

Enforcement Regulations on the Medical Care Act

(Order of the Ministry of Health and Welfare No. 50 of November 5, 1948)

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Chapter I General Provisions

Article 1 Places prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 1-2, paragraph (2) of the Medical Care Act (Act No. 205 of 1948; hereinafter referred to as the "Act") are as follows:

- (i) nursing homes for the elderly provided in Article 20-4 of the Act on Social Welfare for the Elderly (Act No. 133 of 1963) (the same applies in Article 9, paragraph (3), item (iii));
- (ii) intensive care homes for the elderly provided in Article 20-5 of the Act on Social Welfare for the Elderly (the same applies in Article 9, paragraph (3), item (iv));
- (iii) low-cost homes for the elderly provided in Article 20-6 of the Act on Social Welfare for the Elderly (the same applies in Article 9, paragraph (3), item (v)); and
- (iv) fee-based homes for the elderly; and
- (v) beyond the places set forth in the preceding items, places other than the medical institutions provided in Article 1-2, paragraph (2) of the Act (hereinafter referred to simply as "medical institutions") where medical care recipients can live with medical treatment.

(Authorization of Clinically Trained Physicians Having Experience in an Area Where the Securing of Physicians is Particularly Necessary)

Article 1-2 (1) Areas prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 5-2, paragraph (1) of the Act is to be an area within the area provided in Article 30-4, paragraph (2), item (xiv) of the Act (excluding the area provided in Article 30-4, paragraph (6) of the Act) and designated by the governor of a prefecture, which the relevant area belongs to, as an area where the securing of physicians is particularly necessary.

- (2) Experience prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 5-2, paragraph (1) of the Act is to be the experience of a clinically trained physician who has been engaged in medical care for a period of six months or longer at a hospital or clinic in an area where the securing of physicians is particularly necessary as provided in the same paragraph (hereinafter referred to as "hospital, etc. in an area with a small number of physicians" in this Article and Article 7-2), and has provided all of the following services at the hospital, etc.:
- (i) providing continuous medical care and health guidance to individual patients on a wide range of pathological conditions in consideration of their living conditions;
 - (ii) coordinating with other hospitals and coordination with medical service or welfare service providers in order to support patients so that they can live their daily lives in the familiar areas; and
 - (iii) providing services related to health checkups and health guidance for local residents and other community health services.
- (3) Matters prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 1 of the Enforcement Order of the Medical Care Act (Cabinet Order No. 326 of 1948; hereinafter referred to as the "Order") is as follows:
- (i) the details of services related to the provision of medical care provided in an area where the securing of physicians is particularly necessary (including the services set forth in each item of the preceding paragraph);
 - (ii) the period during which the services set forth in the preceding item were provided;
 - (iii) the name and location of the hospital, etc. in an area with a small number of physicians where the services set forth in item (i) were provided;
 - (iv) the reason for providing the services set forth in item (i);
 - (v) the working environment of the hospital, etc. in an area with a small number of physicians where the services set forth in item (i) were provided;
 - (vi) the place of work in the period provided in item (ii) and before and after the period, and other working conditions; and
 - (vii) beyond the particulars set forth in the preceding items, particulars necessary for granting the authorization provided in Article 5-2, paragraph (1) of the Act.

Chapter I-2 Supporting Choices in Medical Care

Article 1-2-2 (1) A report to the prefectural governor under the provisions of Article 6-3, paragraph (1) of the Act is to be made by a method specified by the prefectural governor at least once a year by a date specified by the prefectural

governor.

- (2) Particulars which the administrator of a hospital, clinic, or birthing center (hereinafter referred to as "hospital, etc." except in Chapter VI) must report to the prefectural governor of the location of the hospital, etc. pursuant to the provisions of Article 6-3, paragraph (1) of the Act is as shown in Appended Table 1.

Article 1-2-3 (1) Particulars which the administrator of a hospital, etc. must report to the prefectural governor of the location of the hospital, etc. pursuant to the provisions of Article 6-3, paragraph (2) of the Act must be the basic information set forth in paragraph (1), item (i) of Appended Table 1.

- (2) The report in the preceding paragraph is to be made by a method specified by the prefectural governor pursuant to the provisions of paragraph (1) of the preceding Article.

Article 1-3 (1) When the administrator of a hospital, etc. provides particulars to be described in a document by a method using an electronic data processing system or other methods using information and communications technology (hereinafter referred to as "electronic or magnetic means" in this Chapter) set forth in the following paragraph, in lieu of inspection of the document under the provisions of Article 6-3, paragraph (1) of the Act, pursuant to the provisions of paragraph (3) of the same Article, the administration must indicate to the recipient of medical care in advance the type of the electronic or magnetic means to be used and the form of recording in a file.

- (2) Methods prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 6-3, paragraph (3) of the Act is to be as follows:
- (i) of methods using an electronic data processing system, those set forth in (a), (b), or (c):
 - (a) a method of displaying the information recorded in an electronic or magnetic record (meaning a record made in an electronic form, magnetic form, or any other form not recognizable to human perception, which is used in information processing by computers; the same applies hereinafter) on the screen of an output device;
 - (b) a method of using an electronic data processing system that connects the computer used by the administrator of a hospital, etc. and the computer used by a recipient of medical care through a telecommunications line, by which information is transmitted through that telecommunications line and recorded in a file on the computer used by the recipient;
 - (c) a method of making the particulars set forth in Appended Table 1 that are recorded in a file on a computer used by the administrator of a hospital, etc. available for inspection of a recipient of medical care through a

- telecommunications line and recording the matters in a file on a computer used by the recipient of medical care; or
- (ii) a method of delivering a file containing the matters set forth in Appended Table 1 that is prepared by using a magnetic disk, CD-ROM, or other methods equivalent thereto that can securely store certain particulars (hereinafter referred to as "magnetic disk, etc.").

Article 1-4 Pursuant to the provisions of Article 6-3, paragraph (5) of the Act, the prefectural governor must make matters reported pursuant to the provisions of paragraphs (1) and (2) of the same Article public, by using the Internet with a function that can easily retrieve information on a hospital, etc. or other appropriate methods, in order to support recipients of medical care so that they can easily extract the information necessary for choosing a hospital, etc. and appropriately compare the information for choosing a hospital, etc.

Article 1-5 Pursuant to the provisions of Article 6-4, paragraph (1) of the Act, a physician or dentist responsible for medical care of a patient must prepare a document provided in the same paragraph within seven days from the date of hospitalization (hereinafter referred to as the "inpatient care plan"), deliver the document to the patient or their family, and provide appropriate explanation.

Article 1-6 Cases prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 6-4, paragraph (1) of the Act is to be as follows:

- (i) the patient is expected to be discharged from the hospital in a short period of time;
- (ii) delivering the relevant document may impede the appropriate; medical care of the patient; or
- (iii) delivering the relevant document may cause danger to the life, body, or property of persons.

Article 1-7 Matters prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 6-4, paragraph (1), item (v) of the Act are to be as follows:

- (i) the estimated period of hospitalization; and
- (ii) matters considered by the administrator of a hospital or clinic to be necessary for the provision of appropriate medical care to the patient.

Article 1-8 (1) When the administrator of a hospital or clinic provides particulars to be described in the inpatient care plan by electronic or magnetic means set forth in paragraph (3), in lieu of delivering the plan pursuant to the provisions

of Article 6-4, paragraph (2) of the Act, the administrator must indicate to the patient or their family the type of the electronic or magnetic means to be used and the form of recording in a file, and obtain their consent in advance.

- (2) If the administrator of a hospital or clinic has received a notification from the patient or their family, after obtaining the consent under the preceding paragraph, that they will not receive the particulars by electronic or magnetic means, the administrator must not provide the particulars by the relevant means; provided, however, that this does not apply if the patient or their family gives consent again under the provisions of the preceding paragraph.
- (3) Methods prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 6-4, paragraph (2) of the Act is to be as follows:
 - (i) of methods using an electronic data processing system, those set forth in (a), (b), or (c):
 - (a) a method of displaying the information recorded in an electronic or magnetic record on the screen of an output device;
 - (b) a method of using an electronic data processing system that connects the computer used by the administrator of a hospital or clinic and the computer used by a patient or their family through a telecommunications line, by which information is transmitted through that telecommunications line and recorded in a file on the computer used by the recipient;
 - (c) a method of making the particulars recorded in a file on a computer used by the administrator of a hospital or clinic available for inspection of a patient or their family through a telecommunications line and recording the particulars in a file on a computer used by the patient or their family;
or
 - (ii) a method of delivering a file containing the particulars to be described in the inpatient care plan that is prepared by using a magnetic disk, etc.
- (4) The methods set forth in each item of the preceding paragraph must be those that enable the patient or their family to prepare documents by outputting the records in a file.

Article 1-8-2 (1) A birthing assistant who is responsible for assisting in the birth of a pregnant woman or a woman in labor (hereinafter referred to as "pregnant woman, etc." in this Article through Article 1-8-4 and in Article 15-3), pursuant to the provisions of Article 6-4-2, paragraph (1) of the Act, must deliver the documents provided in the same paragraph to the pregnant woman, etc. or her family, and provide appropriate explanation when the administrator of a birthing center (in the case of a birthing assistant who is engaged in services solely through house calls, the birthing assistant; the same applies in the following Article and Article 1-8-4) promises to provide birthing assistance for the pregnant woman, etc.

(2) The delivery of documents under the provisions of Article 6-4-2, paragraph (1) of the Act is to include the provision of particulars to be described in the documents by a method of describing the particulars in the maternal and child health handbook delivered to the pregnant woman, etc. pursuant to the provisions of Article 16, paragraph (1) of the Maternal and Child Health Act (Act No. 141 of 1965).

Article 1-8-3 Particulars prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 6-4-2, paragraph (1), item (vi) of the Act is to be as follows:

- (i) the telephone number and other contact information in case of an emergency; or
- (ii) particulars that the administrator of a birthing center considers necessary for appropriate birthing assistance and health guidance for the pregnant woman, etc.

Article 1-8-4 (1) When the administrator of a birthing center provides particulars to be described in a document by electronic or magnetic means set forth in paragraph (3), in lieu of delivering the document under the provisions of Article 6, paragraph (1) of the Act, pursuant to the provisions of Article 6-4-2, paragraph (2) of the Act, the administrator must indicate to the pregnant woman, etc. or her family the type of the electronic or magnetic means to be used and the form of recording in a file, and obtain their consent in advance.

(2) If the administrator of a birthing center has received a notification from the pregnant woman, etc. or her family, after obtaining the consent under the preceding paragraph, that they will not receive the particulars by electronic or magnetic means, the administrator must not provide the particulars by the relevant means; provided, however, that this does not apply if the pregnant woman, etc. or her family gives consent again under the provisions of the preceding paragraph.

(3) Electronic or magnetic means prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 6-4-2, paragraph (2) of the Act is to be as follows:

- (i) of methods using an electronic data processing system, those set forth in (a) or (b):
 - (a) a method of using an electronic data processing system that connects the computer used by the administrator of a birthing center and the computer used by a pregnant woman, etc. or her family through a telecommunications line, by which information is transmitted through that telecommunications line and recorded in a file on the computer used by the recipient;

- (b) a method of making the particulars recorded in a file on a computer used by the administrator of a birthing center available for inspection of a pregnant woman, etc. or her family through a telecommunications line and recording the matters in a file on a computer used by the pregnant woman, etc. or her family; or
 - (ii) a method of delivering a file containing the particulars to be described in the documents provided in Article 6-4-2, paragraph (1) of the Act that are prepared by using a magnetic disk, etc.
- (4) The methods set forth in each item of the preceding paragraph must be those that enable the pregnant woman, etc. or her family to prepare documents by outputting the records in a file.

Article 1-9 Standards for the contents and methods of advertisement under Article 6-5, paragraph (2), item (iv) and Article 6-7, paragraph (2), item (iv) of the Act are to be as follows:

- (i) no advertisement is made on the details or effects of treatment using experiences of patients or others (hereinafter referred to as "patients, etc." in the following item and the following Article) based on their subjective or hearsay stories; and
- (ii) no advertisement is made on the details or effects of treatment using photographs, etc. before or after the treatment that may mislead patients, etc.

Article 1-9-2 Cases prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 6-5, paragraph (3) and Article 6-7, paragraph (3) of the Act are to be the cases that satisfy all of the following requirements; provided, however, that the requirements set forth in items (iii) and (iv) are to be limited to cases in which information on medical care not covered by health insurance (meaning examinations, operations, and other treatments that are not subject to the medical insurance acts provided in Article 7, paragraph (1) of the Act on Assurance of Medical Care for Elderly People (Act No. 80 of 1982) or benefits for medical treatment, etc. under the same acts, and benefits pertaining to medical care covered by public expenses provided in Article 1, paragraph (1) of the Ministerial Order on Benefits for Medical Treatment and Claims for Expenses for Medical Care Covered by Public Expenses (Ministry of Health and Welfare Order No. 36 of 1976); the same applies hereinafter) is provided:

- (i) the advertisement must be about or based on a website that displays information that contributes to an appropriate selection concerning medical care and is obtained by patients, etc. upon their choice;
- (ii) the displayed information must specify the contact information or other

- information so that patients, etc. can easily make inquiries;
- (iii) information on particulars pertaining to the details and costs of treatment, etc., normally required for medical care not covered by health insurance must be provided; and
 - (iv) information on particulars pertaining to major risks and adverse reactions, etc., by medical care not covered by health insurance must be provided.

(Method of Combination Pertaining to Clinical Department Names Related to Medical Practices)

Article 1-9-2-2 (1) When combining internal medicine or surgery and the particulars provided in Article 3-2, paragraph (1), item (i), (c), 1. through 4. of the Order pursuant to the provisions of (c) of the same item, the relevant particulars or particulars belonging to different categories of the relevant particular may be combined. In this case, particulars belonging to the same category may not be combined.

(2) The provisions of the preceding paragraph apply mutatis mutandis if the clinical department name set forth in Article 3-2, paragraph (1), item (i), (d), 1. of the Order is combined with the particular provided in (c), 1. through 4. of the same item pursuant to the provisions of (d), 2. of the same item.

Article 1-9-3 (1) Areas of the body, parts, organs, or tissues prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 3-2, paragraph (1), item (i), (c), 1. of the Order or the functions performed by these body parts, organs, or tissues are to be the head, neck, trachea, bronchus, lungs, esophagus, gastrointestinal organs, duodenum, small intestine, large intestine, liver, gallbladder, pancreas, heart, brain, or lipid metabolism.

(2) A name that indicates the gender or age of a patient prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 3-2, paragraph (1), item (i), (c), 2. of the Order is to be perinatal period, newborn baby, child, adolescent, elderly, or elderly persons.

(3) Medical treatment prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 3-2, paragraph (1), item (i), (c), 3. of the Order is to be through Chinese medicine, chemotherapy, artificial dialysis, organ transplantation, bone marrow transplantation, endoscopy, infertility treatment, palliative care, or a pain clinic.

(4) A disease or pathological condition prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 3-2, paragraph (1), item (i), (c), 4. of the Order is to be sexually transmitted diseases or cancer.

Article 1-9-4 (1) An unreasonable combination of names prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 3-2,

paragraph (1), item (i), (c) of the Order is to be a combination of the category of the clinical department name set forth in the left column of the following table and the matter provided in the right column of the same table for the category.

(2) An unreasonable combination of names prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 3-2, paragraph (1), item (i), (d), 2. of the Order is to be a combination of the category of the clinical department name set forth in the left column of the following table and the particulars provided in the right column of the same table for the category.

(Method of Combination Pertaining to Names of Clinical Department Related to Dental Practices)

Article 1-9-5 The provisions of Article 1-9-2-2, paragraph (1) apply mutatis mutandis if dentistry is combined with the particulars provided in Article 3-2, paragraph (1), item (ii), (b), 1. and 2. of the Order pursuant to the provisions of (b) of the same item.

