the medical corporation established in the consolidation-type merger registers the merger at the location of its principal office pursuant to the provisions of a Cabinet Order.

Article 59-5 The provisions of Section 2 (excluding Article 44, paragraphs (2), (4) and (5) and Article 46, paragraph (2)) does not apply to the establishment of a medical corporation established in the consolidation-type merger.

Subsection 2 Split

Division 1 Absorption-Type Split

Article 60 A medical corporation (excluding social medical corporations and those specified by an Order of the Ministry of Health, Labour and Welfare; hereinafter the same applies in this Subsection) may conduct an absorption-type split (meaning that all or part of the rights and obligations which a medical corporation has with respect to its business are succeeded to by another medical corporation after the split; hereinafter the same applies in this

Division). In this case, an absorption-type split agreement is concluded with the medical corporation that succeeds to all or part of the rights and obligations (hereinafter referred to as the "succeeding medical corporation in the absorption-type split" in this Division) held by the relevant medical corporation with respect to its business.

Article 60-2 When a medical corporation conducts an absorption-type split, the following particulars must be stipulated in the absorption-type split agreement:

- (i) the names and locations of the principal offices of the medical corporation that conducts the absorption-type split (hereinafter referred to as the "medical corporation conducting the absorption-type split" in this Division) and the succeeding medical corporation in the absorption-type split;
- (ii) assets, liabilities, employment contracts and other particulars concerning rights and obligations to be succeeded to by the succeeding medical corporation in the absorption-type split from the medical corporation conducting the absorption-type split as a result of the absorption-type split; and
- (iii) beyond the particulars listed in the preceding two items, particulars specified by an Order of the Ministry of Health, Labour and Welfare.

Article 60-3 (1) A medical corporation as an association must obtain the consent of all members of the relevant medical corporation for an absorption-type split agreement.

(2) A medical corporation as a foundation may conduct an absorption-type split only when its act of endowment provides that it may do so.

(3) A medical corporation as a foundation must obtain the consent of two-thirds or more of its directors for an absorption-type split agreement, unless otherwise provided for in its act of endowment.

(4) An absorption-type split is not take effect unless approved by the prefectural governor (in the case where the principal offices of the medical corporation conducting the absorption-type split and the succeeding medical corporation in the absorption-type split are located within the area of two or more prefectures, the governors of all the prefectures where the principal offices of the relevant medical corporation conducting the absorption-type split and the relevant succeeding medical corporation in the absorption-type split are located).

(5) The provisions of Article 55, paragraph (7) apply mutatis mutandis to the approval set forth in the preceding paragraph.

Article 60-4 (1) When a medical corporation has obtained the approval set forth in paragraph (4) of the preceding Article, it must prepare an inventory of

property and a balance sheet within two weeks from the date of the notice of the approval.

- (2) Until the split pertaining to an absorption-type split approved under paragraph (4) of the preceding Article is registered, a medical corporation must keep the inventory of property and balance sheet prepared pursuant to the provisions of the preceding paragraph at its principal office and make them available for inspection upon request from its creditors, pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare.

Article 60-5 (1) A medical corporation, within the period set forth in paragraph (1) of the preceding Article, is to make a public notice to its creditors to the effect that any objection, if any, should be stated within a certain period of time, and must notify each known creditor separately. However, such period is not to be less than two months.

- (2) If creditors do not object to the absorption-type split within the period set forth in the preceding paragraph, it is deemed that they have approved the absorption-type split.
- (3) When a creditor has made an objection, the medical corporation is to pay or provide reasonable security to the creditor or place reasonable property with a trust company, etc. for the purpose of having the creditor receive payment; provided, however, that this does not apply when the absorption-type split is unlikely to harm the creditor.

Article 60-6 (1) The succeeding medical corporation in the absorption-type split, in accordance with the provisions of the absorption-type split agreement, is to succeed to the rights and obligations of the medical corporation conducting the absorption-type split (including the rights and obligations the relevant medical corporation holds with respect to the facilities used for its business under the permission and other dispositions prescribed in this Act).

- (2) Notwithstanding the provisions of the preceding paragraph, any creditor of the medical corporation conducting the absorption-type split who has not received the separate notification set forth in paragraph (1) of the preceding Article may demand performance of the obligation from the medical corporation conducting the absorption-type split within the limit of the value of the property that the medical corporation conducting the absorption-type split possessed on the date of registration of the split set forth in the following Article, even if the absorption-type split agreement stipulates that the creditor may not demand performance of the relevant obligation from the medical corporation conducting the absorption-type split after the absorption-type split.
- (3) Notwithstanding the provisions of paragraph (1), any creditor of the medical corporation conducting the absorption-type split who has not received the

separate notification set forth in paragraph (1) of the preceding Article may demand performance of the obligation from the succeeding medical corporation in the absorption-type split within the limit of the value of the property that it has succeeded to, even if the absorption-type split agreement stipulates that the creditor may not demand performance of the relevant obligation from the succeeding medical corporation in the absorption-type split after the absorption-type split.

Article 60-7 An absorption-type split becomes effective when the succeeding medical corporation in the absorption-type split registers the split at the location of its principal office pursuant to the provisions of a Cabinet Order.

Division 2 Incorporation-Type Split

Article 61 (1) One or two or more medical corporations may conduct an incorporation-type split (meaning that all or part of the rights and obligations which one or two or more medical corporations have with respect to their business are succeeded to by a medical corporation to be established through a split; the same applies hereinafter in this Division). In this case, an incorporation-type split plan must be prepared.

(2) In the case where two or more medical corporations jointly conduct an incorporation-type split, the relevant two or more medical corporations must jointly prepare an incorporation-type split plan.

Article 61-2 When one or two or more medical corporations conduct an incorporation-type split, the following particulars must be specified in the incorporation-type split plan:

- (i) the purpose, name and location of the principal office of the medical corporation to be established as a result of the incorporation-type split (hereinafter referred to as the "medical corporation established in the incorporation-type split" in this Division);
- (ii) particulars specified in the articles of incorporation or act of endowment of the medical corporation established in the incorporation-type split;
- (iii) assets, liabilities, employment contracts and other particulars concerning rights and obligations to be succeeded to by the medical corporation established in the incorporation-type split from the medical corporation that conducts the incorporation-type split (hereinafter referred to as the "medical corporation conducting the incorporation-type split" in this Division) as a result of the incorporation-type split; and
- (iv) beyond the particulars listed in the preceding three items, particulars specified by an Order of the Ministry of Health, Labour and Welfare.

Article 61-3 The provisions of Article 60-3 through Article 60-5 apply mutatis mutandis to the case where a medical corporation conducts an incorporation-type split. In this case, the term "absorption-type split agreement" in Article 60-3, paragraphs (1) and (3) is to be replaced with "incorporation-type split plan", the term "medical corporation conducting the absorption-type split" in paragraph (4) of the same Article is to be replaced with "medical corporation conducting the incorporation-type split", and the term "succeeding medical corporation in the absorption-type split" is to be replaced with "medical corporation established in the incorporation-type split".

Article 61-4 (1) The medical corporation established in the incorporation-type split, in accordance with the provisions of the incorporation-type split plan, is to succeed to the rights and obligations of the medical corporation conducting the incorporation-type split (including the rights and obligations the relevant medical corporation holds with respect to the facilities used for its business under the permission and other dispositions prescribed in this Act).

(2) Notwithstanding the provisions of the preceding paragraph, any creditor of the medical corporation conducting the incorporation-type split who has not received the separate notification set forth in Article 60-5, paragraph (1) as applied mutatis mutandis pursuant to the preceding Article may demand performance of the obligation from the medical corporation conducting the incorporation-type split within the limit of the value of the property that the medical corporation conducting the incorporation-type split possessed on the date of registration of the split set forth in the following Article, even if the incorporation-type split plan stipulates that the creditor may not demand performance of the relevant obligation from the medical corporation conducting the incorporation-type split after the incorporation-type split.

(3) Notwithstanding the provisions of paragraph (1), any creditor of the medical corporation conducting the incorporation-type split who has not received the separate notification set forth in Article 60-5, paragraph (1) as applied mutatis mutandis pursuant to the preceding Article may demand performance of the obligation from the medical corporation established in the incorporation-type split within the limit of the value of the property that it has succeeded to, even if the incorporation-type split plan stipulates that the creditor may not demand performance of the relevant obligation from the medical corporation established in the incorporation-type split after the incorporation-type split.

Article 61-5 An incorporation-type split becomes effective when the medical corporation established in the incorporation-type split registers the split at the location of its principal office pursuant to the provisions of a Cabinet Order.

Article 61-6 The provisions of Section 2 (excluding Article 44, paragraphs (2), (4) and (5) and Article 46, paragraph (2)) does not apply to the establishment of a medical corporation established in the incorporation-type split.

Division 3 Miscellaneous Provisions

Article 62 The provisions of Article 2 through Article 8 (excluding the items of Article 2, paragraph (3) and the items of Article 4, paragraph (3)) of the Act on the Succession to Labor Contracts upon Company Split (Act No. 103 of 2000) and Article 5, paragraph (1) of the Supplementary Provisions of the Act for Partial Revision of the Commercial Code (Act No. 90 of 2000) apply mutatis mutandis to the case where a medical corporation conducts a split pursuant to the provisions of this Subsection. In this case, the term "succeeding company, etc." in Article 2, paragraphs (1) and (2) of the Act on the Succession to Labor Contracts upon Company Split is replaced with "succeeding medical corporation, etc.", the term "split company" in the same paragraph is replaced with "split medical corporation", the term "according to the cases listed in the following items, specified in the relevant items" in paragraph (3) of the same Article is replaced with "two weeks from the day on which a notice of approval under Article 60-3, paragraph (4) of the Medical Care Act (Act No. 205 of 1948) or a notice of approval under Article 60-3, paragraph (4) of the same Act as applied mutatis mutandis by replacing the terms pursuant to Article 61-3 of the same Act is given", the term "split company" in Article 3 through Article 8 (excluding Article 4, paragraph (3)) of the same Act is to be replaced with "split medical corporation", the term "succeeding company, etc." is to be replaced with "succeeding medical corporation, etc.", the term "according to the cases listed in the following items, in the relevant items" in Article 4, paragraph (3) of the same Act is replaced with "the split medical corporation, on the day until the day before the day of registration of the split pertaining to an absorption-type split approved under Article 60-3, paragraph (4) of the Medical Care Act or an incorporation-type split approved under Article 60-3, paragraph (4) of the same Act as applied mutatis mutandis by replacing the terms pursuant to Article 61-3 of the same Act", and the necessary technical replacement of terms is specified by a Cabinet Order.

Article 62-2 The provisions of Article 398-9, paragraphs (3) through (5) and Article 398-10, paragraphs (1) and (2) of the Civil Code (Act No. 89 of 1896) apply mutatis mutandis to the case where a medical corporation conducts a split pursuant to the provisions of this Subsection. In this case, the term "the preceding two paragraphs" in Article 398-9, paragraph (3) of the same Act is

replaced with "paragraph (1) or (2) of the following Article as applied mutatis mutandis pursuant to Article 62-2 of the Medical Care Act (Act No. 205 of 1948)", and the term "the preceding paragraph" is replaced with "the same paragraph".

Subsection 3 Miscellaneous Provisions

Article 62-3 Beyond what is specifically provided for in this Section, necessary particulars concerning mergers and splits of medical corporations is specified by a Cabinet Order.

Section 9 Supervision

Article 63 (1) When a prefectural governor suspects the operations or accounting of a medical corporation to be in violation of laws and regulations, a disposition by the prefectural governor based on laws and regulations, the articles of incorporation, or the act of endowment, or suspects its administration to be significantly inappropriate, the prefectural governor may request the relevant medical corporation to report on the status of its operations or accounting, or may have the relevant officials enter its offices and inspect the status of its operations or accounting.

(2) The provisions set forth in Article 6-8, paragraphs (3) and (4) apply mutatis mutandis to any entry and inspection pursuant to the provisions of the preceding paragraph.

Article 64 (1) When a prefectural governor finds the operations or accounting of a medical corporation to be in violation of laws and regulations, a disposition of the prefectural governor based on laws and regulations, the articles of incorporation, or the act of endowment, or finds its administration to be significantly inappropriate, the prefectural governor may order the relevant medical corporation to take any necessary measures by a set deadline.

(2) When a medical corporation fails to abide by an order as set forth in the preceding paragraph, the prefectural governor may order the relevant medical corporation to suspend all or a part of its operations for a period that the prefectural governor prescribes, or may recommend the dismissal of its officers.

(3) In ordering the suspension of operations or recommending the dismissal of officers pursuant to the provisions of the preceding paragraph, the prefectural governor must hear the opinions of the Prefectural Council on Medical Service Facilities in advance.

Article 64-2 (1) A prefectural governor, where a social medical corporation falls

under any of the following items, may rescind the social medical corporation's authorization, or order all or a part of the profit-making activities to be suspended for a period that the prefectural governor prescribes:

- (i) when the requirements listed in each item of Article 42-2, paragraph (1) are no longer being met;
 - (ii) when operations other than those stipulated in the articles of incorporation or act of endowment have been carried out;
 - (iii) when profits from the profit-making activities are not set aside for the administration of a hospital, clinic, long-term care health facility, or integrated facility for medical and long-term care established by the relevant social medical corporation;
 - (iv) when the continuation of profit-making activities is found to be a hindrance to the operation of a hospital, clinic, long-term care health facility, or integrated facility for medical and long-term care established by a social medical corporation (including a hospital, etc. managed by a designated administrator);
 - (v) when authorization as set forth in Article 42-2, paragraph (1) has been received by unlawful means; or
 - (vi) when the social medical corporation has violated this Act, any order based on this Act, or any disposition based on these.
- (2) In rescinding authorization pursuant to the provisions of the preceding paragraph, the prefectural governor must hear the opinions of the Prefectural Council on Medical Service Facilities in advance.

Article 65 A prefectural governor, when a medical corporation fails to establish or re-open a hospital, clinic, long-term care health facility, or integrated facility for medical and long-term care without justifiable grounds, within one year of the establishment of the relevant medical corporation or within one year of the suspension or abolition of all of its hospitals, clinics, long-term care health facilities, and integrated facilities for medical and long-term care, may rescind its authorization for establishment.

Article 66 (1) A prefectural governor, where a medical corporation has violated the provisions of laws and regulations or an order by the prefectural governor based on the provisions of laws and regulations, may rescind its authorization for establishment, provided that the purpose of supervision cannot be achieved by any other means.

- (2) In rescinding authorization for establishment pursuant to the provisions of the preceding paragraph, the prefectural governor must hear the opinions of the Prefectural Council on Medical Service Facilities in advance.

Article 66-2 When the Minister of Health, Labour and Welfare finds there to be a risk of significant harm to the public interest due to a failure to undertake disposition pursuant to the provisions of Article 64, paragraphs (1) and (2), Article 64-2, paragraph (1), Article 65, or paragraph (1) of the preceding Article, the minister may instruct the prefectural governor to undertake disposition pursuant to the relevant provisions.

Article 66-3 The prefectural governor concerned (meaning the prefectural governor of the location of a hospital, clinic, long-term care health facility or integrated facility for medical and long-term care established by a medical corporation, who is not the prefectural governor of the location of the principal office of the relevant medical corporation) may, when the prefectural governor finds it necessary, express the opinion to the prefectural governor of the location of the principal office of the relevant medical corporation that appropriate measures should be taken against the relevant medical corporation.

Article 67 (1) In issuing a disposition refusing authorization pursuant to the provisions of Article 44, paragraph (1), Article 55, paragraph (6), Article 58-2, paragraph (4) (including the cases where it is applied mutatis mutandis by replacing the terms pursuant to Article 59-2), or Article 60-3, paragraph (4) (including the cases where it is applied mutatis mutandis by replacing the terms pursuant to Article 61-3) or recommending the dismissal of an officer pursuant to the provisions of Article 64, paragraph (2), the prefectural governor is to grant the person named in the relevant disposition or the party under the relevant recommendation the opportunity to give an explanation to a designated official or to another party. In this case, the prefectural governor must give written notice in advance to the person named in the relevant ruling or the party under the relevant recommendation of the date and time and location of the explanation and the grounds for the relevant disposition or the relevant recommendation.

(2) A person who receives a notice as set forth in the preceding paragraph may have a representative appear, and may submit their own supporting evidence.

(3) A person who has given a hearing to an explanation pursuant to the provisions of paragraph (1) must create and retain a hearing record, prepare a written report, and state their opinion to the prefectural governor concerning whether the relevant disposition or recommendation is necessary.

Article 68 The provisions set forth in Article 4, Article 158, and Article 164 of the Act on General Incorporated Associations and General Incorporated Foundations, and Article 662, Article 664, Article 868, paragraph (1), Article 871, Article 874 (limited to parts pertaining to item (i)), Article 875, and

Article 876 of the Companies Act apply mutatis mutandis to medical corporations. In this case, the term "distribute its assets to its partners" in Article 664 of the Companies Act is replaced with "assign its assets to persons with vested interests in residual assets or to the national treasury", and the term "head office" in Article 868, paragraph (1) of the same Act is replaced with "principal office".