Article 1-10 (1) A physician who wishes to obtain the permission provided in Article 6-6, paragraph (1) of the Act for the department of anesthesia as a clinical department name (meaning the name of a department in charge of anesthesia; the same applies hereinafter) under the provisions of the same paragraph must submit an application form stating the following information to the Minister of Health, Labour and Welfare:

(i) the name, address, date of birth, brief personal history, registration number in the register of physicians, and date of registration in the register of physicians of the applicant;

(ii) the names of the institution and clinical department in which the applicant is working, and the title or position of the applicant;

(iii) experience related to the following anesthesia practices (hereinafter referred to as "anesthesia practices"):

(a) the period during which the anesthesia practices were carried out;

(b) the number of cases of anesthesia;

(c) the name of an institution in which the anesthesia practices were carried out; and

(d) the name of a physician who is able to provide sufficient instruction on the implementation of anesthesia (hereinafter referred to as "supervising anesthesiologist").

(2) When the Minister of Health, Labour and Welfare has received an application form provided in the preceding paragraph and finds that the physician has satisfied any of the requirements set forth in the following items, the Minister is to grant the permission provided in Article 6-6, paragraph (1) of the Act:

(i) after obtaining a physician's license, the physician has been trained for two

- years or more in a hospital or clinic which can provide sufficient training for the implementation of anesthesia (meaning medical practices solely for the implementation of anesthesia under the practical instruction of a supervising anesthesiologist; the same applies hereinafter); or
- (ii) after obtaining a physician's license, the physician has been engaged in practices of anesthesia for at least two years, and has at least 300 cases of general anesthesia with tracheal intubation as a physician mainly in charge of the implementation of anesthesia.
- (3) When the Minister of Health, Labour and Welfare finds it necessary for granting the permission provided in the preceding paragraph, the Minister may request the physician to submit the documents set forth in the following items with regard to the patient whom the physician performed anesthesia:
- (i) anesthesia record;
 - (ii) operation record;
 - (iii) other necessary documents.
- (4) The anesthesia record provided in item (i) of the preceding paragraph must contain the following information:
- (i) the name of a physician who performed the anesthesia;
 - (ii) the name of a physician who performed the operation;
 - (iii) the patient's name and other information to identify the anesthesia record;
 - (iv) the date of the anesthesia;
 - (v) the start and end time of the anesthesia;
 - (vi) the method of performing the anesthesia;
 - (vii) the surgical method of the operation;
 - (viii) the name and amount of drugs used for the anesthesia; and
 - (ix) blood pressure and other records on the patient's physical condition.
- (5) The operation record provided in paragraph (3), item (ii) must contain the following information:
- (i) the name of a physician who performed the operation;
 - (ii) the patient's name and other information to identify the operation record;
 - (iii) the date of the operation;
 - (iv) the start and end time of the operation;
 - (v) the surgical method of the operation; and
 - (vi) the name of the disease.
- (6) A physician who wishes to obtain the permission provided in Article 6-6, paragraph (1) of the Act for the department of anesthesia as a clinical department name under the provisions of the same paragraph may request the hospital or clinic in which the physician is or was working to provide the documents set forth in each item of paragraph (3) when necessary for submitting the application form provided in paragraph (1).

Chapter I-3 Ensuring Safety in Medical Care

(Report of Medical Accidents)

Article 1-10-2 (1) A death or stillbirth prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 6-10, paragraph (1) of the Act does not fall under any of the following items, as recognized by the administrator:

- (i) the administrator of a hospital, etc., finds that the medical care professionals, etc. had explained to the recipient of the medical care or their family before the medical care was provided that death or stillbirth was expected;
 - (ii) the administrator of a hospital, etc., finds that the medical care professionals, etc. had recorded in the medical care record or other documents pertaining to the recipient of the medical care before the medical care was provided that death or stillbirth was expected; or
 - (iii) the administrator of a hospital, etc. finds that the medical care professionals, etc. had expected the death or stillbirth before the medical care was provided, based on hearing from the medical care professionals, etc. and the opinions of the committee provided in Article 1-11, paragraph (1), item (ii) (limited to when the relevant committee is held).
- (2) The report to the Japan Medical Safety Research Organization under the provisions of Article 6-10, paragraph (1) of the Act must be made by any of the following methods:
- (i) a method of submitting a document; or
 - (ii) a method of using an electronic data processing system that connects the computer used by the Japan Medical Safety Research Organization and the computer used by a reporter through a telecommunications line.
- (3) Information prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 6-10, paragraph (1) of the Act are to be as follows:
- (i) the name and location of the hospital, etc., and the name and contact information of the administrator;
 - (ii) the gender, age, and other information of the recipient of medical care involved in the medical accident (meaning the medical accident provided in Article 6-10, paragraph (1) of the Act; the same applies hereinafter);
 - (iii) the outline of the implementation plan for the medical accident investigation (meaning the medical accident investigation provided in Article 6-11, paragraph (1) of the Act; the same applies hereinafter); and
 - (iv) beyond what is set forth in the preceding items, information deemed necessary by the administrator concerning the relevant medical accident.
- (4) The administrator of a hospital, etc. is to ensure a system to reliably identify

deaths and stillbirths at the hospital, etc., in order to properly make report under the provisions of Article 6-10, paragraph (1) of the Act.

(Explanation to the Bereaved Family)

Article 1-10-3 (1) Persons prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 6-10, paragraph (2) of the Act are to be the grandparents of a stillborn fetus involved in the medical accident.

(2) Information prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 6-10, paragraph (2) of the Act is to be as follows:

- (i) the date, time, place, and situation of the medical accident;
- (ii) the outline of the implementation plan for the medical accident investigation;
- (iii) the outline of the system for medical accident investigation; and
- (iv) particulars pertaining to obtaining consent for the autopsy or autopsy imaging (meaning the diagnosis of the cause of death by taking pictures of the inside of a corpse using a magnetic resonance imaging device or other devices for diagnostic imaging; the same applies in item (v) of the following Article) if the autopsy or autopsy imaging is necessary for conducting the medical accident investigation.

(Methods for Medical Accident Investigation)

Article 1-10-4 (1) When conducting a medical accident investigation pursuant to the provisions of Article 6-11, paragraph (1) of the Act, the administrator of a hospital, etc., is to select the following particulars within the scope necessary to appropriately conduct the medical accident investigation, and is to collect and compile information on the particulars in order to clarify the cause of the medical accident:

- (i) checking medical records and other records on medical care;
 - (ii) hearing from medical care professionals who provided the medical care involved in the medical accident;
 - (iii) hearing from relevant persons other than those provided in the preceding item;
 - (iv) anatomy of a deceased person or stillborn fetus involved in the medical accident;
 - (v) autopsy imaging of a deceased person or stillborn fetus involved in the medical accident;
 - (vi) checking pharmaceuticals, medical devices, equipment, and other items used to provide medical care involved in the medical accident; and
 - (vii) examination of blood, urine, or other items concerning a deceased person or stillborn fetus involved in the medical accident.
- (2) In making a report under the provisions of Article 6-11, paragraph (4) of the

Act, the administrator of a hospital, etc., must describe the following information and submit a written report processed so that the medical care professionals, etc., involved in the medical accident cannot be identified (including identification by collation with other information; the same applies in the following paragraph):

- (i) the date, time, and place of the medical accident, and the clinical department name involved in the medical accident;
 - (ii) the name and location of the hospital, etc., and the name and contact information of the administrator;
 - (iii) the gender, age, and other information of the recipient of the medical care involved in the medical accident; and
 - (iv) the items, method, and results of the medical accident investigation.
- (3) Information prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 6-11, paragraph (5) of the Act are to be the information set forth in each item of the preceding paragraph (limited to information processed so that the medical care professionals involved in the medical accident cannot be identified).

(Organization of the Council by Support Organizations for Medical Accident Investigation)

Article 1-10-5 (1) The support organizations for medical accident investigation, etc. provided in Article 6-11, paragraph (2) of the Act (hereinafter referred to as "support organizations" in this Article) may jointly organize a council (hereinafter referred to simply as the "council" in this Article) in order to promote measures necessary for providing support under Article 6-11, paragraph (3) of the Act (hereinafter referred to simply as "support" in this Article).

- (2) In order to achieve the purpose provided in the preceding paragraph, the council is to share information on the status of report and medical accident investigation by the administrator of a hospital, etc. provided in Article 6-10, paragraph (1) of the Act and the status of support by the support organizations, as well as exchange necessary opinions.
- (3) Based on the results of the sharing of information and exchange of opinions provided in the preceding paragraph, the council is to perform the following particulars:
 - (i) implementation of training so that report and medical accident investigation by the administrator of a hospital, etc. provided in Article 6-10, paragraph (1) of the Act, and support by support organizations can be smoothly implemented; and
 - (ii) referral of support organizations to the administrator of a hospital, etc.

Article 1-11 (1) The administrator of a hospital, etc. must secure the following systems for safety management under the provisions of Article 6-12 of the Act (provided, however, that with regard to item (ii), limited to hospitals, clinics with facilities for the hospitalization of patients, and birthing centers with admission facilities):

- (i) prepare guidelines for safety management of medical care;
 - (ii) establish a committee for safety management of medical care (hereinafter referred to as the "Medical Safety Management Committee"), and have the committee provide the following services and other services for safety management of medical care:
 - (a) investigation and analysis to promptly determine the cause when a serious problem or other problems that should be dealt with by the Medical Safety Management Committee have occurred in the hospital, etc.;
 - (b) planning and implementation of improvement measures to ensure medical safety using the results of the analysis provided in (a) and dissemination of the measures to employees;
 - (c) investigation of the status of the implementation of improvement measures provided in (b) and review of the measures as necessary;
 - (iii) conduct employee training on basic matters and specific measures for safety management of medical care, with the aim of raising employees' awareness of safety in medical care and awareness of services in coordination with other employees, and improving their skills to provide services safely;
- And
- (iv) take improvement measures with the aim of ensuring safety in medical care including accident reports, etc. in medical institutions.

(2) The administrator of a hospital, etc. must take the following measures for securing the systems set forth in each item of the preceding paragraph (provided, however, that with regard to item (iii)-2, limited to hospitals or clinics equipped with x-ray unit or any of the items set forth in Article 24, items (i) through (viii)-2, and with regard to item (iv), limited to hospitals other than advanced treatment hospitals and core clinical research hospitals (hereinafter referred to as "advanced treatment hospitals, etc.")):

- (i) the following measures to ensure a system for nosocomial infection control (provided, however, that with regard to (b), limited to hospitals, clinics with facilities for the hospitalization of patients, and birthing centers with admission facilities):
 - (a) formulation of guidelines for nosocomial infection control;
 - (b) holding of a committee for nosocomial infection control;
 - (c) providing employee training for nosocomial infection control;
 - (d) report of the status of the outbreak of infectious diseases in the hospital, etc., and taking improvement measures for promoting nosocomial Infection

- control;
- (ii) as measures to ensure the system for safety management of pharmaceuticals, a person responsible for the safety management on the use (hereinafter referred to as "safe use") of pharmaceuticals will be appointed (hereinafter referred to as "person in charge of safety management of pharmaceuticals") to have the person perform the following particulars:
- (a) providing employee training for the safe use of pharmaceuticals;
 - (b) preparation of operation procedures for the safe use of pharmaceuticals and providing services based on the procedures (including measures to ensure that employees provide the services);
 - (c) collection of information on the use of the following pharmaceuticals (hereinafter referred to as "use of unapproved pharmaceuticals") and other information necessary for the safe use of pharmaceuticals and implementation of improvement measures for the safe use of pharmaceuticals:
 - 1. use of pharmaceuticals provided in Article 14, paragraph (1) of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145 of 1960; hereinafter referred to as the "Act on Pharmaceuticals and Medical Devices"), which have not been approved under the same paragraph or Article 19-2, paragraph (1) of the Act on Pharmaceuticals and Medical Devices;
 - 2. use of pharmaceuticals approved pursuant to the provisions of Article 14, paragraph (1) or Article 19-2, paragraph (1) of the Act on Pharmaceuticals and Medical Devices (including approval for changes pursuant to Article 14, paragraph (13) of the Act on Pharmaceuticals and Medical Devices (including the case applied *mutatis mutandis* in Article 19-2, paragraph (5) of the Act on Pharmaceuticals and Medical Devices); the same applies in 2.) (excluding cases falling under 3. when the pharmaceuticals are used for other dosage, administration, efficacy, or effects (hereinafter referred to as "dosage, etc." in 2.) than those pertaining to the approval);
 - 3. use of contraindicated pharmaceuticals;
- (iii) as measures to ensure the system for safety management of medical devices, a person responsible for the safe use of medical devices will be appointed (hereinafter referred to as "person in charge of safety management of medical devices") to have the person perform the following particulars:
- (a) providing employee training for the safe use of medical devices;
 - (b) formulation of plans on the maintenance and inspection of medical devices and appropriate implementation of maintenance and inspection (including measures to ensure that employees properly conduct the maintenance and inspection);

- (c) collection of information on the use of the following medical devices and other information necessary for the safe use of medical devices and implementation of improvement measures for the safe use of medical devices:
1. use of medical devices provided in Article 2, paragraph (4) of the Act on Pharmaceuticals and Medical Devices that have not been approved pursuant to Article 23-2-5, paragraph (1) or Article 23-2-17, paragraph (1) of the Act on Pharmaceuticals and Medical Devices, that have not been certified pursuant to Article 23-2-23, paragraph (1) of the Act on Pharmaceuticals and Medical Devices, or that have not been notified pursuant to the provisions of Article 23-2-12, paragraph (1) of the Act on Pharmaceuticals and Medical Devices;
 2. use of medical devices that have been approved pursuant to Article 23-2-5, paragraph (1) or Article 23-2-17, paragraph (1) of the Act on Pharmaceuticals and Medical Devices (including approval for changes pursuant to Article 23-2-5, paragraph (15) of the Act on Pharmaceuticals and Medical Devices (including the case applied mutatis mutandis in Article 23-2-17, paragraph (5) of the Act on Pharmaceuticals and Medical Devices); the same applies in 2.), that have been certified pursuant to Article 23-2-23, paragraph (1) of the Act on Pharmaceuticals and Medical Devices (including certification for changes pursuant to paragraph (7) of the same Article; the same applies in 2.), or that have been notified pursuant to the provisions of Article 23-2-12, paragraph (1) of the Act on Pharmaceuticals and Medical Devices (including notification for changes pursuant to paragraph (2) of the same Article; the same applies in 2.) (excluding cases falling under 3. when the medical devices are used for other purpose of use, efficacy, or effects (hereinafter referred to as "usage, etc." in 2.) than those pertaining to the approval, certification, or notification);
 3. use of contraindicated or prohibited medical devices;
- (iii)-2 as measures to ensure the system for safety management of medical radiation, a person responsible for the safety management on the use (hereinafter referred to as "safe use") of medical radiation will be appointed to have the person preform the following matters:
- (a) formulation of guidelines for the safe use of medical radiation;
 - (b) providing training for the safe use of medical radiation to persons engaged in radiation treatment;
 - (c) taking improvement measures for the management and records of the radiation exposure dose of persons who receive radiation treatment using any of the following items and for the safe use of medical radiation:

1. medical devices for radiation treatment specified by the Minister of Health, Labour and Welfare;
 2. radioisotope for positron tomography diagnosis provided in Article 24, item (viii);
 3. radioisotope for medical care provided in Article 24, item (viii)-2; and
- (iv) when providing medical care using highly difficult new medical technology (meaning medical technology which has not been used in the relevant hospital (excluding minor changes, etc. in operative methods) and that may result in death of or other serious impact on a patient; the same applies hereinafter) or unapproved new pharmaceuticals, etc. (meaning pharmaceuticals provided in Article 14, paragraph (1) of the Act on Pharmaceuticals and Medical Devices or specially controlled medical devices provided in Article 2, paragraph (5) of the Act on Pharmaceuticals and Medical Devices that have not been used in the relevant hospital and that have not been approved pursuant to Article 14, paragraph (1), Article 19-2, paragraph (1), Article 23-2-5, paragraph (1), or Article 23-2-17, paragraph (1) of the Act on Pharmaceuticals and Medical Devices or have not been certified pursuant to Article 23-2-23, paragraph (1) of the Act on Pharmaceuticals and Medical Devices (excluding those used for research falling under specified clinical trial provided in Article 2, paragraph (2) of the Clinical Trials Act (Act No. 16 of 2017); the same applies hereinafter), efforts should be made to take necessary measures in accordance with the provisions of Article 9-20-2, paragraph (1), items (vii) or (viii).