Article 69 Beyond what is specifically provided for in this Chapter, particulars necessary for the supervision of medical corporations is specified by a Cabinet Order.

Chapter VII Regional Medical Coordination Promotion Corporation

Section 1 Approval

Article 70 (1) The following corporations (excluding profit-oriented corporations; hereinafter referred to as "participating corporations" in this Chapter), and general incorporated associations that have members specified by an Order of the Ministry of Health, Labour and Welfare as persons necessary for efficiently providing high-quality and appropriate medical care in the region and have policies in place for promoting coordination of operations (hereinafter referred to as the "medical coordination promotion policy" in this Chapter) pertaining to a hospital, clinic, long-term care health facility, or integrated facility for medical and long-term care (hereinafter referred to as "hospital, etc." in this Chapter) with the purpose of performing medical coordination promotion operations may obtain approval from the governor of the prefecture to which the area to promote the relevant coordination specified in the articles of incorporation belongs (hereinafter referred to as "medical coordination promotion area") (in the case where the relevant medical coordination promotion area extends over two or more prefectures, any one of these prefectures):

- (i) a corporation that establishes a hospital, etc. in the medical coordination promotion area; or
- (ii) a corporation that establishes or manages in the medical coordination promotion area a facility or office related to nursing care business (meaning business that provides welfare services or health and medical services to persons with physical or mental disabilities that hinder them from performing daily activities, including care for bathing, excretion, meals, etc., functional training, nursing care and medical treatment management, and other services, to enable them to lead self-reliant daily lives according to their abilities) and other businesses that contribute to the establishment of a community-based integrated care system (referring to the community-based

integrated care system prescribed in Article 2, paragraph (1) of the Act on Promotion of Comprehensive Securing of Medical Care and Nursing Care in the Region; the same applies in Article 70-7) (hereinafter referred to as "nursing care business, etc." in this Chapter).

- (2) The medical coordination promotion operations set forth in the preceding paragraph means the following operations and other operations performed for the purpose of promoting coordination of operations pertaining to a hospital, etc. in accordance with the medical coordination promotion policy:
- (i) training to improve the qualities of medical care professionals;
 - (ii) supplying medicines, medical equipment and other supplies necessary for operations pertaining to a hospital, etc.; and
 - (iii) fund lending and other support specified by an Order of the Ministry of Health, Labour and Welfare as support for raising funds necessary for a participating corporation to perform operations pertaining to a hospital, etc.

Article 70-2 (1) A general incorporated association that intends to obtain the approval set forth in paragraph (1) of the preceding Article (hereinafter referred to as "approval for medical coordination promotion" in this Chapter), pursuant to the provisions of a Cabinet Order, must apply to the prefectural governor with a medical coordination promotion policy.

- (2) The medical coordination promotion policy must contain the following particulars:
- (i) the medical coordination promotion area;
 - (ii) particulars concerning the sharing of functions and the coordination of operations among hospitals, etc. established by the participating corporations (referred to as "participating hospitals, etc." in paragraph (4) and Article 70-11) in the medical coordination promotion area;
 - (iii) particulars concerning the targets of the particulars listed in the preceding item; and
 - (iv) other particulars specified by an Order of the Ministry of Health, Labour and Welfare.
- (3) A medical coordination promotion area is established by taking into consideration the vision area specified in the medical care plan of the prefecture to which the relevant medical coordination promotion area belongs.
- (4) Beyond the particulars listed in each item of paragraph (2), the medical coordination promotion policy may contain particulars concerning the coordination of operations among participating hospitals, etc. and participating nursing care facilities, etc. (referring to facilities or offices pertaining to nursing care business, etc. established or managed by a participating corporation in a medical coordination promotion area; the same applies in Article 70-11).

(5) When the medical coordination promotion area pertaining to an application for approval for medical coordination promotion extends over two or more prefectures, the prefectural governor who conducts the affairs concerning the approval for medical coordination promotion must be determined through consultation among the governors of the prefectures to which the relevant medical coordination promotion area belongs. In this case, the prefectural governor who has received the application for approval for medical coordination promotion is to notify the general incorporated association that has applied for approval for medical coordination promotion of the prefectural governor who is to conduct the affairs concerning the approval for medical coordination promotion.

Article 70-3 (1) When the prefectural governor finds that a general incorporated association that has applied for approval for medical coordination promotion conforms to the following standards, the prefectural governor may grant approval for medical coordination promotion to the relevant general incorporated association:

- (i) the main purpose of the general incorporated association is to perform medical coordination promotion operations (which means the medical coordination promotion operations prescribed in Article 70, paragraph (2); the same applies hereinafter in this Chapter);
- (ii) the general incorporated association has the financial basis and technical capability necessary to perform medical coordination promotion operations;
- (iii) in the performance of medical coordination promotion operations, the general incorporated association does not provide any special benefits to its members, directors, auditors, employees or any other related parties specified by Cabinet Order;
- (iv) when the general incorporated association conducts any operations other than medical coordination promotion operations, there is no risk that the implementation of medical coordination promotion operations will be hindered by conducting any operations other than medical coordination promotion operations;
- (v) the medical coordination promotion policy does not violate the provisions of paragraphs (2) and (3) of the preceding Article;
- (vi) the medical coordination promotion area is specified in the articles of incorporation;
- (vii) the articles of incorporation stipulate that the members should be limited to participating corporations and persons specified by an Order of the Ministry of Health, Labour and Welfare as necessary for efficiently providing high-quality and appropriate medical care in the medical coordination promotion area;

- (viii) the number of participating corporations establishing a hospital, etc. is two or more and other requirements for the composition of the participating corporations specified by an Order of the Ministry of Health, Labour and Welfare as appropriate in light of the purpose prescribed in Article 70, paragraph (1) (referred to as the "purpose of medical coordination promotion" in the following item and item (x), (a)) are met;
- (ix) no unfairly discriminatory conditions or other unreasonable conditions are attached to the member's acquisition or loss of qualification in light of the purpose of medical coordination promotion;
- (x) each member has one voting right. However, this does not apply if provisions of the articles of incorporation concerning voting rights of members, such as the number of voting rights that may be exercised at a general meeting of members, particulars on which voting rights may be exercised, conditions for exercising voting rights, fall under all of the following:
 - (a) the voting rights of members are not treated in an unfairly discriminatory manner in light of the purpose of medical coordination promotion;
 - (b) the voting rights of members are not treated differently according to the value of money or other property that the members have provided to the general incorporated association;
- (xi) the total number of voting rights held by the participating corporations accounts for a majority of the voting rights of all members;
- (xii) the articles of incorporation stipulate that persons specified by an Order of the Ministry of Health, Labour and Welfare as those who are likely to have an undue influence on the resolution of a general meeting of members due to their interest in a profit-oriented organization or its officers or other circumstances should not be designated as members, directors or auditors (referred to as "officers" in the following item);
- (xiii) the general incorporated association falls under all of the following with regard to its officers:
 - (a) the general incorporated association has three or more directors and one or more auditors as its officers;
 - (b) no more than one-third of the total number of officers consist of an officer, their spouse, their relatives within the third degree of kinship, or other persons who have a special relationship with the officer as specified by an Order of the Ministry of Health, Labour and Welfare;
 - (c) at least one of the directors is a representative of an organization of academic experts on medical treatment or other persons specified by an Order of the Ministry of Health, Labour and Welfare as necessary for the effective implementation of medical coordination promotion operations;
- (xiv) the general incorporated association has one representative director;

- (xv) the general incorporated association has a board of directors;
- (xvi) the articles of incorporation stipulate that the general incorporated association should have a council that meets the following requirements (referred to as the "council for regional medical coordination promotion" in Article 70-13, paragraph (2)):
 - (a) the council consists of recipients of medical care or nursing care, organizations of academic experts on medical treatment and other related organizations, persons with academic background, and other related persons;
 - (b) the council is able to provide necessary opinions to the general incorporated association when the relevant general incorporated association expresses the opinions prescribed in the following item;
 - (c) the council is able to evaluate the status of the implementation of the operations of the general incorporated association in light of the targets set forth in paragraph (2), item (iii) of the preceding Article, and to state its opinions at a general meeting of members and board of directors meeting when it finds it necessary;
- (xvii) the articles of incorporation stipulate that the participating corporations should, prior to making decisions on the following particulars and other important particulars, seek the opinions of the general incorporated association:
 - (a) decision or change of the budget;
 - (b) borrowings (excluding temporary borrowings to be redeemed with income within the fiscal year);
 - (c) disposal of important assets;
 - (d) decision or change of the business plan;
 - (e) change of the articles of incorporation or act of endowment;
 - (f) merger or split;
 - (g) dissolution due to inability to succeed in the intended business or other reasons specified by an Order of the Ministry of Health, Labour and Welfare;
- (xviii) the articles of incorporation stipulate that in the event that a disposition of rescission of the approval for medical coordination promotion is made pursuant to the provisions of Article 70-21, paragraph (1) or (2), when there is a residual amount of property acquired for the purpose of medical coordination promotion set forth in Article 30. paragraph (2) of the Act on Authorization of Public Interest Incorporated Associations and Public Interest Incorporated Foundations (Act No. 49 of 2006) as applied mutatis mutandis by replacing the terms under Article 70-22, the equivalent amount of property should be donated to the national government, local governments, medical corporations or other medical care providers specified by an Order of