Article 1-12 A party prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 6-13, paragraph (3) of the Act is as follows:

- (i) general incorporated association or general incorporated foundation; and
- (ii) beyond those set forth in the preceding item, a party who has been approved by a prefectural governor, mayor of a city with a health center, or mayor of a special ward as a person who can properly, fairly, and neutrally provide the services of a medical care safety support center provided in each item of Article 6-13, paragraph (1) of the Act.

Article 1-13 The administrator of a hospital, etc., must endeavor to take appropriate measures in response to advice of a prefectural governor, mayor of a city with a health center, or mayor of a special ward provided based on the provisions of Article 6-13, paragraph (1), item (i) of the Act.

(Application for Designation)

Article 1-13-2 (1) A person who wishes to be designated by the Japan Medical Safety Research Organization pursuant to the provisions of Article 6-15,

paragraph (1) of the Act must submit an application form describing the following information to the Minister of Health, Labour and Welfare:

- (i) its name, address, and representative;
 - (ii) the name and location of the principal office where investigation services, etc. are to be provided;
 - (iii) the date on which investigation services, etc. are to be commenced.
- (2) The following documents must be attached to the application form set forth in the preceding paragraph:
- (i) the articles of incorporation or the articles of endowment and the certificate of registered information;
 - (ii) a document explaining that the applicant does not fall under the provisions of each item of the following Article;
 - (iii) a document stating the names and personal histories of its officers;
 - (iv) a plan for the provision of investigation services, etc.; and
 - (v) if providing any service other than investigation services, etc., a document stating the type and the outline of the service.

(Standards for Designation)

Article 1-13-3 A person who falls under any of the following items may not be designated under Article 6-15, paragraph (1) of the Act:

- (i) a person who was sentenced to a fine or severer punishment for violation of the Act or an order under the Act, and whom two years have not passed since either the execution of the sentence was completed or since the person ceased to be subject to the execution of the sentence;
- (ii) a person whom the designation provided in Article 6-15, paragraph (1) of the Act was rescinded pursuant to the provisions of Article 6-26, paragraph (1) of the Act, and two years have not passed since the date of the rescission;
or
- (iii) a person which any of whose officers falls under any of the preceding two items.

Article 1-13-4 When the Minister of Health, Labour and Welfare has received an application for designation provided in Article 6-15, paragraph (1) of the Act, the Minister must not make the designation of the same paragraph unless the Minister finds that the application complies with all of the following items:

- (i) it is not intended for profit;
- (ii) investigation services, etc. are part of the purposes of the corporation;
- (iii) the corporation is capable of providing investigation services, etc. on a nationwide basis, and has adequate achievements;
- (iv) the corporation has the accounting foundation necessary for proper and smooth provision of investigation services, etc. on a nationwide basis;

- (v) the corporation does not have an interest in the provision of investigation services, etc.;
- (vi) when the corporation is engaged in any service other than investigation services, etc., the service is not likely to make the management of the investigation services, etc. unfair;
- (vii) the constitution of the corporation's officers is not likely to inhibit fair management of investigation services, etc.;
- (viii) the corporation has a committee consisting of members with expert knowledge or expertise in investigation services, etc.;
- (ix) none of the committee members provided in the preceding item has an interest in the provision of investigation services, etc.; and
- (x) the corporation has established procedures that ensure fair and adequate investigation services, etc.

(Particulars Stated in Operational Rules)

Article 1-13-5 Particulars prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 6-18, paragraph (1) of the Act are to be as follows:

- (i) particulars pertaining to the hours for providing investigation services, etc. and holidays;
- (ii) particulars pertaining to the office where investigation services, etc. are provided;
- (iii) particulars pertaining to the method of providing investigation services, etc.;
- (iv) particulars pertaining to the appointment and dismissal of officers of the Japan Medical Safety Research Organization;
- (v) particulars pertaining to the maintenance of confidentiality of investigation services, etc.;
- (vi) particulars pertaining to the management and preservation of books and documents related to investigation services, etc.; and
- (vii) beyond what is set forth in the preceding items, particulars necessary for investigation services, etc.

(Application for Approval for Operational Rules)

Article 1-13-6 (1) When the Japan Medical Safety Research Organization wishes to obtain approval for the operational rules pursuant to the provisions of Article 6-18, paragraph (1), first sentence of the Act, the organization must submit an application form describing that effect, attached with the operational rules, to the Minister of Health, Labour and Welfare.

(2) When the Japan Medical Safety Research Organization wishes to obtain approval for changes in the operational rules pursuant to the provisions of

Article 6-18, paragraph (1), second sentence of the Act, the organization must submit an application form describing the following particulars to the Minister of Health, Labour and Welfare:

- (i) the details of the change;
- (ii) the date on which the change is to be made; and
- (iii) the reason for the change.

(Business Plan)

Article 1-13-7 (1) When the Japan Medical Safety Research Organization wishes to obtain approval for a business plan and income and expenditure budget pursuant to the provisions of Article 6-19, paragraph (1), first sentence of the Act, the organization must submit an application form attached with the business plan and income and expenditure budget to the Minister of Health, Labour and Welfare by one month prior to the start of every business year (in the case of a business year containing the day on which the organization received a designation set forth in Article 6-15, paragraph (1) of the Act, after receiving the designation without delay).

(2) When the Japan Medical Safety Research Organization wishes to obtain approval for changes in the business plan or income and expenditure budget pursuant to the provisions of Article 6-19, paragraph (1), second sentence of the Act, the organization must submit an application form describing the details and reason for the change to the Minister of Health, Labour and Welfare.

(Submission of Business Report)

Article 1-13-8 The Japan Medical Safety Research Organization must submit the business report and income and expenditure budget provided in Article 6-19, paragraph (2) of the Act, attached with the balance sheet, to the Minister of Health, Labour and Welfare within three months after the end of every business year.

(Application for Permission for Suspension or Discontinuation of Service)

Article 1-13-9 When the Japan Medical Safety Research Organization wishes to obtain permission pursuant to the provisions of Article 6-20 of the Act, the organization must submit an application form describing the following particulars to the Minister of Health, Labour and Welfare by two weeks prior to the date on which the organization intends to suspend or discontinue its services:

- (i) the scope of the investigation services, etc. to be suspended or discontinued;
- (ii) the date on which the investigation services, etc. are to be suspended or discontinued, and in the case of suspension, the period of suspension; and

(iii) the reason for the suspension or discontinuation.

(Storage of Books)

Article 1-13-10 (1) The Japan Medical Safety Research Organization must prepare a book describing the particulars set forth in the following paragraph and store it for three years from the date on which the final entry is made, pursuant to the provisions of Article 6-23 of the Act.

(2) Particulars prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 6-23 of the Act is to be as follows:

(i) the date on which the organization received report on the results of the medical accident investigation from the administrator of a hospital, etc., pursuant to the provisions of Article 6-11, paragraph (4) of the Act;

(ii) the outline of the medical accident pertaining to the report provided in the preceding item; and

(iii) the summary and outline of analysis results pursuant to the provisions of Article 6-16, paragraph (1), item (i) of the Act pertaining to the report provided in item (i).

Chapter I-4 Foundation of Hospitals, Clinics, and Birthing Centers

Article 1-14 (1) A person who wishes to obtain permission for the establishment of a hospital or clinic pursuant to the provisions of Article 7, paragraph (1) of the Act must submit an application form stating the following information to the prefectural governor of the place of establishment (for a clinic or birthing center to be established in an area of a city specified by Cabinet Order pursuant to the provisions of Article 5, paragraph (1) of the Community Health Act (Act No. 101 of 1947) (hereinafter referred to as "city with a health center") or a special ward, the mayor of the city with a health center or the mayor of the special ward; the same applies in paragraphs (3) and (4), Article 2, Article 3, Article 4, Article 5, Articles 7 through 9, and Article 23); provided, however, that when the organizer of a hospital or clinic has transferred the hospital or clinic, or when there has been an inheritance or merger of the organizer of a hospital or clinic, the successor of the hospital or clinic, the heir, the corporation surviving a merger, or the corporation established by a merger may omit the entry of information set forth in items (ix) through (xiii) that have not been changed:

(i) the address and name of the organizer (for a corporation, its name and the location of its principal office), and when the organizer is a clinically trained physician or clinically trained dentist, a statement to that effect (present the registration certificate for completion of clinical training or attach its copy (if the organizer is a person who has received an order from the Minister of

- Health, Labour and Welfare pursuant to the provisions of Article 7-2, paragraph (1) of the Medical Practitioners Act (Act No. 201 of 1948) or an order from the Minister of Health, Labour and Welfare pursuant to the provisions of Article 7-2, paragraph (1) of the Dental Practitioners Act (Act No. 202 of 1948), the registration certificate for completion of clinical training and the registration certificate for completion of re-educational training));
- (ii) the name;
 - (iii) the place of establishment;
 - (iv) the department in which the medical care is provided;
 - (v) if the organizer is a person other than a clinically trained physician or clinically trained dentist, the purpose of the establishment and maintenance method;
 - (vi) if the organizer is a clinically trained physician or clinically trained dentist who has established or managed a hospital or clinic or is working at a hospital or clinic, a statement to that effect;
 - (vii) if the organizer is a clinically trained physician or clinically trained dentist who wishes to establish two or more hospitals or clinics at the same time, a statement to that effect;
 - (viii) the fixed number of physicians, dentists, pharmacists, nurses, and other employees;
 - (ix) the area of the site and floor plan;
 - (x) the sketch drawing around the site;
 - (xi) the structural outline and floor plan of the buildings (specify the purpose of use of each room, and the existence of a mental disorder room, infectious disease room, tuberculosis room, or long-term care bed room, if applicable);
 - (xii) for a hospital, whether there are facilities set forth in Article 21, paragraph (1), items (ii) through (viii) and item (x) of the Act, and the outline of the buildings and equipment;
 - (xii)-2 for a hospital with long-term care beds, the outline of the buildings and equipment of the facilities set forth in Article 21, paragraph (1), items (xi) and (xii) of the Act;
 - (xiii) for a hospital or clinic carrying out dental practices that will have a dental laboratory, the outline of the buildings and equipment;
 - (xiv) for a hospital or clinic having hospital rooms, the number of beds, the number of beds for each bed classification, and the number of beds for each hospital room;
 - (xv) if the organizer is a corporation, the articles of incorporation, articles of endowment, or Municipal Ordinance; and
 - (xvi) the scheduled date of establishment.
- (2) A person who wishes to obtain permission for the establishment of a hospital

pursuant to the provisions of Article 7, paragraph (1) of the Act and discharge polluted water (meaning polluted water provided in Article 16-5, paragraph (1) of the Enforcement Order of the River Act (Cabinet Order No. 14 of 1965); the same applies hereinafter) of the hospital into the public water area provided in Article 2, paragraph (1) of the Water Pollution Prevention Act (Act No. 138 of 1970) must attach a document stating the following information to the application form provided in the preceding paragraph:

- (i) the type and name of the public water area which polluted water is to be discharged;
- (ii) the place where polluted water is to be discharged;
- (iii) the method of discharging polluted water;
- (iv) the amount of polluted water to be discharged;
- (v) the quality of polluted water to be discharged;
- (vi) the treatment method of polluted water to be discharged; and
- (vii) the outline of the polluted water discharge routes (including sewage treatment systems).

(3) Particulars for which a person who has established a hospital or a person other than a clinically trained physician or clinically trained dentist who has established a clinic must obtain permission from the prefectural governor pursuant to the provisions of Article 7, paragraph (2) of the Act are the particulars set forth in paragraph (1), item (v), item (viii), item (ix), and items (xi) through (xiv); provided, however, that when the number of beds in the hospital room is reduced in the case of changing the particulars set forth in item (xiv) of the same paragraph, permission is not required to be obtained.

(4) Particulars of which the person provided in the preceding paragraph must notify the prefectural governor pursuant to the provisions of Article 4, paragraph (1) of the Order are to be the particulars set forth in paragraph (1), item (i), item (ii), item (iv), item (vi), item (xiv), and item (xv) (with regard to the particulars set forth in item (xiv) of the same paragraph, limited to those pertaining to the cases provided in the proviso to the preceding paragraph) and the particulars set forth in each item of paragraph (2) (limited to those pertaining to hospitals).

(5) A person who wishes to obtain permission for the provision of beds pursuant to the provisions of Article 7, paragraph (3) of the Act must submit an application form stating the following particulars (if an application for the permission is only for general beds, limited to the matters set forth in item (iii)) to the prefectural governor of the location of the clinic:

- (i) the fixed number of physicians, nurses, and other employees;
- (ii) the outline of the buildings and equipment of the facilities set forth in Article 21, paragraph (2), items (ii) and (iii) of the Act; and
- (iii) the number of beds, the number of beds for each bed classification, and the

number of beds for each hospital room.

- (6) Particulars for which a person who has provided beds in a clinic must obtain permission of the prefectural governor pursuant to the provisions of Article 7, paragraph (3) of the Act are to be the particulars set forth in each item of the preceding paragraph (if the clinic will have only general beds as a result of the permission, limited to the particulars set forth in item (iii)).
- (7) Cases prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 7, paragraph (3) of the Act are to be as follows; provided, however, that in the cases set forth in item (v), this applies only to cases pertaining to the period for which the medical care provided in the same item (limited to a period not exceeding six months) is provided:
- (i) when a person wishes to provide long-term care beds or general beds in a clinic approved by the prefectural governor, based on the opinions of the Prefectural Council on Medical Service Facilities, as that required for the promotion of the provision of medical care set forth in Article 30-7, paragraph (2), item (ii) of the Act and for the building of an integrated community care system (meaning an integrated community care system provided in Article 2, paragraph (1) of the Act on Promotion of Securing Comprehensive Medical Care and Long-Term Care in Local Communities (Act No. 64 of 1989));
 - (ii) when a person wishes to provide long-term care beds or general beds in a clinic approved by the prefectural governor, based on the opinions of the Prefectural Council on Medical Service Facilities, as that required for the provision of medical care, medical care for children, perinatal care, and emergency medical care in a remote area, and for the provision of good quality and appropriate medical care in other areas;
 - (iii) when a person who has provided long-term care beds or general beds in a clinic provided in the preceding two items wishes to increase the number of long-term care beds or general beds (excluding the cases set forth in the following item) in the case of changing the particulars set forth in paragraph (5), item (iii);
 - (iv) when a person who has provided long-term care beds or general beds in a clinic wishes to reduce the number of long-term care beds or general beds, or to change the number of beds in a room for long-term care beds or general beds in the case of changing the particulars set forth in paragraph (5), item (iii); and
 - (v) when a person who has established a clinic in an area of a specified prefecture provided in Article 38, paragraph (1) of the Act on Special Measures for Novel Influenza (Act No. 31 of 2012) wishes to provide beds in a clinic for the purpose of providing medical care in the event of novel influenza or other emergency situations provided in Article 32, paragraph (1)

- of the same Act, or wishes to change the number of beds in the clinic, the bed classification, or other particulars set forth in each item of paragraph (5).
- (8) Particulars of which a person who falls under either item (i) or (ii) of the preceding paragraph and has provided long-term care beds or general beds in a clinic must notify the prefectural governor pursuant to the provisions of Article 3-3 of the Order are to be the particulars set forth in each item of paragraph (5) (if the beds are general beds only, item (iii) of the same paragraph).
- (9) Particulars of which a person who falls under either paragraph (7), item (iii) or (iv) and has changed the number of long-term care beds or general beds or the number of beds in a room for long-term care beds or general beds must notify the prefectural governor pursuant to the provisions of Article 4, paragraph (2) of the Order are to be the particulars set forth in each item of paragraph (5) (if the beds are general beds only, item (iii) of the same paragraph).
- (10) Particulars of which a person who falls under paragraph (7), item (v) and has provided beds in a clinic must notify the prefectural governor pursuant to the provisions of Article 3-3 of the Order are to be the particulars set forth in each item of paragraph (5) (if the beds are general beds only, item (iii) of the same paragraph).
- (11) Particulars of which a person who falls under paragraph (7), item (v) and has changed the number of beds in a clinic, the bed classification, or the particulars set forth in each item of paragraph (5) must notify the prefectural governor pursuant to the provisions of Article 4, paragraph (2) of the Order are to be the particulars set forth in each item of paragraph (5).
- (12) Conditions prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 7, paragraph (5) of the Act are to be the provision of medical care in beds pertaining to the application in which the number of existing beds according to the classification of the function of beds provided in Article 30-13, paragraph (1) of the Act (hereinafter referred to as "functional classification of beds") in the conceptual area that includes the location of the hospital or clinic pertaining to the application (meaning the conceptual area provided in Article 30, paragraph (2), item (vii) of the Act as provided in a medical care plan specified by the prefecture of the location of the hospital or clinic pursuant to the provisions of Article 30-4, paragraph (1) of the Act (hereinafter referred to simply as "medical care plan"); the same applies hereinafter) is less than the number of beds required in the future provided in (a) of the same item in the conceptual area provided in the medical care plan (hereinafter referred to as the "number of beds required in the future" in Article 30-28-3).

Article 2 (1) A person who wishes to obtain permission for the establishment of a

birthing center pursuant to the provisions of Article 7, paragraph (1) of the Act must submit an application form stating the following information to the prefectural governor of the place of establishment; provided, however, that when the organizer of a birthing center has transferred the birthing center, or when there has been an inheritance or merger of the organizer of a birthing center, the successor of the birthing center, the heir, the corporation surviving a merger, or the corporation established by a merger may omit the entry of information set forth in items (v) and (vi) that have not been changed:

- (i) the address and name of the organizer (if the organizer is a corporation, its name and the location of its principal office);
 - (ii) the name;
 - (iii) the place of establishment;
 - (iv) the fixed number of birthing assistants and other employees;
 - (v) the area of the site and floor plan;
 - (vi) the structural outline and floor plan of the buildings (specify the purpose of use of each room, and the capacity of a room for pregnant women, women in labor, or women resting after childbirth);
 - (vii) if the organizer is a corporation, the articles of incorporation, articles of endowment, or Municipal Ordinance; and
 - (viii) the scheduled date of establishment.
- (2) Information for which a person who is not a birthing assistant (for a person who has received order of the Minister of Health, Labour and Welfare pursuant to the provisions of Article 15-2, paragraph (1) of the Act on Public Health Nurses, Midwives, and Nurses (Act No. 203 of 1948), limited to a person registered pursuant to the provisions of paragraph (3) of the same Article) and has established a birthing center must obtain permission of the prefectural governor pursuant to the provisions of Article 7, paragraph (2) of the Act are to be the information set forth in items (iv) through (vi) of the preceding paragraph.
- (3) Information of which a person provided in the preceding paragraph must notify the prefectural governor pursuant to the provisions of Article 4, paragraph (1) of the Order is to be the information set forth in paragraph (1), items (i), (ii), and (vii).

Article 2-2 (1) Particulars prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 7-3, paragraph (1) of the Act are to be the reason why it is necessary to establish a hospital or increase beds of a hospital in the relevant conceptual area, and the details of the scheduled bed functions pertaining to the application of the same paragraph.

- (2) Cases prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 7-3, paragraph (4) of the Act are to be as follows:

- (i) when an agreement has not been reached at the place of consultation provided in Article 7-3, paragraph (2) of the Act; and
- (ii) when it is found to be difficult for the applicant who has been requested by the prefectural governor pursuant to the provisions of Article 7-3, paragraph (2) of the Act to hold a consultation at the place of consultation due to not participating in the consultation provided in the same paragraph or any other reason.

Article 3 (1) Information of which a person who has obtained permission for the establishment of a hospital, clinic, or birthing center must notify the prefectural governor pursuant to the provisions of Article 4-2, paragraph (1) of the Order are to be as follows:

- (i) the date of establishment;
 - (ii) the address and name of the administrator (present the registration certificate for completion of clinical training or license or attach its copy);
 - (iii) the names of physicians or dentists engaged in medical care (present the license or attach its copy), the names of the clinical departments they are in charge, and the days and hours of medical care, or the names of birthing assistants engaged in services (present the license or attach its copy), working days, and working hours;
 - (iv) the names of pharmacists, if applicable; and
 - (v) for a birthing center that handles labor, the address and name of a physician provided in Article 15-2, paragraph (1) (hereinafter referred to as "contract physician") (attach a document stating that the request was made to the physician) or the address and name of a hospital or clinic provided in paragraph (2) of the same Article (attach a document stating that the hospital or clinic has a department of obstetrics or department of obstetrics and gynecology in its clinical department names, and a document stating that the request was made to the hospital or clinic under the same paragraph), and the address and name of a contract hospital or clinic provided in paragraph (3) of the same Article (attach a document stating that the request was made to the hospital or clinic).
- (2) Particulars prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 4-2, paragraph (2) of the Order are to be the particulars set forth in item (v) of the preceding paragraph.

Article 3-2 (1) Particulars prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 4-3 of the Order pertaining to advanced treatment hospitals are to be the particulars set forth in Article 6-3, paragraph (1), items (i) through (v) and the buildings and equipment of the facilities set forth in Article 22-2, item (ii) and Article 22-4 of the Act; provided, however,

that in the case of a hospital established by the national government, the particulars set forth in Article 6-3, paragraph (1), items (i), (ii), (iv), and (v) are to be excluded.

- (2) When the Minister of Health, Labour and Welfare has received a notification set forth in Article 4-3 of the Order pertaining to a change in the particulars set forth in Article 6-3, items (ii) and (iii) from an advanced treatment hospital, the Minister must provide public notice of the particulars pertaining to the change.

Article 3-3 (1) Particulars prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 4-3 of the Order pertaining to core clinical research hospitals are to be the particulars set forth in Article 6-5-2, paragraph (1), items (i) through (v) and the buildings and equipment of the facilities set forth in Article 22-3, item (ii) and Article 22-8 of the Act; provided, however, that in the case of a hospital established by the national government, the particulars set forth in Article 6-5-2, paragraph (1), items (i), (ii), (iv), and (v) are to be excluded.

- (2) When the Minister of Health, Labour and Welfare has received a notification set forth in Article 4-3 of the Order pertaining to a change in the particulars set forth in Article 6-5-2, paragraph (1), items (ii) and (iii) from a core clinical research hospital, the Minister must provide public notice of the particulars pertaining to the change.

Article 4 Particulars of which a clinically trained physician or clinically trained dentist who has established a clinic must notify the prefectural governor pursuant to the provisions of Article 8 of the Act are to be as follows; provided, however, that when the organizer of a clinic has transferred the clinic, or when there has been an inheritance of the organizer of a clinic, the successor of the clinic or the heir may omit the notification of matters set forth in Article 1-14, paragraph (1), items (ix), (xi), and (xiii) that have not been changed:

- (i) the address and name of the organizer (present the registration certificate for completion of clinical training or attach its copy (if the organizer is a person who has received an order from the Minister of Health, Labour and Welfare pursuant to the provisions of Article 7-2, paragraph (1) of the Medical Practitioners Act or an order from the Minister of Health, Labour and Welfare pursuant to the provisions of Article 7-2, paragraph (1) of the Dental Practitioners Act, the registration certificate for completion of clinical training and the registration certificate for completion of re-educational training));
- (ii) Matters set forth in Article 1-14, paragraph (1), items (ii) through (iv), items (vi) through (ix), item (xi), item (xiii), and item (xiv); and

(iii) particulars set forth in Article 3, paragraph (1), items (i) through (iv).

Article 5 Particulars of which a birthing assistant who has established a birthing center must notify the prefectural governor pursuant to the provisions of Article 8 of the Act are to be as follows; provided, however, that when the organizer of a birthing center has transferred the birthing center, or when there has been an inheritance of the organizer of a birthing center, the successor of the birthing center or the heir may omit the notification of matters set forth in Article 2, paragraph (1), items (v) and (vi) that have not been changed:

- (i) the address and name of the organizer (present the license or attach its copy (if the organizer is a person who has received an order from the Minister of Health, Labour and Welfare pursuant to the provisions of Article 15-2, paragraph (1) of the Act on Public Health Nurses, Midwives, and Nurses, the license and the registration certificate for completion of re-educational training));
- (ii) particulars set forth in Article 2, paragraph (1), items (ii) through (vi);
- (iii) if the organizer has established or managed a birthing center or is working at a hospital, clinic, or birthing center, a statement to that effect;
- (iv) if the organizer wishes to establish two or more birthing centers at the same time, a statement to that effect; and
- (v) particulars set forth in Article 3, paragraph (1), items (i) through (iii) and item (v).

Article 6 (1) A person who wishes to obtain approval for the bearing of a name of a regional medical care support hospital pursuant to the provisions of Article 4, paragraph (1) of the Act must submit an application form stating the following particulars to the prefectural governor of the location of the hospital:

- (i) the address and name of the organizer (if the organizer is a corporation, its name and the location of its principal office);
 - (ii) the name;
 - (iii) the location;
 - (iv) the number of beds; and
 - (v) the buildings and equipment of the facilities set forth in Article 22, item (i) and items (iv) through (viii) of the Act and the facilities set forth in Article 22.
- (2) The following documents must be attached to the application form set forth in the preceding paragraph:
- (i) a document certifying that the hospital has established a system for providing medical care to patients referred from other hospitals or clinics (hereinafter referred to as "referred patients");

- (ii) a document certifying that the hospital has established a system for shared use (meaning that all or part of the buildings, equipment, instruments, or tools of a hospital are allowed to be used by physicians, dentists, pharmacists, nurses, and other medical care professionals who do not work at the hospital for their practices, research, or training; the same applies hereinafter);
- (iii) a document certifying that the hospital is capable of providing emergency medical care;
- (iv) a document certifying that the hospital is capable of carrying out training to enhance the quality of community medical care professionals;
- (v) a document concerning the method of managing medical care records;
- (vi) a document concerning the method of managing records on the management and operation of the hospital;
- (vii) a document concerning the method of inspection of medical care records;
- (viii) a document concerning the method of inspection of records on the management and operation of the hospital; and
- (ix) a written acceptance of assumption by members of the committee provided in Article 9-19, paragraph (1) and their resumes.

Article 6-2 The number prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 4, paragraph (1), item (iv) of the Act is to be 200; provided, however, that this does not apply when the prefectural governor finds it necessary for ensuring medical care in the region.

Article 6-3 (1) A person who wishes to obtain approval for the bearing of a name of advanced treatment hospital pursuant to the provisions of Article 4-2, paragraph (1) of the Act must submit an application form stating the following information to the Minister of Health, Labour and Welfare:

- (i) the address and name of the organizer (if the organizer is a corporation, its name and the location of its principal office);
- (ii) the name;
- (iii) the location;
- (iv) the clinical department names;
- (v) the number of beds;
- (vi) the number of physicians, dentists, pharmacists, nurses, assistant nurses, registered dietitians, and other employees;
- (vii) the administrator's experience in safety management of medical care;
- (viii) the average number of inpatients, outpatients, and dispensations in the previous year;
- (ix) the average number of inpatients and outpatients for dentistry, orthodontics, pediatric dentistry, and dental surgery in the previous year;
- (x) the buildings and equipment of the facilities set forth in Article 22, items

- (iv) through (viii) of the Act, the facilities set forth in Article 22-2, item (ii) of the Act, and the facilities set forth in Article 22-4;
 - (xi) the average referral rate provided in Article 9-20, item (vi), (a) in the previous year;
 - (xii) the average reverse referral rate provided in Article 9-20, item (vii), (a) in the previous year; and
 - (xiii) the list of members of the audit committee provided in Article 15-4, item (ii), the reason for the selection of the members, and the status of publication of the list of the members and the reason for the selection of the members.
- (2) The following documents must be attached to the application form set forth in the preceding paragraph:
- (i) a document certifying that the hospital is capable of providing advanced medical care;
 - (ii) a document certifying that the hospital is capable of developing and evaluating advanced medical technology;
 - (iii) a document certifying that the hospital is capable of carrying out training on advanced medical care;
 - (iv) a document concerning the method of managing medical care records;
 - (v) a document concerning the method of managing records on the management and operation of the hospital;
 - (vi) a document concerning the method of inspection of medical care records;
 - (vii) a document concerning the method of inspection of records on the management and operation of the hospital;
 - (viii) the floor plan of the buildings;
 - (ix) a document concerning the operation of the panel under the provisions of Article 10-2, paragraph (2) of the Act;
 - (x) a document concerning the operation of the panel under the provisions of Article 16-3, paragraph (2) of the Act;
 - (xi) a document concerning the authority of the administrator under the provisions of Article 19-2, item (i) of the Act;
 - (xii) a document certifying that the hospital has established an audit committee under the provisions of Article 19-2, item (ii) of the Act;
 - (xiii) a document concerning a system for ensuring that the services provided by the administrator under the provisions of Article 19-2, item (iii) of the Act comply with laws and regulations, and a system for the supervision of the services of the advanced treatment hospital by the organizer;
 - (xiv) for hospitals where the value provided in item (x) of the preceding paragraph is less than 50 percent, a specific annual plan to increase the referral rate to 50 percent within approx. five years;
 - (xv) for hospitals where the value provided in item (xi) of the preceding paragraph is less than 40 percent, a specific annual plan to increase the

reverse referral rate to 40 percent within approx. five years; and
(xvi) a document certifying that the hospital has maintained a system set forth in each item of Article 1-11, paragraph (1), has made publication under the provisions of Article 7-2-2, and has undertaken the particulars set forth in Article 9-20-2, paragraph (1), items (i) through (xiii) and Article 15-4, item (iv).

- (3) With regard to the application of the provisions of the preceding paragraph concerning an advanced treatment hospital providing advanced and specialized medical care for cancer, cardiovascular disease, and other diseases that have a serious impact on citizens' health, the term "50 percent" in item (xiv) of the same paragraph is to be replaced with "80 percent" and the term "40 percent" in item (xv) of the same paragraph is deemed to be replaced with "60 percent"
- (4) When the Minister of Health, Labour and Welfare has received an application form provided in paragraph (1), the Minister must send a copy of the application form to the prefectural governor of the location of the hospital without delay.
- (5) When the Minister of Health, Labour and Welfare has granted approval provided in Article 4-2, paragraph (1) of the Act, the Minister must provide a public notice of the name and location of the hospital and the date of approval.