- the Ministry of Health, Labour and Welfare (referred to as "the state, etc." in the following item) within one month from the day of the relevant disposition of rescission of the approval for medical coordination promotion;
- (xix) the articles of incorporation stipulate that in the case of liquidation, the residual property is to be attributed to the state, etc.; and
 - (xx) beyond what is listed in each of the preceding items, the general incorporated association meets the requirements specified by an Order of the Ministry of Health, Labour and Welfare as necessary for the appropriate performance of medical coordination promotion operations.
- (2) In granting approval for medical coordination promotion, the prefectural governor must give consideration to consistency with the regional medical care vision specified in the medical care plan of the prefecture and hear the opinions of the Prefectural Council on Medical Service Facilities in advance.

Article 70-4 A general incorporated association that falls under any of the following is not eligible to receive approval for medical coordination promotion:

- (i) any of its directors and auditors falls under any of the following:
 - (a) in the case where a regional medical coordination promotion corporation (which means a regional medical coordination promotion corporation prescribed in paragraph (1) of the following Article) has had its approval for medical coordination promotion rescinded pursuant to the provisions of Article 70-21, paragraph (1) or (2), a person who was a director engaged in the operations of the relevant regional medical coordination promotion corporation within one year prior to the day on which the fact that caused the rescission occurred and for whom five years have not yet elapsed from the day of the rescission;
 - (b) a person sentenced to a fine or severer punishment pursuant to the provisions of this Act or other laws concerning healthcare or social welfare that are specified by a Cabinet Order for whom five years have not passed from the day on which the execution of the sentence was completed or the sentence became no longer applicable;
 - (c) a person sentenced to imprisonment or severer punishment for whom five years have not passed from the day on which the execution of the sentence was completed or the sentence became no longer applicable;
 - (d) a person who is a member of an organized crime group prescribed in item (vi) of Article 2 of the Act on Prevention of Unjust Acts by Organized Crime Group Members (Act No. 77 of 1991) (hereinafter referred to as an "organized crime group member" in this item) or a person for whom five years have not passed from the day on which the person ceased to be an organized crime group member (referred to as an "organized crime group member, etc." in item (iii));

- (ii) a general incorporated association which has had its approval for medical coordination promotion rescinded pursuant to the provisions of Article 70-21, paragraph (1) or (2) and for which five years have not passed from the date of such rescission; or
- (iii) a general incorporated association whose business activities are controlled by an organized crime group member, etc.

Article 70-5 (1) A general incorporated association that has obtained approval for medical coordination promotion (hereinafter referred to as a "regional medical coordination promotion corporation") must use the words "regional medical coordination promotion corporation" in its name.

(2) A regional medical coordination promotion corporation is deemed to have amended its articles of incorporation to change the words "general incorporated association" in its name to "regional medical coordination promotion corporation".

(3) A written application for registration of the change of name pursuant to the provisions of the preceding paragraph is accompanied by a document certifying that the corporation has obtained approval for medical coordination promotion.

(4) A person who is not a regional medical coordination promotion corporation must not use the words in its name or trade name that may be misunderstood as a regional medical coordination promotion corporation.

(5) A regional medical coordination promotion corporation must not use a name or trade name that may be misunderstood as another regional medical coordination promotion corporation for wrongful purposes.

Article 70-6 When a prefectural governor has granted approval for medical coordination promotion, the prefectural governor must make a public announcement to that effect pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare.

Section 2 Business

Article 70-7 A regional medical coordination promotion corporation must voluntarily strengthen its operational base, promote coordination of operations of participating corporations that establish hospitals, etc. or establish or manage facilities or offices pertaining to nursing care business, etc. in the medical coordination promotion area, and ensure transparency of the management thereof, thereby endeavoring to play an active role that contributes to the achievement of the regional medical care vision and the establishment of the community-based integrated care system.

- Article 70-8 (1) A regional medical coordination promotion corporation, only when the particulars prescribed in Article 70-2, paragraph (4) are stated in the medical coordination promotion policy, in accordance with the medical coordination promotion policy, may conduct business aimed at promoting coordination of operations of hospitals, etc. established by participating corporations and those of facilities or offices established or managed by participating corporations and engaged in nursing care business, etc.
- (2) A regional medical coordination promotion corporation may make an investment only when the following requirements are met:
- (i) the business operator receiving the investment is engaged in a business related to the medical coordination promotion operations in the medical coordination promotion area;
 - (ii) the investment profit is to be used in the medical coordination promotion operations; and
 - (iii) other requirements specified by an Order of the Ministry of Health, Labour and Welfare as unlikely to hinder the implementation of the medical coordination promotion operations are met.
- (3) When a regional medical coordination promotion corporation intending to establish a hospital, etc. (including management of a public hospital, etc. conducted as a designated administrator as set forth in Article 244-2, paragraph (3) of the Local Autonomy Act), or establish or manage a facility or office specified by an Order of the Ministry of Health, Labour and Welfare and engaged in nursing care business, etc., must receive prior confirmation from the prefectural governor who has granted approval for medical coordination promotion (hereinafter referred to as the "prefectural governor having granted approval" in this Chapter) that it will pose no obstacle to the implementation of the medical coordination promotion operations.
- (4) A regional medical coordination promotion corporation may not apply for permission to establish a hospital, permission under Article 62, paragraph (2) of the Social Welfare Act (limited to that pertaining to the establishment of facilities specified by an Order of the Ministry of Health, Labour and Welfare), or any other permission specified by an Order of the Ministry of Health, Labour and Welfare without receiving the confirmation set forth in the preceding paragraph.
- (5) Prior to making a disposition with regards to making the confirmation or not under paragraph (3), the prefectural governor must hear the opinions of the Prefectural Council on Medical Service Facilities in advance.

Article 70-9 The provisions of Article 18 of the Act on Authorization of Public Interest Incorporated Associations and Public Interest Incorporated Foundations apply *mutatis mutandis* to a regional medical coordination

promotion corporation. In this case, the term "business property for public interest purposes" in the same Article is replaced with "business property for the purpose of medical coordination promotion", the term "business for public interest purposes" is replaced with "medical coordination promotion operations set forth in Article 70, paragraph (2) of the Medical Care Act (Act No. 205 of 1948) (hereinafter referred to as "medical coordination promotion operations" in this Article)", the term "Cabinet Office Order" is replaced with "Order of the Ministry of Health, Labour and Welfare", the term "approval for public interest" in item (i) of the same Article is replaced with "approval for medical coordination promotion set forth in Article 70-2, paragraph (1) of the Medical Care Act (hereinafter referred to as "approval for medical coordination promotion" in this Article)", the term "business for public interest purposes" is replaced with "medical coordination promotion operations", the term "approval for public interest" in items (ii) and (iii) of the same Article is replaced with "approval for medical coordination promotion", the term "business for public interest purposes" is replaced with "medical coordination promotion operations", the term "approval for public interest" in item (iv) of the same Article is replaced with "approval for medical coordination promotion", the term "profit-making businesses, etc." is replaced with "businesses other than medical coordination promotion operations", the term "Cabinet Office Order" is replaced with "Order of the Ministry of Health, Labour and Welfare", the term "approval for public interest" in item (vii) of the same Article is replaced with "approval for medical coordination promotion", the term "Cabinet Office Order" is replaced with "Order of the Ministry of Health, Labour and Welfare", the term "business for public interest purposes" is replaced with "medical coordination promotion operations", the term "business for public interest purposes" in item (viii) of the same Article is replaced with "medical coordination promotion operations", and the term "Cabinet Office Order" is replaced with "Order of the Ministry of Health, Labour and Welfare".

Article 70-10 The provisions of Article 41 apply mutatis mutandis to a regional medical coordination promotion corporation. In this case, the term "scale, etc. of the medical institutions established by the medical corporation" in paragraph (2) of the same Article is replaced with "medical coordination promotion operations prescribed in Article 70, paragraph (2) conducted by a regional medical coordination promotion corporation prescribed in Article 70-5, paragraph (1)".

Article 70-11 A participating corporation must display a mark at participating hospitals, etc. and participating nursing care facilities, etc. it establishes to indicate that the coordination of operations of the relevant participating

hospitals, etc. and participating nursing care facilities, etc. is being promoted in accordance with the medical coordination promotion policy.

Article 70-12 (1) The provisions of Article 46-5-3, paragraph (3) apply mutatis mutandis to the directors of a regional medical coordination promotion corporation, and the provisions of Article 46-5, paragraph (9) and Article 46-5-3, paragraph (3) apply mutatis mutandis to the auditors of a regional medical coordination promotion corporation.

(2) When applying the provisions of Article 100 of the Act on General Incorporated Associations and General Incorporated Foundations to the auditors of a regional medical coordination promotion corporation, the term "directors (in the case of a general incorporated association with a board of directors, the board of directors)" in the same Article is replaced with "prefectural governor having granted approval (referred to the prefectural governor having granted approval prescribed in Article 70-8, paragraph (3) of the Medical Care Act (Act No. 205 of 1948)), the general meeting of members, or the board of directors".

Article 70-13 (1) A regional medical coordination promotion corporation must publicize the results of the evaluation set forth in Article 70-3, paragraph (1), item (xvi), (c).

(2) A regional medical coordination promotion corporation is to respect the opinions of the council for regional medical coordination promotion set forth in Article 70-3, paragraph (1), item (xvi), (c).

Article 70-14 The provisions of Section 4 of the preceding Chapter (excluding Article 50, Article 50-2, Article 51-2, paragraph (5) and Article 51-4, paragraph (1)) apply mutatis mutandis to the accounting of a regional medical coordination promotion corporation. In this case, the term "report on the status of transactions with related business operators" in Article 51, paragraph (1) is replaced with "report on the status of transactions with related business operators, a report on the status of support set forth in Article 70, paragraph (2), item (iii), and a report on the status of investment set forth in Article 70-8, paragraph (2)", the terms "medical corporation (limited to those that meet the standards specified by an Order of the Ministry of Health, Labour and Welfare in consideration of the scale of their business activities and other circumstances)" in paragraph (2) of the same Article, "medical corporation set forth in paragraph (2)" in paragraph (5) of the same Article, and "medical corporation (limited to those that meet the standards specified by an Order of the Ministry of Health, Labour and Welfare in consideration of the scale of their business activities and other circumstances)" in Article 51-3 is replaced

with "regional medical coordination promotion corporation", the term "paragraph (3) of the preceding Article (including cases where it is applied mutatis mutandis by replacing the terms pursuant to paragraph (5) of the same Article)" in the same Article is replaced with "paragraph (3) of the preceding Article", the term "social medical corporation and a medical corporation set forth in Article 51, paragraph (2) (excluding a social medical corporation)" in Article 51-4, paragraph (2) is replaced with "regional medical coordination promotion corporation", the term "documents (limited to medical corporations set forth in Article 51, paragraph (2) in the case of documents listed in item (ii))" is replaced with "documents", the term "documents listed in each item of the preceding paragraph" in item (i) of the same paragraph is replaced with "business report, etc., audit report set forth in Article 46-8, item (iii) and the articles of incorporation", the term "auditor's audit report" in paragraph (3) of the same Article is replaced with "audit report set forth in Article 46-8, item (iii)", the term "preceding three paragraphs" in paragraph (4) of the same Article is replaced with "preceding two paragraphs", the term "auditor's audit report" in Article 52, paragraph (1), item (ii) is replaced with "audit report set forth in Article 46-8, item (iii)", and the term "in the case of a medical corporation set forth in Article 51, paragraph (2), the audit report of a certified public accountant, etc." in item (iii) of the same paragraph is replaced with "the audit report of a certified public accountant, etc.".

Article 70-15 The provisions of Section 7 of the preceding Chapter (excluding Article 55, paragraph (1) (limited to the part pertaining to items (iv) and (vii)) and Article 55, paragraph (3)) apply mutatis mutandis to the dissolution and liquidation of a regional medical coordination promotion corporation. In this case, the term "prefectural governor" in paragraph (6) of the same Article is replaced with "prefectural governor having granted approval (meaning the prefectural governor having granted approval prescribed in Article 70-8, paragraph (3); hereinafter the same applies in this Section)", the term "prefectural governor" in paragraphs (7) and (8) of the same Article is replaced with "prefectural governor having granted approval", the term "or (v), or paragraph (3), item (i)" in paragraph (8) of the same Article is replaced with "or (v)", the term "decision to merge or to commence bankruptcy proceedings" in Article 56, paragraph (1) and Article 56-3 is replaced with "decision to commence bankruptcy proceedings", the term "prefectural governor" in Article 56-6 and Article 56-11 is replaced with "prefectural governor having granted approval", the term "liquidation" in Article 56-12, paragraph (1) is replaced with "liquidation (limited to the part pertaining to dissolution and liquidation prescribed in this Section (excluding Article 55, paragraph (1) (limited to the part pertaining to items (iv) and (vii)) and Article 55, paragraph (3)) as applied

mutatis mutandis by replacing the terms pursuant to Article 70-15)", and the term "prefectural governor" in paragraphs (3) and (4) of the same Article is replaced with "prefectural governor having granted approval".

Article 70-16 The provisions of Article 5, paragraph (1), Article 49, paragraph (2) (limited to the part pertaining to item (vi) (limited to the part pertaining to the general meeting of members set forth in item (iii) of Article 148)), Article 67, paragraphs (1) and (3), and Chapter V of the Act on General Incorporated Associations and General Incorporated Foundations do not apply to a regional medical coordination promotion corporation.

Section 3 Supervision

Article 70-17 Beyond the particulars listed in each item of Article 11, paragraph (1) of the Act on General Incorporated Associations and General Incorporated Foundations and the provisions of the articles of incorporation prescribed in Article 70-3, paragraph (1), items (vi), (vii), (xii) and (xvi) through (xix), a regional medical coordination promotion corporation must provide for in the following particulars in its articles of incorporation:

- (i) provisions concerning assets and accounting;
- (ii) provisions concerning officers;
- (iii) provisions concerning the board of directors;
- (iv) provisions concerning dissolution;
- (v) provisions concerning change of the articles of incorporation; and
- (vi) names and locations of hospitals, etc. it has established (including hospitals, etc. it manages as a designated administrator) or facilities or offices engaged in nursing care business, etc. it has established or manages, which are specified by an Order of the Ministry of Health, Labour and Welfare, if any.

Article 70-18 (1) The provisions of Article 54-9 (excluding paragraphs (1) and (2)) apply mutatis mutandis to the change of the articles of incorporation of a regional medical coordination promotion corporation. In this case, the term "prefectural governor" in paragraph (3) of the same Article is replaced with "prefectural governor having granted approval (meaning the prefectural governor having granted approval prescribed in Article 70-8, paragraph (3)); the same applies in the following paragraph and paragraph (5)", the term "prefectural governor" in paragraph (4) of the same Article is replaced with "prefectural governor having granted approval", the term "particulars prescribed in Article 45, paragraph (1) and" is replaced with "whether the assets of the regional medical coordination promotion corporation (meaning the

regional medical coordination promotion corporation prescribed in Article 70-5, paragraph (1)) pertaining to the relevant application meet the requirements set forth in Article 41 as applied mutatis mutandis by replacing the terms pursuant to Article 70-10, whether the content of the articles of incorporation after change does not violate the provisions of laws and regulations, and", and the term "prefectural governor" in paragraph (5) of the same Article is replaced with "prefectural governor having granted approval".

(2) A prefectural governor having granted approval, when giving the approval set forth in Article 54-9, paragraph (3) (limited to the approval pertaining to the particulars listed in item (vi) of the preceding Article and other important particulars specified by an Order of the Ministry of Health, Labour and Welfare; hereinafter the same applies in this paragraph) as applied mutatis mutandis by replacing the terms in accordance with the preceding paragraph or making a disposition not to give the approval, must hear the opinions of the Prefectural Council on Medical Service Facilities in advance.

Article 70-19 (1) The selection and dismissal of a representative director is not take effect without the approval of an authorized prefectural governor.

(2) An authorized prefectural governor, when giving the approval or making a disposition not to give the approval set forth in the preceding paragraph, must hear the opinions of the Prefectural Council on Medical Service Facilities in advance.