Article 6-4 (1) An advanced treatment hospital is to include a department of internal medicine, department of surgery, department of psychiatry, department of pediatrics, department of dermatology, department of urology, department of obstetrics and gynecology or department of obstetrics and department of gynecology, department of ophthalmology, department of otorhinolaryngology, department of radiology, and emergency department (excluding when a clinical department name is a name combined with these clinical department names pursuant to the provisions of Article 3-2, paragraph (1), item (i), (c) or (d), 2. of the Order), department of neurosurgery and department of orthopedics under the provisions of (c) of the same item, dentistry (excluding when a clinical department name is a name combined with dentistry pursuant to the provisions of item (ii), (b) of the same paragraph; the same applies in paragraph (4)), and clinical department names under the provisions of Article 6-6, paragraph (1) of the Act (limited to clinical department names permitted by the Minister of Health, Labour and Welfare pursuant to the provisions of the same paragraph) in its clinical department names.

- (2) With regard to the application of the provisions of the preceding paragraph concerning an advanced treatment hospital providing specialized medical care in internal medicine or surgery, the term "department of internal medicine, department of surgery" in the same paragraph is replaced with "department of

internal medicine (including all clinical departments combining a department of internal medicine with respiratory, digestive, cardiovascular, kidney, nerve, blood, endocrine, metabolic, infectious disease, or allergic disease pursuant to the provisions of Article 3-2, paragraph (1), item (i), (c) of the Order and department of rheumatology), department of surgery (including all clinical departments combining a department of surgery with respiratory, digestive, lactating gland, heart, blood vessel, endocrine, or pediatrics pursuant to the provisions of (c) of the same item)," and the term "name combined with these clinical department names" is replaced with "name combined with these clinical department names (excluding a name combined with the department of internal medicine or the department of surgery)."

- (3) Notwithstanding the provisions of the preceding paragraph, in the cases of the following items, a clinical department provided in each item may not be included in the clinical department name:
 - (i) if medical care pertaining to a clinical department with a name combined with a department of internal medicine that is applied by replacing terms pursuant to the provisions of the preceding paragraph or a department of rheumatology is provided by a different clinical department with a name combined with the department of internal medicine, a department of rheumatology, or other medical departments: a clinical department with a name combined with the department of internal medicine pertaining to the medical care or a department of rheumatology; or
 - (ii) if medical care pertaining to a clinical department with a name combined with a department of surgery that is applied by replacing terms pursuant to the provisions of the preceding paragraph is provided by a different clinical department with a name combined with the department of surgery or other medical departments: a clinical department with a name combined with the department of surgery pertaining to the medical care.
- (4) With regard to the application of the provisions of paragraphs (1) and (2) concerning an advanced treatment hospital providing advanced and specialized medical care for cancer, cardiovascular disease, and other diseases that have a serious impact on citizens' health, the term "include" in paragraph (1) is with "include 10 or more clinical department names from among" and the term "department of obstetrics and gynecology or department of obstetrics and department of gynecology" is replaced with "department of obstetrics and gynecology, department of obstetrics, department of gynecology."
- (5) Notwithstanding the provisions of paragraph (1), in the case of an advanced treatment hospital having dentists or an advanced treatment hospital that has established a system to provide dental care in close coordination with other hospitals or clinics, dentistry may not be included in its clinical department names.

Article 6-5 The number prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 4-2, paragraph (1), item (v) of the Act is to be 400.

Article 6-5-2 (1) A person who wishes to obtain approval for the bearing of a name of core clinical research hospital pursuant to the provisions of Article 4-3, paragraph (1) of the Act must submit an application form stating the following information to the Minister of Health, Labour and Welfare:

- (i) the address and name of the organizer (if the organizer is a corporation, its name and the location of its principal office);
 - (ii) the name;
 - (iii) the location;
 - (iv) the clinical department names;
 - (v) the number of beds
 - (vi) the number of physicians, dentists, pharmacists, nurses, and other employees;
 - (vii) the administrator's experience in safety management of medical care;
 - (viii) the buildings and equipment of the facilities set forth in Article 22, items (iv) through (viii) of the Act, the facilities set forth in Article 22-3, item (ii) of the Act, and the facilities set forth in Article 22-8; and
 - (ix) the list of members of the audit committee provided in Article 9-25, item (iv), (e), the reason for the selection of the members, and the status of publication of the list of the members and the reason for the selection of the members.
- (2) The following documents must be attached to the application form set forth in the preceding paragraph:
- (i) a document certifying that the hospital is capable of preparing and implementing a plan for specified clinical trial (meaning the specified clinical trial provided in Article 4-3, paragraph (1), item (i) of the Act; the same applies in this Article, Article 9-2-3, Article 9-24, Article 9-25, and Article 22-7);
 - (ii) if the hospital conducts specified clinical trial jointly with other hospitals or clinics, a document certifying that the hospital is capable of playing a leading role in the implementation of the specified clinical trial;
 - (iii) a document certifying that the hospital is capable of providing consultation on the implementation of specified clinical trial and providing necessary information, advice, and other support to other hospitals or clinics;
 - (iv) a document certifying that the hospital is capable of carrying out training on specified clinical trial;
 - (v) a document concerning the method of managing medical care and specific

- clinical research records;
 - (vi) a document concerning the method of managing records on the management and operation of the hospital;
 - (vii) the floor plan of the buildings; and
 - (viii) a document certifying that the hospital has maintained a system set forth in each item of Article 1-11, paragraph (1) and each item of Article 9-25.
- (3) When the Minister of Health, Labour and Welfare has received an application form provided in paragraph (1), the Minister must send a copy of the application form to the prefectural governor of the location of the hospital without delay.
- (4) When the Minister of Health, Labour and Welfare has granted approval provided in Article 4-3, paragraph (1) of the Act, the Minister must provide public notice of the name and location of the hospital and the date of approval.

Article 6-5-3 Standards prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 4-3, paragraph (1), item (i) of the Act falls under any of the following items:

- (i) the clinical trial complies with the Ministerial Order on Good Clinical Practice for Pharmaceuticals (Ministry of Health and Welfare Order No. 28 of 1997), the Ministerial Order on Good Clinical Practice for Medical Devices (Order of the Ministry of Health, Labour and Welfare No. 36 of 2005), or the Ministerial Order on Good Clinical Practice for Regenerative Medical Products (Order of the Ministry of Health, Labour and Welfare No. 89 of 2014) (meaning a clinical trial provided in Article 80-2, paragraph (2) of the Act on Pharmaceuticals and Medical Devices); or
- (ii) the clinical research is that provided in Article 2, paragraph (1) of the Clinical Trials Act to be conducted pursuant to the provisions of the Act.

Article 6-5-4 (1) A core clinical research hospital is to include 10 or more clinical department names from among a department of internal medicine, department of surgery, department of psychiatry, department of pediatrics, department of dermatology, department of urology, department of obstetrics and gynecology, department of obstetrics, department of gynecology, department of ophthalmology, department of otorhinolaryngology, department of radiology, and emergency department (excluding when a clinical department name is a name combined with these clinical department names pursuant to the provisions of Article 3-2, paragraph (1), item (i), (c) or (d), 2. of the Order), department of neurosurgery and department of orthopedics under the provisions of (c) of the same item, dentistry (excluding when a clinical department name is a name combined with dentistry pursuant to the provisions of item (ii), (b) of the same paragraph), and clinical department

names under the provisions of Article 6-6, paragraph (1) of the Act (limited to clinical department names permitted by the Minister of Health, Labour and Welfare pursuant to the provisions of the same paragraph) in its clinical department names.

- (2) With regard to the application of the provisions of the preceding paragraph concerning a core clinical research hospital providing specialized clinical research in internal medicine or surgery, the term "department of internal medicine, department of surgery" in the same paragraph is replaced with "department of internal medicine (including all clinical departments combining a department of internal medicine with respiratory, digestive, cardiovascular, kidney, nerve, blood, endocrine, metabolic, infectious disease, or allergic disease pursuant to the provisions of Article 3-2, paragraph (1), item (i), (c) of the Order and department of rheumatology), department of surgery (including all clinical departments combining a department of surgery with respiratory, digestive, lactating gland, heart, blood vessel, endocrine, or pediatrics pursuant to the provisions of (c) of the same item)," and the term "name combined with these clinical department names" is replaced with "name combined with these clinical department names (excluding a name combined with the department of internal medicine or the department of surgery)."
- (3) Notwithstanding the provisions of the preceding paragraph, in the cases of the following items, a clinical department provided in each item may not be included in the clinical department name:
 - (i) if medical care pertaining to a clinical department with a name combined with a department of internal medicine that is applied by replacing terms pursuant to the provisions of the preceding paragraph or a department of rheumatology is provided by a different clinical department with a name combined with the department of internal medicine, a department of rheumatology, or other medical departments: a clinical department with a name combined with the department of internal medicine pertaining to the medical care or a department of rheumatology; or
 - (ii) if medical care pertaining to a clinical department with a name combined with a department of surgery that is applied by replacing terms pursuant to the provisions of the preceding paragraph is provided by a different clinical department with a name combined with the department of surgery or other medical departments: a clinical department with a name combined with the department of surgery pertaining to the medical care.

Article 6-5-5 The number prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 4-3, paragraph (1), item (vi) of the Act is to be 400.

Article 6-6 Standards prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 18 of the Act is to be that a hospital or a clinic where three or more physicians regularly work is to have an exclusive pharmacist.

Article 7 When the organizer of a hospital or clinic wishes to obtain permission under the provisions of the proviso to Article 18 of the Act, the organizer must submit an application form stating the following information to the prefectural governor of the location of the hospital or clinic:

- (i) the clinical department names of the hospital or clinic;
- (ii) in the case of a hospital, the number of beds; and
- (iii) the reason for not having an exclusive pharmacist.

(Hospital with Authorized Clinically Trained Physician as Its Administrator)

Article 7-2 (1) A hospital prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 10, paragraph (3) of the Act is to be a regional medical care support hospital that dispatches physicians to a hospital, etc. in an area with a small number of physicians or provides services that contribute to the improvement of the quality of medical care or development of the environment in an area where the securing of physicians is particularly necessary.

(2) Cases prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 10, paragraph (3) of the Act is to be as follows:

- (i) when having a person who is considered to be appropriate to manage the hospital in order to ensure medical care in the region (limited to a physician other than a physician who started clinical training on or after April 1, 2020) manage the hospital; or
- (ii) beyond the cases set forth in the preceding item, when it was not expected that the former hospital had no administrator and when the prefectural governor of the location of the hospital finds that there are unavoidable circumstances that a person who has not obtained authorization set forth in Article 5-2, paragraph (1) of the Act manages the hospital.

Chapter II Management of Hospitals, Clinics, and Birthing Centers

Article 7-2-2 When the organizer of an advanced treatment hospital appoints an administrator provided in Article 10-2, paragraph (1) of the Act, the organizer must determine the following particulars in advance as standards for the quality and capabilities of the administrator and make them public:

- (i) the quality and capabilities necessary for ensuring safety in medical care;
- and

- (ii) the quality and capabilities necessary for managing and operating the hospital, such as organization management capabilities.

Article 7-3 (1) The panel provided in Article 10-2, paragraph (2) of the Act must satisfy the following requirements:

- (i) committee members are selected by a council or other organizations that make decisions for the hospital (hereinafter referred to as "council, etc."), and the list of committee members and the reason for the selection of the members are made public;
 - (ii) the number of committee members is five or more, and two or more committee members are selected from among persons other than those having a special relationship with the hospital (meaning persons who satisfy the conditions set forth in each item of the following paragraph); and
 - (iii) the selection results, selection process, and the reason for the selection of the administrator are made public without delay.
- (2) Persons having a special relationship prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 10-2, paragraph (2) of the Act are those who satisfy the following conditions:
- (i) a person who has an employment relationship with the organizer of the hospital in the last 10 years;
 - (ii) a person who has received donations or contract money, etc. exceeding a certain amount from the organizer of the hospital in the last three years; and
 - (iii) a person who has made a donation to the organizer exceeding a certain amount in the last three years.

Article 8 When the organizer of a hospital, clinic, or birthing center wishes to obtain permission under the provisions of the proviso to Article 12, paragraph (1) of the Act, the organizer must submit an application form stating the reason for obtaining permission, and the address and name of a person to be the administrator, to the prefectural governor of the location of the hospital, clinic, or birthing center, attached with a copy of the registration certificate for completion of clinical training, a physician's license, or a dentist's license, or a copy of a midwife's license of the person to be the administrator or a certified copy of the list of midwives.

Article 9 (1) When the organizer of a hospital, clinic, or birthing center wishes to obtain permission under the provisions of Article 12, paragraph (2) of the Act, the organizer must submit an application form stating the following information to the prefectural governor of the location of the hospital, clinic, or birthing center:

- (i) the names, locations, clinical department names, number of beds, and fixed

- number of employees of the hospital, clinic, or birthing center that the physician, dentist, or birthing assistant has currently managed, and of the hospital, clinic, or birthing center that the physician, dentist, or birthing assistant will newly manage;
- (ii) the reason for having the physician, dentist, or birthing assistant manage the hospital, clinic, or birthing center;
 - (iii) the distance and the time required for communication between the hospital, clinic, or birthing center currently managed and the hospital, clinic, or birthing center newly managed; and
 - (iv) applicable provisions of the items of Article 12, paragraph (2) of the Act.
- (2) Facilities prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 12, paragraph (2), item (ii) of the Act are to be as follows:
- (i) long-term care health facilities;
 - (ii) long-term care homes;
 - (iii) nursing homes;
 - (iv) intensive care homes;
 - (v) low-cost homes for the elderly;
 - (vi) fee-based homes for the elderly; and
 - (vii) social welfare facilities provided in Article 62, paragraph (1) of the Social Welfare Act (Act No. 45 of 1951).
- (3) Cases prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 12, paragraph (2), item (v) of the Act are to be as follows:
- (i) when a physician who has managed a hospital or clinic intends to manage a clinic to be established in an area equivalent to an area where the securing of physicians is particularly necessary, and if the prefectural governor finds it appropriate; and
 - (ii) other cases found to be appropriate by the prefectural governor.

- Article 9-2 (1) The organizer of a regional medical care support hospital must submit a written report on services that includes the following particulars to the prefectural governor:
- (i) the outcome of provision of medical care to referred patients and referral of patients to other hospitals or clinics;
 - (ii) the outcome of shared use;
 - (iii) the outcome of provision of emergency medical care;
 - (iv) the outcome of training to enhance the quality of community medical care professionals;
 - (v) the method of systematically managing records on medical care and the management and operation of the hospital;
 - (vi) the method and outcome of inspection of records on medical care and the management and operation of the hospital;

- (vii) the outcome of holding committee meetings provided in Article 9-19, paragraph (1); and
 - (viii) the outcome of patient consultations.
- (2) The written report provided in the preceding paragraph is to be submitted to the prefectural governor by October 5 every year.
- (3) The prefectural governor is to make public the details of the written report provided in paragraph (1) using the Internet or by other appropriate means pursuant to the provisions of Article 12-2, paragraph (2) of the Act.

Article 9-2-2 (1) The organizer of an advanced treatment hospital must submit a written report on services that includes the following particulars to the Minister of Health, Labour and Welfare:

- (i) the number of advanced medical care provided;
- (ii) the number of advanced medical technology developed and evaluated;
- (iii) the number of trainings on advanced medical care provided;
- (iv) the method of systematically managing records on medical care and the management and operation of the hospital;
- (v) the method and number of inspection of records on medical care and the management and operation of the hospital provided;
- (vi) the outcome of provision of medical care to referred patients and referral of patients to other hospitals or clinics;
- (vii) the number of physicians, dentists, pharmacists, nurses, assistant nurses, registered dietitians, and other employees;
- (viii) the administrator's experience in safety management of medical care;
- (ix) the number of inpatients, outpatients, and dispensations;
- (x) the number of inpatients and outpatients for dentistry, orthodontics, pediatric dentistry, and dental surgery;
- (xi) the status concerning the operation of the panel under the provisions of Article 10-2, paragraph (2) of the Act;
- (xii) the status concerning the operation of the panel under the provisions of Article 16-3, paragraph (2) of the Act;
- (xiii) the status concerning the authority of the administrator under the provisions of Article 19-2, item (i) of the Act;
- (xiv) the status concerning the securing of a system for ensuring that the services provided by the administrator under the provisions of Article 19-2, item (iii) of the Act comply with laws and regulations, and a system for the supervision of the services of the advanced treatment hospital by the organizer;
- (xv) the list of members of the audit committee provided in Article 15-4, item (ii), the reason for the selection of the members, and the status of publication of the list of the members and the reason for the selection of the members;

and

- (xvi) the status concerning the securing of a system set forth in each item of Article 1-11, paragraph (1), publication under the provisions of Article 7-2-2, and the matters set forth in Article 9-20-2, paragraph (1), items (i) through (xiii) and Article 15-4, items (ii) and (iv).
- (2) The written report provided in the preceding paragraph is to be submitted to the Minister of Health, Labour and Welfare by October 5 every year.
- (3) When the Minister of Health, Labour and Welfare has received a written report provided in paragraph (1), the Minister must send a copy of the report to the prefectural governor of the location of the hospital without delay.
- (4) The provisions of paragraph (3) of the preceding Article apply mutatis mutandis if the Minister of Health, Labour and Welfare makes public the details of the written report of paragraph (1) pursuant to the provisions of Article 12-3, paragraph (2) of the Act.

Article 9-2-3 (1) The organizer of a core clinical research hospital must submit a written report on services that includes the following particulars to the Minister of Health, Labour and Welfare:

- (i) the number of planning and implementation of specified clinical trials conducted;
 - (ii) if the hospital conducts specified clinical trial jointly with other hospitals or clinics, the outcome showing that the hospital played a leading role in the implementation of the specified clinical trial;
 - (iii) the outcome showing that the hospital provided consultation on the implementation of specified clinical trial and provided necessary information, advice, and other support to other hospitals or clinics;
 - (iv) the outcome of training on specified clinical trial;
 - (v) the method of systematically managing records on medical care, clinical research, and the management and operation of the hospital;
 - (vi) the number of physicians, dentists, pharmacists, nurses, and other employees;
 - (vii) the administrator's experience in safety management of medical care;
 - (viii) the list of members of the audit committee provided in Article 9-25, item (iv), (e), the reason for the selection of the members, and the status of publication of the list of the members and the reason for the selection of the members; and
 - (ix) the status on the maintenance of a system set forth in each item of Article 1-11, paragraph (1) and each item of Article 9-25.
- (2) The written report provided in the preceding paragraph is to be submitted to the Minister of Health, Labour and Welfare by October 5 every year.
 - (3) When the Minister of Health, Labour and Welfare has received a written

report provided in paragraph (1), the Minister must send a copy of the report to the prefectural governor of the location of the hospital without delay.

(4) The provisions of Article 9-2, paragraph (3) apply mutatis mutandis if the Minister of Health, Labour and Welfare makes public the details of the written report of paragraph (1) pursuant to the provisions of Article 12-4, paragraph (2) of the Act.

Article 9-3 The administrator of a hospital or clinic must post the particulars set forth in Article 14-2, paragraph (1), items (i) through (iii) of the Act and the particulars set forth in the following Article in a visible location near the entrance, reception, or waiting area of the hospital or clinic.

Article 9-4 Particulars prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 14-2, paragraph (1), item (iv) of the Act is to be the information concerning the inside of the buildings (limited to hospitals).

Article 9-5 The administrator of a birthing center must post the particulars set forth in Article 14-2, paragraph (2), items (i) through (iii) of the Act and the particulars set forth in the following Article in a visible location near the entrance, reception, or waiting area of the birthing center.

Article 9-6 Particulars prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 14-2, paragraph (2), item (iv) of the Act is to be the name of the contract physician of the birthing center or the name of the hospital or clinic provided in Article 15-2, paragraph (2) (the name of the clinical department of which the physician in the same paragraph is in charge is to also be presented), and the name of the hospital or clinic commissioned by the birthing center.

Article 9-7 Standards prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 15-2 of the Act are as follows; provided, however, that the standards set forth in item (v) (limited to those pertaining to the ledgers set forth in (b) or (c) of the same item) apply only when internal quality control survey (meaning quality control on specimen examination conducted by medical care professionals of the hospital, etc.; the same applies in paragraph (1) of the following Article and Article 9-7-3, paragraph (1)) or external quality control survey (meaning quality control survey conducted by a prefecture or other persons deemed to be appropriate; the same applies in paragraph (2) of the following Article and Article 9-7-3, paragraph (2)) has been conducted:

(i) persons provided in (a) through (c) below are secured as persons responsible for ensuring the accuracy of specimen examination, according to the types of

- place set forth in (a) through (c) below:
- (a) a hospital or clinic carrying out medical practices, or a hospital or clinic carrying out medical and dental practices that mainly carries out medical practices: a physician or clinical laboratory technician;
 - (b) a hospital or clinic carrying out dental practices, or a hospital or clinic carrying out medical and dental practices that mainly carries out dental practices: a dentist or clinical laboratory technician;
 - (c) a birthing center: a birthing assistant;
- (ii) for providing services of genetic and chromosomal examination provided in Article 1, item (vii) of the Enforcement Regulation on the Act on Clinical Laboratory Technicians (Ministry of Health and Welfare Order No. 24 of 1958) (hereinafter referred to as "genetic and chromosomal examination"), persons provided in (a) and (b) below are secured as persons responsible for ensuring the accuracy of the genetic and chromosomal examination, according to the types of place set forth in (a) and (b) below:
- (a) a hospital or clinic carrying out medical practices, or a hospital or clinic carrying out medical and dental practices that mainly carries out medical practices: a physician or clinical laboratory technician with considerable experience in services of genetic and chromosomal examination or a person with considerable knowledge and experience in services of genetic and chromosomal examination;
 - (b) a hospital or clinic carrying out dental practices, or a hospital or clinic carrying out medical and dental practices that mainly carries out dental practices: a dentist or clinical laboratory technician with considerable experience in services of genetic and chromosomal examination or a person with considerable knowledge and experience in services of genetic and chromosomal examination;
- (iii) the following standard operation manuals are always available and made known to persons engaged in services of specimen examination (hereinafter referred to as "examination services"); provided, however, that in the case of a hospital, etc. which carries out separation of blood into serum and blood clots only (hereinafter referred to as "serum separation"), it is not required to describe particulars other than those pertaining to serum separation in the standard operation manual set forth in (b), and in the case of a hospital, etc. which does not carry out serum separation, it is not required to describe particulars pertaining to serum separation in the standard operation manual set forth in (b):
- (a) the standard operation manual for maintenance and management of examination equipment;
 - (b) the standard operation manual for measurement;
- (iv) the following work logs are prepared; provided, however, that in the case of

a hospital, etc. which carries out serum separation only, it is not required to describe particulars other than those pertaining to serum separation in the work log set forth in (b), and in the case of a hospital, etc. which does not carry out serum separation, it is not required to describe particulars pertaining to serum separation in the work log set forth in (b):

- (a) the work log for maintenance and management of examination equipment;
- (b) the work log for measurements;
- (v) the following ledgers are prepared; provided, however, that in the case of a hospital, etc. which carries out serum separation only, it is not required to prepare the ledgers:
 - (a) the reagent management ledger;
 - (b) the statistical quality control ledger; and
 - (c) the external quality control ledger.

Article 9-7-2 (1) When the administrator of a hospital, etc. provides examination services (excluding those related to genetic and chromosomal examination; the same applies in this Article) in the hospital, etc., the administrator must endeavor to give consideration so that internal quality control (excluding those related to genetic and chromosomal examination) is carried out by establishing a system for quality control in which a person responsible for ensuring the accuracy of specimen examination is assigned under the administrator.

- (2) The administrator of a hospital, etc. must endeavor to undertake external quality control survey with regard to the examination services in the hospital, etc.; provided, however, that this does not apply to a hospital, etc. which carries out serum separation only.
- (3) The administrator of a hospital, etc. must endeavor to have persons engaged in examination services take necessary training on examination services of the hospital, etc.

Article 9-7-3 (1) When the administrator of a hospital, etc. provides services related to genetic and chromosomal examination in the relevant hospital, etc., the administrator must endeavor to give consideration so that internal quality control (limited to those related to genetic and chromosomal examination) is carried out by establishing a system for quality control conducted mainly by a person, under the administrator, responsible for ensuring the accuracy of genetic and chromosomal examination.

- (2) When the administrator of a hospital, etc. provides services of genetic and chromosomal examination in the hospital, etc., the administrator must endeavor to mutually confirm the accuracy of genetic and chromosomal examination by undertaking external quality control survey or through

coordination with the administrator of other hospitals, etc. which conduct one or more genetic and chromosomal examinations, the organizer of a sanitary inspection station, or a person set forth in Article 15-3, paragraph (1), item (ii) of the Act to use specimens they store or possess, in order to ensure the accuracy of genetic and chromosomal examination; provided, however, that this does not apply to a hospital, etc. which carries out serum separation only.

- (3) The administrator of a hospital, etc. must have persons engaged in services of genetic and chromosomal examination take necessary training on services of genetic and chromosomal examination in the hospital, etc.

Article 9-7-4 Places prescribed by Order of the Ministry of Health, Labour and Welfare, as provided in Article 15-3, paragraph (1), item (ii) of the Act are to be facilities specified by the Minister of Health, Labour and Welfare pursuant to the provisions of Article 20-3, paragraph (1) of the Act on Clinical Laboratory Technicians (Public Notice of the Ministry of Welfare No. 17 of 1981; hereinafter referred to as "facility public notice" in the following Article).

Article 9-8 (1) Standards prescribed by Order of the Ministry of Health, Labour and Welfare in a hospital or clinic provided in Article 15-3, paragraph (1), item (ii) of the Act or facility provided in the preceding Article (excluding facilities provided in item (iv) of the facility public notice) are to be as follows:

- (i) as a person responsible for services entrusted (hereinafter referred to as "entrusted services"), a physician with considerable experience in the examination services has been assigned to the place where entrusted services are provided or, as a person responsible for entrusted services, a clinical laboratory technician with considerable experience in the examination services has been assigned to the place where entrusted services are provided, and a physician for the instruction and supervision of entrusted services (hereinafter referred to as "supervising physician" in Appended Table 1-3) has been appointed;
- (ii) as persons engaged in entrusted services, the necessary number of physicians or clinical laboratory technicians, and other persons who have knowledge and skills for providing entrusted services has been assigned to the place where entrusted services are provided;
- (iii) beyond the person responsible for entrusted services set forth in item (i) and the person set forth in the preceding item, a physician or clinical laboratory technician (limited to those who have considerable experience in the examination services and considerable knowledge and experience in quality control) is secured as a person who is solely engaged in quality control (meaning appropriately maintaining the accuracy of specimen examination; the same applies hereinafter);

- (iv) in the case of providing services of genetic and chromosomal examination, a physician or clinical laboratory technician with considerable experience in services of genetic and chromosomal examination or a person with considerable knowledge and experience in services of genetic and chromosomal examination is secured as a person responsible for ensuring the accuracy of genetic and chromosomal examination;
- (v) beyond an electric refrigerator, electric freezer, and centrifuge, examination machines and devices set forth in the right column of Appended Table 1-2 are prepared for conducting examinations listed in the left column of the same Table according to the details of examination listed in the middle column of the same Table; provided, however, that this does not apply if examination machines and devices of the entrusting person are used;
- (vi) a standard operation manual containing particulars set forth in Appended Table 1-3 is always available and made known to persons engaged in services;
- (vii) an operational guide containing the following particulars is always available:
 - (a) the examination method;
 - (b) the reference values and determination criteria;
 - (c) the range of examination values for which an urgent report is made to a hospital or clinic;
 - (d) in the case of examination conducted outside the hospital or clinic, the number of days required;
 - (e) in the case of entrusting a part of examination, the name of a person who actually conducts the examination;
 - (f) the conditions, containers, and quantity of specimens to be collected;
 - (g) the conditions for the submission of specimens;
 - (h) the items to be provided in the examination request and specimen label;
 - (i) the service management system;
- (viii) the following work logs (limited to those for which a column for describing responses to accidents and abnormalities is provided) are prepared in accordance with the procedures for entry in work logs provided in the standard operation manual listed in the left column of Appended Table 1-3; provided, however, that in the case of a place which carries out serum separation only, it is not required to prepare the work logs set forth in (c) and (f), and in the case of a place which does not carry out serum separation, it is not required to prepare the work log set forth in (d):
 - (a) the work log for specimen reception;
 - (b) the work log for specimen transportation;
 - (c) the work log for acceptance and sorting of specimens;
 - (d) the work log for serum separation;

- (e) the work log for maintenance and management of examination equipment;
- (f) the work log for measurement;
- (ix) the following ledgers are prepared in accordance with the procedures for entry in ledgers provided in the standard operation manual listed in the left column of Appended Table 1-3; provided, however, that in the case of a place which carries out serum separation only, it is not required to prepare the ledgers set forth in (b) through (g) and (j):
 - (a) a ledger for entrusted examination management;
 - (b) a reagent management ledger;
 - (c) a ledger for temperature and equipment management;
 - (d) a statistical quality control ledger;
 - (e) an external quality control ledger;
 - (f) a ledger for storage, return, and disposal of specimens;
 - (g) a ledger for examination request information and examination result information;
 - (h) a ledger for examination results report;
 - (i) a complaint processing ledger;
 - (j) a ledger for educational training and skill evaluation record; and
- (x) appropriate training is provided to persons engaged in services.
- (2) Standards prescribed by Order of the Ministry of Health, Labour and Welfare in the facility of the preceding Article as provided in Article 15-3, paragraph (1), item (ii) of the Act (limited to facilities provided in item (iv) of the facility public notice) are the organizer of the facility.

Article 9-8-2 Medical devices prescribed by Order of the Ministry of Health, Labour and Welfare as provided in Article 4-7, item (iv) of the Order is to be medical devices requiring special maintenance and management provided in Article 2, paragraph (8) of the Act on Pharmaceuticals and Medical Devices.