Article 70-20 The provisions of Article 6-8, paragraphs (3) and (4), Article 63, paragraph (1) and Article 64 apply mutatis mutandis to a regional medical coordination promotion corporation. In this case, the term "paragraph (1)" in Article 6-8, paragraphs (3) and (4) is replaced with "Article 63, paragraph (1) as applied mutatis mutandis by replacing the terms pursuant to Article 70-20", the term "prefectural governor" in Article 63, paragraph (1) is replaced with "prefectural governor having granted approval (meaning the prefectural governor having granted approval prescribed in Article 70-8, paragraph (3); hereinafter the same applies in this paragraph and the following Article) ", the term "by the prefectural governor" is replaced with "by the prefectural governor having granted approval", and the term "prefectural governor" in Article 64 is replaced with "prefectural governor having granted approval".

Article 70-21 (1) In the case where a regional medical coordination promotion corporation falls under any of the following items, the prefectural governor having granted approval must rescind the approval for medical coordination promotion:

(i) when the regional medical coordination promotion corporation has come to

- fall under Article 70-4, item (i) or (iii); or
- (ii) when the regional medical coordination promotion corporation has received the approval for medical coordination promotion by deception or other wrongful means.
- (2) In the case where a regional medical coordination promotion corporation falls under any of the following items, the prefectural governor having granted approval may rescind the approval for medical coordination promotion:
- (i) when the regional medical coordination promotion corporation no longer conforms to any of the standards listed in each item of Article 70-3, paragraph (1);
 - (ii) when the regional medical coordination promotion corporation has filed an application for revocation of the approval for medical coordination promotion; or
 - (iii) when the regional medical coordination promotion corporation has violated this Act or any order under this Act or any disposition thereunder.
- (3) A prefectural governor having granted approval, when rescinding the approval for medical coordination promotion pursuant to the provisions of the preceding two paragraphs, must hear the opinions of the Prefectural Council on Medical Service Facilities in advance.
- (4) A prefectural governor having granted approval who rescinded the approval for medical coordination promotion pursuant to the provisions of paragraph (1) or (2) must make a public announcement to that effect in accordance with an Order of the Ministry of Health, Labour and Welfare.
- (5) A regional medical coordination promotion corporation that has received a disposition of rescission of the approval for medical coordination promotion pursuant to the provisions of paragraph (1) or paragraph (2) is deemed to have amended its articles of incorporation to change the words "regional medical coordination promotion corporation" in its name to "general incorporated association".
- (6) A prefectural governor having granted approval who rescinded the approval for medical coordination promotion pursuant to the provisions of paragraph (1) or (2) must immediately commission the registration of the change of the name of the relevant regional medical coordination promotion corporation to the registration office having jurisdiction over the location of the principal office or secondary office of the relevant regional medical coordination promotion corporation.
- (7) The written commission for registration of the change of the name pursuant to the provisions of the preceding paragraph must be accompanied by a document certifying that the disposition pertaining to the cause of the relevant registration has been made.

Article 70-22 The provisions of Article 30 of the Act on Authorization of Public Interest Incorporated Associations and Public Interest Incorporated Foundations apply mutatis mutandis to the case where a prefectural governor having granted approval rescinds the approval for medical coordination promotion pursuant to the provisions of paragraph (1) or (2) of the preceding Article. In this case, the term "the remaining amount of the public interest purposes acquired property" in Article 30 of the same Act is deemed to be replaced with "the remaining amount of the acquired property for the purpose of medical coordination promotion", the term "in the event that, or a public interest corporation ceases to exist as a result of a merger (excluding a case in which a corporation that succeeds its rights and obligations is a public interest corporation)" in paragraph (1) of the same Article is replaced with "in the event that", the term "item (xvii) of Article 5" is replaced with "Article 70-3, paragraph (1), item (xviii) of the Medical Care Act (Act No. 205 of 1948)", the term "after the day of, or such merger" is replaced with "after the day of", the term "the national government, in case the Prime Minister is the administrative agency, or the prefecture, in case the prefectural governor is the administrative agency" is replaced with "the prefecture governed by the prefectural governor having granted approval (meaning the prefectural governor having granted approval prescribed in Article 70-8, paragraph (3) of the same Act; the same applies in paragraph (4))", the term "the corporation, or the corporation that succeeds the rights and obligations of the public interest corporation that ceases to exist as a result of the merger" is replaced with "the corporation", the term "authorization cancelled corporation, etc." is replaced with "authorization cancelled corporation", the term "property for business for public interest purposes (excluding those acquired before the day on which public interest corporation authorization was granted, in case of the property listed in item (vi) of Article 18)" in paragraph (2), item (i) of the same Article is replaced with "property for business for the purpose of medical coordination promotion (which means property for business for the purpose of medical coordination promotion prescribed in Article 18 as applied mutatis mutandis by replacing the terms pursuant to Article 70-9 of the Medical Care Act; the same applies in the following item and item (iii)) ", the term "business for public interest purposes" in items (ii) and (iii) of the same paragraph is replaced with "medical coordination promotion operations", the term "property for business for public interest purposes" is replaced with "property for business for the purpose of medical coordination promotion", the term "Cabinet Office Order" in the same item and paragraph (3) of the same Article is replaced with "Order of the Ministry of Health, Labour and Welfare", the term "authorization cancelled corporation, etc." in paragraph (4) of the same Article is replaced with "authorization cancelled corporation", the term "the national government or

the prefecture" is replaced with "the prefecture governed by the prefectural governor having granted approval", and the term "item (xvii) of Article 5" in paragraph (5) of the same Article is replaced with "Article 70-3, paragraph (1), item (xviii) of the Medical Care Act".

Article 70-23 The provisions of Article 66-2 and Article 67 apply mutatis mutandis to a regional medical coordination promotion corporation. In this case, the term "Article 64, paragraphs (1) and (2), Article 64-2, paragraph (1), Article 65, and paragraph (1) of the preceding Article" in Article 66-2 is replaced with "Article 64, paragraphs (1) and (2) as applied mutatis mutandis by replacing the terms pursuant to Article 70-20 and Article 70-21, paragraphs (1) and (2) ", and the term "prefectural governor" is replaced with "prefectural governor having granted approval (meaning the prefectural governor having granted approval prescribed in Article 70-8, paragraph (3); the same applies in Article 67, paragraphs (1) and (3))", the term "prefectural governor" in Article 67, paragraph (1) is replaced with "prefectural governor having granted approval", the term "Article 44, paragraph (1), Article 55, paragraph (6), Article 58-2, paragraph (4) (including cases where it is applied mutatis mutandis by replacing the terms pursuant to Article 59-2), or Article 60-3, paragraph (4) (including the cases where it is applied mutatis mutandis by replacing the terms pursuant to Article 61-3)" is replaced with "disposition of not granting approval for medical coordination promotion or Article 55, paragraph (6) as applied mutatis mutandis by replacing the terms pursuant to Article 70-15", the term "Article 64, paragraph (2)" is replaced with "Article 64, paragraph (2) as applied mutatis mutandis by replacing the terms pursuant to Article 70-20", and the term "prefectural governor" in paragraph (3) of the same Article is replaced with "prefectural governor having granted approval".

Section 4 Miscellaneous Provisions

Article 71 Beyond what is specifically provided for in this Chapter, approval for medical coordination promotion and supervision of a regional medical coordination promotion corporation in the case where the medical coordination promotion area extends over two or more prefectures, and other necessary particulars concerning the approval for medical coordination promotion and supervision of a regional medical coordination promotion corporation is specified by a Cabinet Order, and other necessary particulars concerning the enforcement of the provisions of this Chapter is specified by an Order of the Ministry of Health, Labour and Welfare.

Chapter VIII Miscellaneous Provisions

Article 72 (1) A prefectural council on medical service facilities is established in the prefectures in order to carry out investigations and deliberations on particulars placed under their jurisdiction by this Act, and in order to carry out investigations and deliberations on significant particulars related to ensuring the system for providing medical care in the relevant prefecture in response to consultations with the prefectural governor.

(2) Any necessary particulars concerning the organization and operation of a prefectural council on medical service facilities is stipulated by Cabinet Order.

Article 73 Designated cities set forth in Article 252-19, paragraph (1) of the Local Autonomy Act (hereinafter referred to as "designated cities" in this Article), pursuant to the provisions of a Cabinet Order, are to handle affairs specified by a Cabinet Order to be handled by prefectures in this Act. In this case, provisions set forth in this Act concerning prefectures apply *mutatis mutandis* to designated cities as provisions concerning designated cities.

Article 74 (1) Affairs placed under the jurisdiction of a prefectural governor, mayor of a city with a public health center, or mayor of a special ward of Tokyo pursuant to the provisions of Article 5, paragraph (2), Article 23-2, Article 24, paragraph (1), Article 24-2, and Article 25, paragraphs (1) and (2), where the Minister of Health, Labour and Welfare finds there to be an urgent necessity therefor in order to protect the health of the citizens, this is to be undertaken by the Minister of Health, Labour and Welfare, prefectural governor, mayor of a city with a public health center, or mayor of a special ward of Tokyo. In this case, provisions set forth in this Act concerning a prefectural governor, mayor of a city with a public health center, or mayor of a special ward of Tokyo (limited to those pertaining to the relevant affairs) apply *mutatis mutandis* to the Minister of Health, Labour and Welfare as provisions concerning the Minister of Health, Labour and Welfare.

(2) In the case set forth in the preceding paragraph, when the relevant affairs are undertaken by the Minister of Health, Labour and Welfare, a prefectural governor, mayor of a city with a public health center, or mayor of a special ward of Tokyo, they are to be undertaken under close mutual cooperation.

Article 75 (1) The authority of the Minister of Health, Labour and Welfare pursuant to the provisions of this Act may be delegated to the Director-General of a Regional Bureau of Health and Welfare, pursuant to the provisions of an 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

delegated to the Director-General of a regional branch bureau of health and welfare pursuant to the provisions of an Order of the Ministry of Health, Labour and Welfare.

Article 76 Where an order has been established, revised, or abolished based on the provisions of this Act, the relevant order may specify any necessary transitional measures (including transitional measures related to penal provisions) within the scope reasonably necessary in accordance with the relevant establishment, revision, or abolition.

Chapter IX Penal Provisions

Article 77 When an officer of a social medical corporation has acted in a manner that is contrary to their duties for the purpose of promoting their own interest or the interest of a third party, or with the object of inflicting damage on the social medical corporation, and has inflicted financial damage on the relevant social medical corporation, the relevant officer is punished by imprisonment for up to seven years, a fine of up to five million yen, or both.

Article 78 When a social medical corporation's representative bondholder (meaning a social medical corporation's representative bondholder appointed pursuant to the provisions of Article 736, paragraph (1) of the Companies Act as applied mutatis mutandis pursuant to Article 54-7; the same applies in Article 81, paragraph (1) and Article 91) or resolution administrator (meaning a resolution administrator pursuant to the provisions of Article 737, paragraph (2) of the same Act as applied mutatis mutandis pursuant to Article 54-7; the same applies in Article 81, paragraph (1) and Article 91) has acted in a manner that is contrary to their duties for the purpose of promoting their own interest or the interest of a third party, or with the object of inflicting damage on the social medical corporation bondholders, and has inflicted financial damage on the relevant social medical corporation bondholders, the relevant person is punished by imprisonment for up to five years, a fine of up to five million yen, or both.

Article 79 Any attempt to commit the crimes set forth in the preceding two Articles is punished.

Article 80 (1) In soliciting subscribers for social medical corporation bonds, when an officer of a social medical corporation or a person entrusted with soliciting subscribers for social medical corporation bonds has used a prospectus related to the affairs of the social medical corporation and other particulars or has

used advertisements or other documents related to the relevant subscription that include a false statement on an important particular or, where electronic or magnetic records (meaning records as prescribed by an Order of the Ministry of Health, Labour and Welfare that are prepared in an electronic form, a magnetic form, or any other form not recognizable to human perception, which are used in information processing by computers; the same applies hereinafter) have been created in lieu of the relevant documents, where such a person has supplied electromagnetic records that include a false statement on an important matter for use in the relevant solicitation, the relevant person is punished by imprisonment for up to five years, a fine of up to five million yen, or both.

- (2) When a person undertaking the sale of social medical corporation bonds has used documents related to the relevant sale that include a false statement on an important particular, or, where electronic or magnetic records have been created in lieu of the relevant documents, when such a person has supplied electronic or magnetic records that include a false statement on an important particulars for use in the relevant sale, the provisions of the preceding paragraph apply.

Article 81 (1) When an officer of a social medical corporation, a social medical corporation's representative bondholder, or a resolution administrator has accepted, solicited, or promised to accept a financial benefit in connection with a duty with agreement to perform an act in response to a wrongful request, the officer is punished by imprisonment for up to five years or a fine of up to five million yen.

- (2) A person who has given, offered, or promised to give benefits as set forth in the preceding paragraph is punished by imprisonment for up to three years or a fine of up to three million yen.

Article 82 (1) A person who has accepted, solicited or promised to accept property benefits in relation to any one of the following matters, with agreement to perform an act in response to a wrongful request, is punished by imprisonment for not more than five years or a fine of not more than five million yen::

- (i) a statement of opinion or the exercise of a voting right at a social medical corporation bondholders meeting; or
 - (ii) the exercise of the rights of a social medical corporation bondholder who holds one-tenth or more of the total amount of social medical corporation bonds (excluding bonds that have been redeemed).
- (2) The provisions of the preceding paragraph also apply to a person who has given, offered, or promised to give the benefit set forth in that paragraph.

Article 83 In cases as set forth in Article 81, paragraph (1) or paragraph (1) of the preceding Article, benefits accepted by the offender is confiscated. When it is not possible to confiscate all or part of such benefits, an equivalent value thereof is collected therefrom.

Article 84 (1) The crimes set forth in Article 77 through Article 79, Article 81, paragraph (1), and Article 82, paragraph (1) also apply to persons who committed such crimes outside Japan.

(2) The crimes set forth in Article 81, paragraph (2), and Article 82, paragraph (2) is governed by Article 2 of the Penal Code (Act No. 45 of 1907).

Article 85 When the person provided for in Article 78, Article 80, or Article 81, paragraph (1) is a corporation, these provisions and the provisions of Article 79 apply mutatis mutandis to the director, executive officer, or any other business-administering officer or manager who has committed such an act.

Article 86 (1) A person who is or was a public officer engaged in affairs related to the submission of medical records or birth records pursuant to the provisions of Article 5, paragraph (2), Article 25, paragraph (2) or (4), or the inspection of medical records or birth records pursuant to the provisions of paragraph (1) or paragraph (3) of the same Article, who has, without justifiable grounds, divulged any secret or personal confidential information in relation to the services of physicians, dentists, or midwives which has come to their knowledge through the execution of their duties, are punished by imprisonment for up to one year or a fine of up to 500,000 yen.

(2) The provisions of the preceding paragraph also apply to a person who is or was a public officer other than those who have come to have knowledge of a secret in the course of their duties as set forth in the preceding paragraph, who has divulged such a secret without justifiable grounds.

(3) A person who has violated the provisions of Article 6-13, paragraph (4), Article 6-21, Article 6-22, paragraph (2), Article 30-21, paragraph (5), or Article 30-25, paragraph (6) is punished by imprisonment for up to one year or a fine of up to 500,000 yen.

Article 87 A person who falls under any of the following items is punished by imprisonment for up to six months or a fine of up to 300,000 yen:

- (i) a person who has violated the provisions of Article 6-5, paragraph (1), Article 6-6, paragraph (4), Article 6-7, paragraph (1), or Article 7, paragraph (1);
- (ii) a person who has violated the provisions of Article 14; or

(iii) a person who has violated an order or disposition based on the provisions of Article 6-8, paragraph (2), Article 7-2, paragraph (3), Article 23-2, Article 24, Article 28, Article 29, paragraph (1), or Article 30-15, paragraph (6).

Article 88 In any of the cases listed in the following items, an officer or employee of the medical accident investigation and support center who has committed the violation is punished by a fine of up to 300,000 yen:

- (i) when they have abolished all of the investigation services, etc. without obtaining the approval under Article 6-20;
- (ii) when they have failed to make entries in the books, made false entries, or failed to preserve the books pursuant to the provisions of Article 6-23; or
- (iii) when they have failed to make a report or made a false report set forth in Article 6-24, paragraph (1), or refused, obstructed, or evaded an inspection set forth in the same paragraph.