Article 9-9 (1) Standards for a person who is capable of properly providing services of sterilization or disinfection of medical devices, clothing used for medical treatment or surgery, or other textile products (hereinafter referred to as "sterilization and disinfection") pursuant to the provisions of Article 15-3, paragraph (2) of the Act are as follows; provided, however, that if disinfection of clothing and other textile products (hereinafter referred to as "textile products") used for medical treatment or surgery performed pursuant to the provisions of Article 3, paragraph (3), item (v) of the Laundries Act (Act No. 207 of 1950) is solely entrusted, the standards are to be those set forth in item (xiii):

- (i) a physician, dentist, pharmacist, nurse, dental hygienist, clinical laboratory

- technician, or clinical engineer with considerable experience in the services of sterilization and disinfection (hereinafter referred to as "sterilization and disinfection services") has been secured as a person responsible for entrusted services; provided, however, that when providing sterilization and disinfection services in a hospital, clinic, or birthing center, a person with considerable knowledge and experience in sterilization and disinfection services may be appointed as a person responsible for entrusted services;
- (ii) a physician, etc. with considerable knowledge and experience in sterilization and disinfection services has been appointed as a person who provides instruction and advice on entrusted services; provided, however, that this does not apply when sterilization and disinfection services are provided in facilities of a hospital, clinic, or birthing center;
 - (iii) a person with knowledge and skills necessary for handling devices used in sterilization and disinfection processes and for providing entrusted services has been secured as a person engaging in services;
 - (iv) the buildings and equipment are safe and sanitary;
 - (v) the sterilization and disinfection room, room for cleaning and packaging textile products, and room for storing sterilized or disinfected medical devices or textile products are separated;
 - (vi) the sterilization and disinfection room has a sufficient space and structure to provide entrusted services appropriately;
 - (vii) the devices and equipment in the sterilization and disinfection room are placed in order of operation process;
 - (viii) the materials for the floor and inner wall of the sterilization and disinfection room are impermeable materials (meaning concrete, tile, and other materials that do not permeate polluted water);
 - (ix) the storage room has a structure which indoor air is not directly polluted by air from the outside and from other areas;
 - (x) the following devices and equipment or devices and equipment with alternative functions have been prepared:
 - (a) high-pressure steam sterilizer;
 - (b) ethylene oxide gas sterilizer and forced deaerator;
 - (c) ultrasonic cleaner;
 - (d) washer disinfectant device (meaning a device which continuously performs cleaning and disinfection) or washer sterilizer device (meaning a device which continuously performs cleaning and sterilization);
 - (xi) sewage treatment facilities and drainage facilities have been established; provided, however, that this does not apply when shared sewage treatment facilities are used;
 - (xii) a transporting vehicle and a sealed, waterproof, and penetration-resistant transporting container have been prepared; provided, however, that it is not

- required to have a transporting vehicle when sterilization and disinfection services are provided in facilities of a hospital, clinic, or birthing center;
- (xiii) when disinfection of textile products is performed at a facility pursuant to the provisions of Article 3, paragraph (3), item (v) of the Laundries Act, a notification on the establishment of a cleaning office has been made to the prefectural governor pursuant to the provisions of Article 5, paragraph (1) of the Laundries Act;
 - (xiv) a standard operation manual containing the following particulars is always available and made known to persons engaged in services:
 - (a) transportation;
 - (b) the method of sterilization and disinfection process;
 - (c) the maintenance and inspection of devices used for sterilization and disinfection process;
 - (d) particulars pertaining to the responsibility in the case of a defect in the sterilization and disinfection process;
 - (xv) an operation guide containing the following items is always available:
 - (a) the items of medical devices and textile products handled;
 - (b) the method of sterilization and disinfection process;
 - (c) the method of checking sterilization;
 - (d) the transportation method;
 - (e) the required number of days;
 - (f) the outline of facilities where sterilization and disinfection are performed;
 - (g) the service management system; and
 - (xvi) appropriate training is provided to persons engaged in services.
- (2) Notwithstanding the provisions of the preceding paragraph, if the sterilization and disinfection services are provided in facilities of a hospital, clinic, or birthing center, and if it is found that the hospital, clinic, or birthing center has appropriate buildings and equipment for providing sterilization and disinfection services, the provisions of items (iv) through (xi) of the preceding paragraph do not apply.

Article 9-10 The requirements for a party with the ability to properly undertake the operations of providing meals for patients, pregnant women, women in labor, or women resting after childbirth (hereinafter referred to as "providing meals for patients, etc.") at a hospital under Article 15-3, paragraph (2) of the Act are as follows:

- (i) when cooking operations are entrusted, the place to perform the entrusted operations has a person who has considerable knowledge and experience of the operations of providing meals for patients, etc. as a person responsible for the entrusted operations;
- (ii) when cooking operations are entrusted, the party has any of the following

- persons as a person who provides guidance and advice on the entrusted operations:
- (a) a physician with experience as the administrator of a hospital;
 - (b) a physician with experience as a person responsible for the food service section of a hospital;
 - (c) a physician with expertise relevant to clinical nutrition; or
 - (d) a registered dietitian who has at least five years' experience in the operations of providing meals for patients, etc. at a hospital;
- (iii) when cooking operations are entrusted, the place to perform the entrusted operations has a dietitian (when menu preparation operations are entrusted, a dietitian who has knowledge and skills concerning therapeutic diets (meaning diets for treatment or health recovery));
- (iv) the party has persons with knowledge and skills necessary for performing the entrusted operations as employees;
- (v) when cooking operations are entrusted, the place to perform the entrusted operations has the employees referred to in the preceding item (limited to those engaged in cooking operations);
- (vi) when dish washing operations are performed outside a hospital, the party has dish disinfection equipment;
- (vii) when cooking operations or dish washing operations are performed outside the hospital, appropriate sanitary measures are taken with regard to the means of transportation;
- (viii) standard operation manuals containing the following particulars are always available and made known to employees:
- (a) the method of providing timely meals at a proper temperature;
 - (b) the method of treating dishes; and
 - (c) the method of maintaining cleanliness of the facilities where the entrusted operations are performed;
- (ix) operational guides describing the following particulars are always available:
- (a) the distribution of personnel;
 - (b) the method of providing timely meals at a proper temperature, and whether or not to provide meals where the menu can be chosen by patients; and
 - (c) the business management system;
- (x) the party has the ability to perform the entrusted operations in a continuous and stable manner;
- (xi) the party can formulate a specific improvement plan for a hospital's goals related to providing meals;
- (xii) appropriate health management is provided for employees; and
- (xiii) appropriate training is provided to employees.

Article 9-11 The requirements for a party with the ability to properly undertake the operations of transporting patients, pregnant women, women in labor, or women resting after childbirth between hospitals, clinics, or birthing centers, and other transportation operations, including transporting grave patients together with physicians or dentists, under Article 15-3, paragraph (2) of the Act are as follows:

- (i) the party has a person who has considerable knowledge and experience of transporting patients, pregnant women, women in labor, or women resting after childbirth as a person responsible for the entrusted operations;
- (ii) the party has persons with knowledge and skills necessary for performing the entrusted operations as employees;
- (iii) the party has an automobile for transportation that meets the following requirements:
 - (a) it can securely fix a stretcher or wheelchair;
 - (b) it is equipped with a car phone or mobile phone;
 - (c) if a physician is to be on board, it has space large enough to perform medical treatment;
 - (d) it has a sufficient buffer; and
 - (e) it is equipped with a ventilator and air conditioner;
- (iv) the party has the following materials and instruments:
 - (a) stretchers, pillows, rugs, blankets, thermometers, kidney dishes, and waste containers; and
 - (b) when a physician is to be on board, a stethoscope, sphygmomanometer, electrocardiograph, manual or automatic ventilator, oxygen inhaler, aspirator, and equipment for hanging an infusion bag;
- (v) standard operation manuals containing the following particulars are always available and made known to employees:
 - (a) the method of first-aid treatment for any sudden change in a patient being transported;
 - (b) patient observation guidelines;
 - (c) coordination with the attending physician; and
 - (d) the sterilization or disinfection and maintenance of the automobile for transportation, and of the materials and instruments to be loaded thereon;
- (vi) operational guides describing the following particulars are always available:
 - (a) use charges;
 - (b) the structure of the automobile for transportation, and the materials and instruments to be loaded thereon; and
 - (c) the business management system;
- (vii) appropriate training is provided to employees.

Article 9-12 The requirements for a party with the ability to properly undertake the operations of maintaining and inspecting the medical devices prescribed in Article 9-8-2 under Article 15-3, paragraph (2) of the Act are as follows:

- (i) the party has a person who has considerable knowledge and at least three years' experience in the operations of maintaining and inspecting medical devices as a person responsible for the entrusted operations;
- (ii) the party has persons with knowledge and skills necessary for performing the following operations as employees:
 - (a) maintenance and inspection;
 - (b) when the operations of maintaining and inspecting medical devices used to provide medical care using hyperbaric oxygen or other dangerous or harmful substances are entrusted, the exchange and delivery of the dangerous or harmful substances;
 - (c) communication with medical institutions; and
 - (d) when the operations of maintaining and inspecting medical devices provided for medical care outside a hospital, clinic, or birthing center are entrusted, communication with patients and their families;
- (iii) standard operation manuals containing the following particulars are always available and made known to employees:
 - (a) the maintenance and inspection method; and
 - (b) inspection records;
- (iv) operational guides describing the following particulars are always available:
 - (a) the maintenance and inspection method; and
 - (b) contact information and remedies in the event of failure; and
 - (c) the business management system;
- (v) appropriate training is provided to employees.

Article 9-13 The requirements for a party with the ability to properly undertake the operations of maintaining and inspecting gas supply equipment provided for medical care under Article 15-3, paragraph (2) of the Act are as follows:

- (i) the party has a person who has a qualification as a Sales Safety Chief or a Production Safety Manager under the High Pressure Gas Safety Act (Act No. 204 of 1951) and at least three years' experience in the operations of maintaining and inspecting gas supply equipment provided for medical care as a person responsible for the entrusted operations;
- (ii) the party has persons with knowledge necessary for performing the entrusted operations as employees;
- (iii) the party has a pressure gauge (including a vacuum gauge), airtightness test equipment, flow meter, oxygen content meter, and other materials and

- instruments necessary for maintaining and inspecting gas supply equipment provided for medical care;
- (iv) standard operation manuals containing the following particulars are always available and made known to employees:
 - (a) the maintenance and inspection method; and
 - (b) inspection records;
- (v) operational guides describing the following particulars are always available:
 - (a) the maintenance and inspection method; and
 - (b) the business management system;
- (vi) appropriate training is provided to employees.

Article 9-14 The requirements for a party with the ability to properly undertake the operations of washing the bedding of patients, pregnant women, women in labor, or women resting after childbirth, or clothing lent thereto (hereinafter referred to as "bedding, etc.") under Article 15-3, paragraph (2) of the Act are as follows; provided, however, that when the operations at a clinic or birthing center are entrusted, the following items other than item (x) are excluded:

- (i) the party has employees necessary for performing the entrusted operations;
- (ii) laundry facilities are separated by partitions and others from the outside and other facilities such as living rooms and toilets;
- (iii) respective places to receive, wash, finish, and deliver bedding, etc. have the space and structure necessary for treating and sanitarily maintaining the laundry, and are separated from one another;
- (iv) laundry facilities are structurally capable of being well lighted, illuminated, and ventilated;
- (v) the party has necessary machines and tools for disinfection, washing, spinning, drying, and pressing;
- (vi) the party has a storage cabinet, closet, or the like dedicated for storing disinfectants, detergents, organic solvents, and others used for treating the laundry;
- (vii) facilities for storing the finished laundry are installed in a clean place;
- (viii) places to receive and deliver bedding, etc. are equipped with a receiving table and a delivering table of an appropriate size corresponding to the quantity to be handled;
- (ix) appropriate sanitary measures are taken with regard to the means of transporting bedding, etc.;
- (x) with regard to the facilities where the entrusted operations are performed, a notification of the establishment of a laundry has been submitted to the relevant prefectural governor pursuant to the provisions of Article 5, paragraph (1) of the Laundries Act;

- (xi) standard operation manuals containing the following particulars are always available and made known to employees:
 - (a) the method of transportation;
 - (b) the method of treating the laundry received from a medical institution; and
 - (c) the method of maintaining cleanliness of the facilities;
- (xii) operational guides describing the following particulars are always available:
 - (a) the method of washing bedding, etc.; and
 - (b) the business management system;
- (xiii) appropriate training is provided to employees.

Article 9-15 The requirements for a party with the ability to properly undertake the operations of cleaning facilities provided for physicians' or dentists' medical care or birthing assistants' duties, or facilities provided for patients' hospitalization, under Article 15-3, paragraph (2) of the Act are as follows; provided, however, that this does not apply when the operations at a clinic or birthing center are entrusted:

- (i) the place to perform the entrusted operations has a person who has considerable knowledge and experience of the cleaning of facilities as a person responsible for the entrusted operations;
- (ii) the place to perform the entrusted operations has persons with knowledge necessary for performing the entrusted operations as employees;
- (iii) the party has a set of cleaning equipment, such as a vacuum cleaner (when cleaning clean areas (meaning an operating room, intensive care unit and other places that particularly need to be kept clean), a vacuum cleaner with a high-performance air filter or any other device having an alternative function) and a floor polisher;
- (iv) standard operation manuals containing the following particulars are always available and made known to employees:
 - (a) the method of operation at each area;
 - (b) the methods of using and managing cleaning equipment, disinfectants and others; and
 - (c) the prevention of infection;
- (v) operational guides describing the following particulars are always available:
 - (a) the business outline, and the method of operation;
 - (b) cleaning equipment; and
 - (c) the business management system;
- (vi) appropriate training is provided to employees.

Article 9-15-2 The cases prescribed by Order of the Ministry of Health, Labour, and Welfare referred to in Article 16 of the Act are the cases where the prefectural governor of the location of a hospital recognizes in advance that the administrator of the hospital has ensured a system for providing prompt medical care by a physician thereof even if the symptoms of a patient hospitalized therein change suddenly.

Article 9-16 The administrator of a regional medical care support hospital must undertake the particulars set forth in Article 16-2, paragraph (1), items (i) through (vi) of the Act in accordance with the following items:

- (i) implementing shared use in accordance with the following:
 - (a) ensuring a system for the smooth implementation of shared use;
 - (b) determining the scope of buildings, equipment, instruments, or tools of the relevant hospital that become subject to shared use in advance after consultation with physicians, dentists, pharmacists, nurses, and other medical care professionals related to the shared use;
 - (c) providing information on the scope of buildings, equipment, instruments, or tools of the relevant hospital that become subject to shared use and other particulars concerning shared use to physicians, dentists, pharmacists, nurses, and other medical care professionals in the relevant area; and
 - (d) securing beds dedicated for shared use at all times;
- (ii) providing emergency medical care in accordance with the following:
 - (a) ensuring a system for providing medical care to severe emergency patients at all times; and
 - (b) ensuring a system for smoothly accepting emergency patients from other hospitals, clinics, and others;
- (iii) appropriately providing lifelong education and other training to local medical care professionals in order to enhance their qualities;
- (iv) appointing a person responsible for and a person in charge of the management of records concerning medical care and the management and operation of the relevant hospital, and managing the records by appropriately classifying them;
- (v) designating a person responsible for and a person in charge of the inspection of records concerning medical care and the management and operation of the relevant hospital, as well as a place to respond to requests for the inspection, and posting the place in a clearly visible manner;
- (vi) providing medical care to referral patients in accordance with the following:
 - (a) limiting the provision of medical care at the hospital under the management of the administrator to referral patients, in principle; and

- (b) referring a referral patient who has been provided with necessary medical care to the medical institution which has made the referral or any other appropriate medical institution according to the symptoms of the patient.

Article 9-17 The persons as prescribed by Order of the Ministry of Health, Labour and Welfare provided for in Article 16-2, paragraph (1), item (v) of the Act are local governments and a dentist who wishes to refer a patient to the relevant regional medical care support hospital.

Article 9-18 The records which are prescribed by Order of the Ministry of Health, Labour and Welfare provided for in Article 16-2, paragraph (1), item (v) of the Act are books that clarify the results of shared use, the results of provision of emergency medical care, the results of training for enhancing the qualities of local medical care professionals, the results of inspections, and the results of provision of medical care to referral patients and referral of patients to other hospitals or clinics.

Article 9-19 (1) The particulars as prescribed by Order of the Ministry of Health, Labour and Welfare provided for in Article 16-2, paragraph (1), item (vii) of the Act are to establish a committee mainly consisting of persons with relevant expertise who do not work at the relevant hospital and to ensure a system for appropriately responding to consultations from patients in the hospital.

(2) The committee established pursuant to the provisions of the preceding paragraph is to deliberate on the particulars that are necessary for the appropriate implementation of operations related to the necessary support to ensure community medical care, and is to state its opinions to the administrator of the relevant hospital as necessary.