Article 89 A person who falls under any of the following items is punished by a fine of up to 200,000 yen:

- (i) a person who has violated the provisions of Article 3, Article 4, paragraph (3), Article 4-2, paragraph (3), Article 4-3, paragraph (3), Article 8, Article 8-2, paragraph (2), Article 9, Article 10, Article 11, Article 12, Article 16, Article 18, Article 19, paragraph (1) or (2), Article 21, paragraph (1), items (ii) through (xi) or , paragraph (2), item (ii), Article 22, items (i) or (iv) through (viii), Article 22-2, item (ii) or (v), Article 22-3, item (ii) or (v), or Article 27;
- (ii) a person who has failed to report or submit or has falsely reported pursuant to the provisions of Article 5, paragraph (2), Article 6-8, paragraph (1), or Article 25, paragraphs (1) through (4), or who has refused, obstructed, or evaded an inspection of their duties pursuant to the provisions of Article 6-8, paragraph (1) or Article 25, paragraphs (1) through (3); or
- (iii) a person who has failed to post or falsely posted pursuant to the provisions of Article 14-2, paragraph (1) or (2).

Article 90 When the representative of a corporation, or the agent, employee, or other worker of a corporation or individual commits any one of the violations set forth in Article 87 or the preceding Article with regard to the business of such corporation or individual, not only the offender, but the relevant corporation or individual, as well, is punished by the fine prescribed in the relevant Articles.

Article 91 Where the officer of a social medical corporation, the administrator of a social medical corporation bond registry (meaning a person pursuant to the

provisions of Article 683 of the Companies Act as applied mutatis mutandis pursuant to Article 54-7), a social medical corporation bond administrator, the social medical corporation bond administrator who succeeds to the administration of social medical corporation bonds (meaning a social medical corporation bond administrator who succeeds to the affairs of a social medical corporation bond administrator pursuant to the provisions of Article 711, paragraph (1), or Article 714, paragraph (1) or (3) of the Companies Act as applied mutatis mutandis pursuant to Article 54-7), a social medical corporation's representative bondholder, or a resolution administrator falls under any one of the following items, the relevant person is subject to a civil fine of up to one million yen; provided, however, that this does not apply when such an act should be made subject to criminal punishment:

- (i) when the person has failed to give public notice or notice or has given improper public notice or notice under the provisions of the Companies Act as applied mutatis mutandis under this Act;
- (ii) when, in violation of the provisions of the Companies Act as applied mutatis mutandis under this Act, the person has refused to allow the inspection or copying of documents or anything that shows the particulars recorded in electronic or magnetic records in a manner prescribed by an Order of the Ministry of Health, Labour and Welfare, or has refused to deliver a transcript or extract of documents, to provide particulars recorded in electronic or magnetic records by electronic or magnetic means, or to deliver a document that states such particulars, without justifiable grounds;
- (iii) when the person has refused, obstructed, or evaded an inspection under the provisions of the Companies Act as applied mutatis mutandis under this Act;
- (iv) when the person has made a false statement or concealed facts at a social medical corporation bondholders meeting;
- (v) when the person has failed to enter or record particulars to be entered or recorded in the social medical corporation bond registry, the minutes (meaning minutes prepared pursuant to the provisions of Article 731, paragraph (1) of the Companies Act as applied mutatis mutandis pursuant to Article 54-7; the same applies in the following item), or the documents or electronic or magnetic records set forth in Article 682, paragraph (1), or Article 695, paragraph (1) of the Companies Act as applied mutatis mutandis pursuant to Article 54-7, or has entered or recorded false particulars therein;
- (vi) when the person has failed to keep a social medical corporation bond registry or minutes, in violation of the provisions of Article 684, paragraph (1), or Article 731, paragraph (2) of the Companies Act as applied mutatis mutandis pursuant to Article 54-7;
- (vii) when the person has issued social medical corporation bond certificates

- prior to the date of issue of social medical corporation bonds;
- (viii) when the person has failed to issue social medical corporation bond certificates without delay, in violation of the provisions of Article 696 of the Companies Act as applied mutatis mutandis pursuant to Article 54-7;
 - (ix) when the person has failed to enter or has falsely entered any particular that must be entered on a social medical corporation bond certificate; or
 - (x) when the person has issued social medical corporation bonds in violation of the provisions of Article 54-5, or has failed to appoint a social medical corporation bond administrator to succeed to the administration of social medical corporation bonds, in violation of the provisions of Article 711, paragraph (1) of the Companies Act as applied mutatis mutandis pursuant to Article 54-7.

Article 92 A person who has violated an order set forth in Article 30-13, paragraph (5) is subject to a civil fine of up to 300,000 yen.

Article 93 In any of the cases under the each of the following items, the director, auditor, or liquidator of a medical corporation, or the director, auditor or liquidator of a regional medical coordination promotion corporation is subject to a civil fine of up to 200,000 yen; provided, however, that this does not apply when such an act should be made subject to criminal punishment:

- (i) when the person has failed to complete registration pursuant to the provisions of a Cabinet Order based on this Act;
- (ii) when the person has failed to keep an inventory of assets pursuant to the provisions of Article 46, paragraph (2), or has failed to enter or has falsely entered a particular that must be entered therein;
- (iii) when the person has neglected to keep the minutes pursuant to the provisions of Article 57, paragraphs (2) through (4) of the Act on General Incorporated Associations and General Incorporated Foundations as applied mutatis mutandis pursuant to Article 46-3-6, Article 193, paragraphs (2) through (4) of the same Act as applied mutatis mutandis pursuant to Article 46-4-7, or Article 97, paragraphs (1) through (3) of the same Act as applied mutatis mutandis pursuant to Article 46-7-2, paragraph (1), has failed to state or record particulars that should be stated or recorded therein, has made false statements or records, or has refused inspection or copying thereof under these provisions;
- (iv) when the person has failed to give public notice as prescribed in Article 51-3 (including if it is applied mutatis mutandis pursuant to Article 70-14) or has given false public notice;
- (v) when the person has neglected to keep the documents pursuant to the provisions of Article 51-4, paragraph (1) (including if it is applied mutatis

- mutandis pursuant to paragraph (4) of the same Article; the same applies hereinafter in this item), paragraph (2) (including if it is applied mutatis mutandis by replacing the terms pursuant to paragraph (4) of the same Article (including if it is applied mutatis mutandis by replacing the terms pursuant to Article 70-14; the same applies hereinafter in this item) and Article 70-14; the same applies hereinafter in this item), or paragraph (3) (including if it is applied mutatis mutandis by replacing the terms pursuant to Article 51-4, paragraph (4) and Article 70-14), has failed to state the particulars to be stated therein, or has made false statements, or has refused inspection thereof under Article 51-4, paragraph (1) or (2) without justifiable grounds;
- (vi) when the person has failed to give a notification or has given a false notification in violation of the provisions of Article 52, paragraph (1) (including if it is applied mutatis mutandis pursuant to Article 70-14) or Article 54-9, paragraph (5) (including if it is applied mutatis mutandis pursuant to Article 70-18, paragraph (1));
 - (vii) when the person has distributed dividends of surplus, in violation of the provisions of Article 54 (including if it is applied mutatis mutandis pursuant to Article 70-14);
 - (viii) when the person has failed to file a petition for the commencement of bankruptcy procedures pursuant to the provisions of Article 55, paragraph (5), or Article 56-10, paragraph (1) (including if these provisions are applied mutatis mutandis pursuant to Article 70-15);
 - (ix) when the person has failed to provide the public notice pursuant to the provisions of Article 56-8, paragraph (1), or Article 56-10, paragraph (1) (including if these provisions are applied mutatis mutandis pursuant to Article 70-15), or has falsely provided such public notice;
 - (x) when the person has neglected to keep the documents pursuant to the provisions of Article 58-3, paragraph (2) (including if it is applied mutatis mutandis pursuant to Article 59-2) or Article 60-4, paragraph (2) (including if it is applied mutatis mutandis pursuant to Article 61-3), has failed to state the particulars to be stated therein, or has made false statements, or has refused inspection thereof under these provisions;
 - (xi) when the person has conducted an absorption-type merger, consolidation-type merger, absorption-type split, or incorporation-type split in violation of the provisions of Article 58-4, paragraph (1) or (3) (including if these provisions are applied mutatis mutandis pursuant to Article 59-2) or Article 60-5, paragraph (1) or (3) (including if these provisions are applied mutatis mutandis pursuant to Article 61-3);
 - (xii) when the person has failed to report or falsely reported pursuant to the provisions of Article 63, paragraph (1) (including if it is applied mutatis

mutandis pursuant to Article 70-20; the same apply hereinafter in this item), or has refused, obstructed, or evaded inspection pursuant to the provisions of the same paragraph; or

(xiii) when the person has undertaken operation, in breach of an order pursuant to the provisions of Article 64, paragraph (2) (including if it is applied mutatis mutandis pursuant to Article 70-20), or Article 64-2, paragraph (1).

Article 94 A person who has violated the provisions of Article 40 or Article 70-5, paragraph (4) or (5) is subject to a civil fine of up to 100,000 yen.