Article 9-20 (1) The administrator of an advanced treatment hospital must undertake the particulars set forth in the items of Article 16-3, paragraph (1) of the Act in accordance with the following items:

- (i) providing advanced medical care in accordance with the following:
 - (a) providing medical care that is usually difficult to provide at hospitals other than advanced treatment hospitals;
 - (b) ensuring a system for appropriately conducting clinical examinations and pathological diagnoses;
 - (c) ensuring the systems set forth in the items of Article 1-11, paragraph (1), and carrying out the particulars set forth in paragraph (1), items (i) through (xiii) of the following Article; and
 - (d) preparing the written report provided for in paragraph (1), item (xiv) of the following Article;

- (ii) carrying out the development and evaluation of advanced medical technology in accordance with the following:
 - (a) researching and developing technology related to medical care that is usually difficult to provide at hospitals other than at advanced treatment hospitals; and
 - (b) appropriately evaluating the validity and safety of medical technology;
- (iii) appropriately providing clinical training on advanced medical care (excluding that prescribed by Article 16-2, paragraph (1) of the Medical Practitioners Act and Article 16-2, paragraph (1) of the Dental Practitioners Act);
- (iii)-2 carrying out the particulars provided for in the items of paragraph (1) of the following Article as those related to ensuring a high level of safety in medical care;
- (iv) appointing a person responsible for and a person in charge of the management of records concerning medical care and the management and operation of the relevant hospital, and managing the records by appropriately classifying them;
- (v) designating a person responsible for and a person in charge of the inspection of records concerning medical care and the management and operation of the relevant hospital, as well as a place to respond to requests for the inspection, and posting the place in a clearly visible manner;
- (vi) providing medical care to referral patients in accordance with the following:
 - (a) with regard to the hospital under the management of the administrator, maintaining the number obtained by dividing the total number of referral patients and patients transported by ambulance by the number of patients seen for the first time (excluding those seen on holidays or at night; the same applies in (a) of the following item) (hereinafter referred to as the "referral rate" in this item), and endeavoring to increase the maintained referral rate; and
 - (b) for a hospital whose referral rate is lower than fifty percent, endeavoring to increase the referral rate to fifty percent within approximately five years, preparing a concrete annual plan for increasing it, and submitting the annual plan to the Minister of Health, Labour and Welfare;
- (vii) referring patients to other hospitals or clinics in accordance with the following:
 - (a) with regard to the hospital under the management of the administrator, maintaining the number obtained by dividing the number of patients referred to other hospitals or clinics by the number of patients seen for the first time (hereinafter referred to as the "reverse referral rate" in this item), and endeavoring to increase the maintained reverse referral rate;

and

(b) for a hospital whose reverse referral rate is lower than forty percent, endeavoring to increase the reverse referral rate to forty percent within approximately five years, preparing a concrete annual plan for increasing it, and submitting the annual plan to the Minister of Health, Labour and Welfare;

(2) For the purpose of application of the provisions of the preceding paragraph to advanced treatment hospitals that provide advanced and specialized medical care for cancers, cardiovascular diseases, and other diseases having a serious impact on the health of citizens, the term "fifty percent" in item (vi), (b) of the same paragraph is deemed to be replaced with "eighty percent," and the term "forty percent" in item (vii), (b) of the same paragraph is deemed to be replaced with "sixty percent."

Article 9-20-2 (1) The particulars provided for in paragraph (1), item (iii)-2 of the preceding Article are as follows:

- (i) assigning a person responsible for medical safety management, and having the person supervise the medical safety management division provided for in item (vi), medical safety management committee, person responsible for pharmaceutical safety management, and person responsible for medical device safety management;
- (ii) assigning a full-time person who takes measures against nosocomial infection;
- (iii) having the person responsible for pharmaceutical safety management carry out the following particulars beyond the matters set forth in Article 1-11, paragraph (2), item (ii), (a) through (c):
 - (a) arranging and disseminating information on pharmaceuticals that contributes to operations for their safe use, and checking the dissemination status;
 - (b) with regard to the use of unapproved pharmaceuticals, constructing a systematic mechanism to ascertain the usage status of the unapproved pharmaceuticals, and checking the state of discussions on the necessity of the use of unapproved pharmaceuticals ascertained through the mechanism, providing necessary guidance, and sharing the results thereof; and
 - (c) appointing a person in charge of properly implementing the measures set forth in (a) and (b);
- (iv) assigning a person responsible for the explanations referred to in Article 1-4, paragraph (2) of the Act, preparing rules for persons present when the medical care professional provided for in the same paragraph (hereinafter referred to as the "medical care professional" in this item) gives the

- explanations, the standard contents of the explanations, and other methods necessary for providing the explanations in order to ensure that the medical care professional giving the explanations properly gains the understanding of the recipients of medical care;
- (v) appointing a person responsible for the management of medical and other records concerning medical care (hereinafter referred to as the "medical records, etc." in this item), having the responsible person check the contents of the medical records, etc., and thereby appropriately managing the medical records, etc.;
 - (vi) establishing a division for safety management related to medical care that has full-time physicians, pharmacists, and nurses (hereinafter referred to as the "medical safety management division" in this paragraph), and have the division perform the following operations:
 - (a) affairs related to the relevant medical safety management committee;
 - (b) if an accident or any other event deemed by the relevant administrator that requires to be handled by the medical safety management division occurs, checking medical and other records concerning medical care, explaining to relevant patients and their families, checking the status of responses, such as an investigation into the cause of the event, and providing necessary guidance to employees based on the results of the check;
 - (c) liaison and coordination concerning safety management related to medical care;
 - (d) promoting measures to ensure safety related to medical care; and
 - (e) ascertaining the status of medical care that contributes to ensuring safety related to medical care, and checking how much employees' awareness of medical safety is improved;
 - (vii) in the course of providing medical care using highly difficult new medical technology, taking the following measures:
 - (a) when providing medical care using highly difficult new medical technology, establishing a division that determines whether or not the highly difficult new medical technology should be provided;
 - (b) when providing medical care using highly difficult new medical technology, preparing rules specifying the particulars to be observed by employees and those to be checked by the division provided for in (a) in accordance with the standards separately prescribed by the Minister of Health, Labour and Welfare; and
 - (c) having the division provided for in (a) check the status of employees' compliance with the particulars specified in the rules provided for in (b);
 - (viii) in the course of providing medical care using unapproved new pharmaceuticals, taking the following measures:

- (a) when providing medical care using unapproved new pharmaceuticals, setting conditions for the use of the unapproved new pharmaceuticals, and establishing a division that determines whether or not the unapproved new pharmaceuticals should be used;
- (b) when providing medical care using unapproved new pharmaceuticals, preparing rules specifying the particulars to be observed by employees and those to be checked by the division provided for in (a) in accordance with the standards separately prescribed by the Minister of Health, Labour and Welfare; and
- (c) having the division provided for in (a) check the status of employees' compliance with the particulars specified in the rules provided for in (b);
- (ix) taking the following measures in order to contribute to safety management related to medical care:
 - (a) in the following cases, having employees promptly report to the medical safety management division on the following respective circumstances:
 1. when a hospitalized patient dies: the fact of the death and the situation prior to the death; or
 2. other than the case set forth in 1., when an event occurs at or above the level specified by the relevant administrator as requiring treatment or care that is not required under normal progress: the fact of the occurrence of the event and the situation prior to the occurrence;
 - (b) in the case of (a), having the medical safety management committee perform the following operations beyond those set forth in Article 1-11, paragraph (1), item (ii), (a) through (c):
 1. checking the status of implementation of the report under (a), and reporting the results of the check to the relevant administrator; and
 2. when the status of implementation provided for in 1. is insufficient, providing training and guidance to employees for appropriate reports;
- (x) taking the following measures in coordination with the administrators of other advanced treatment hospitals and the like:
 - (a) having employees enter another advanced treatment hospital or the like at least once a year and provide technical advice for improving safety management related to medical care as needed; and
 - (b) accepting the entry of employees provided for in (a) that is conducted by the administrator of another advanced treatment hospital or the like at least once a year, and receiving the technical advice provided for in (a);
- (xi) ensuring a system for appropriately responding to consultations related to safety management from patients in the relevant hospital;
- (xii) beyond the training for employees provided for in Article 1-11, paragraph (1), item (iii), providing training for employees on the following particulars:
 - (a) particulars concerning those set forth in the preceding items and in

- Article 15-4, items (ii) and (iv);
- (b) when the audit committee provided for in Article 19-2, item (ii) of the Act expresses its opinions as referred to in Article 15-4, item (ii), (d), 2., particulars concerning the opinions; and
 - (c) particulars concerning knowledge and skills required for physicians, dentists, pharmacists, nurses, and other employees to provide advanced medical care in coordination and cooperation;
 - (xiii) having the person responsible for medical safety management, person responsible for pharmaceutical safety management, and person responsible for medical device safety management regularly receive training for safety management related to medical care, and personally making an effort to regularly receive the training;
 - (xiv) if any of the following accidents or cases requiring to be reported (hereinafter referred to as the "accident, etc.") occurs in the relevant medical institution, preparing a written report on the case containing the following particulars (hereinafter referred to as a "written accident report") within two weeks from the date of occurrence of the case:
 - (a) a case where it is clear that incorrect medical care or management has been performed, and a patient dies or is left with mental or physical disability, or needs treatment or other care that is unexpected or
 - (b) a case where, although it is not clear that incorrect medical care or management has been performed, a patient dies or is left with mental or physical disability, or needs treatment or other care that is unexpected or exceeds what was initially expected as a result of the performed medical care or management (including a case suspected to be caused by the performed medical care or management, and limited to a case whose occurrence is unexpected); or
 - (c) beyond what is set forth in (a) and (b), a case that contributes to preventing the occurrence and recurrence of accidents in the medical institution.
- (2) The written accident report is to contain the following information:
- (i) the date, time, and place of occurrence of the accident, etc., and the relevant clinical department name;
 - (ii) information on the patient involved in the accident, etc., including the gender, age, and disease name thereof;
 - (iii) information on the medical personnel involved in the accident, etc., including the occupation thereof;
 - (iv) information on the details of the accident, etc.; and
 - (v) beyond what is set forth in the preceding items, necessary information on the accident, etc.

Article 9-21 The persons as prescribed by Order of the Ministry of Health, Labour and Welfare provided for in Article 16-3, paragraph (1), item (vi) of the Act are the national government, local governments, and a dentist who wishes to refer a patient to the relevant advanced treatment hospital.

Article 9-22 The records which are prescribed by Order of the Ministry of Health, Labour and Welfare provided for in Article 16-3, paragraph (1), item (vi) of the Act are books that clarify the number of employees, and books that clarify the results of provision of advanced medical care, the results of development and evaluation of advanced medical technology, the results of training on advanced medical care, the results of inspection, the results of provision of medical care to referral patients and referral of patients to other hospitals or clinics, the numbers of inpatients, outpatients, and dispensed prescriptions, as well as the particulars set forth in Article 9-20-2, paragraph (1), items (i) through (xiii) and the items of Article 15-4, and the status of ensuring the systems set forth in the items of Article 1-11, paragraph (1).

Article 9-23 (1) The particulars prescribed by Order of the Ministry of Health, Labour and Welfare provided for in Article 16-3, paragraph (2) of the Act are the relevant hospital's operating policies, mid-term plans, budgets and settlements, and other important particulars concerning its operation.

(2) The administrator of an advanced treatment hospital must deliberate on the particulars prescribed in the preceding paragraph with a council based on the provisions of Article 16-3, paragraph (2) of the Act and make a summary of the deliberation known to employees in order to manage and operate the hospital appropriately.

Article 9-24 The administrator of a core clinical research hospital must undertake the particulars set forth in the items of Article 16-4 of the Act in accordance with the following items:

- (i) drafting and implementing plans concerning specified clinical trials in accordance with the following:
 - (a) carrying out that in accordance with the standards provided for in the items of Article 6-5-3;
 - (b) ensuring the systems set forth in the items of Article 1-11, paragraph (1) and the items of Article 9-25; and
 - (c) maintaining the frequency of specified clinical trials, and endeavoring to increase the maintained frequency;
- (ii) when conducting a specified clinical trial jointly with other hospitals or clinics, playing a leading role in conducting the specified clinical trial in accordance with any of the following:

- (a) appointing a responsible person in the core clinical research hospital who supervises operations related to the implementation of the specified clinical trial; and
- (b) providing comprehensive support to the other hospitals or clinics with regard to the implementation of the specified clinical trial;
- (iii) providing other hospitals or clinics with consultation on the implementation of specified clinical trials, necessary information, advice, and other appropriate support, maintaining the frequency of the support, and endeavoring to increase the maintained frequency;
- (iv) providing appropriate training on specified clinical trials; and
- (v) appointing a person responsible for and a person in charge of the management of records concerning medical care, clinical research, and the management and operation of the relevant hospital, and managing the records by appropriately classifying them.

Article 9-25 The particulars as prescribed by Order of the Ministry of Health, Labour and Welfare provided for in Article 16-4, item (vi) of the Act are as follows:

- (i) ensuring a system for properly conducting specified clinical trials as follows:
 - (a) ensuring a management system, including establishing a committee for ensuring the proper implementation of specified clinical trials;
 - (b) establishing rules and procedures for ensuring the proper implementation of specified clinical trials; and
 - (c) establishing a contact point for accepting information from informants when any doubt arises concerning the proper implementation of specified clinical trials;
- (ii) ensuring a system for supporting specified clinical trials as follows:
 - (a) establishing a division for supporting the implementation of specified clinical trials;
 - (b) assigning a full-time person who is engaged in operations related to supporting the implementation of specified clinical trials; and
 - (c) establishing rules and procedures for operations related to supporting the implementation of specified clinical trials;
- (iii) ensuring a system for managing data to be used for statistical analysis and the like in conducting specified clinical trials as follows:
 - (a) establishing a division for managing data to be used for statistical analyses and the like in conducting specified clinical trials;
 - (b) assigning a full-time person who manages data to be used for statistical analyses and the like in conducting specified clinical trials; and
 - (c) establishing rules and procedures for the management of data to be used for statistical analyses and the like in conducting specified clinical trials.

- (iv) ensuring a system for safety management as follows:
 - (a) assigning a full-time person who manages pharmaceuticals and others to be used in specified clinical trials and a full-time person who manages safety related to specified clinical trials;
 - (b) establishing rules and procedures for safety management operations related to specified clinical trials;
 - (c) carrying out the particulars set forth in Article 9-20-2, paragraph (1), items (i), (iii) through (x), and (xiii);
 - (d) beyond the training for employees provided for in Article 1-11, paragraph (1), item (iii), providing training for employees on the following particulars:
 - 1. particulars concerning the matters set forth in Article 9-20-2, paragraph (1), items (i) and (iii) through (x), and (e) and (f);
 - 2. when the audit committee provided for in (e) expresses its opinions as referred to in (e), 4., ii., particulars concerning the opinions; and
 - 3. particulars concerning knowledge and skills required for physicians, dentists, pharmacists, nurses, and other employees to provide advanced medical care in coordination and cooperation;
 - (e) establishing an audit committee meeting the following requirements, and requesting the organizer of the relevant hospital to submit to the Minister of Health, Labour and Welfare and to publicize documents containing the list of committee members and the reasons for selecting the committee members:
 - 1. the number of committee members is three or more, and the chairperson and more than half of the committee members are appointed from persons who have no interest in the relevant hospital;
 - 2. the persons who have no interest provided for in 1. include the following persons:
 - i. persons with insight on safety management or laws related to medical care, or those with other relevant expertise; and
 - ii. persons other than medical care professionals, such as a recipient of medical care (excluding the persons set forth in i.);
 - 3. meetings are held at least twice a year;
 - 4. the following operations are conducted:
 - i. requesting reports from the administrator or the like on the status of operations performed by the person responsible for medical safety management, medical safety management division, medical safety management committee, person responsible for pharmaceutical safety management, person responsible for medical device safety management, and others, or checking the status thereof personally as necessary;
 - ii. if necessary, expressing an opinion that the organizer or administrator

- of the relevant hospital should take rectification measures for safety management related to medical care; and
- iii. publicizing the results of the operations set forth in i. and ii.;
 - (f) establishing a contact point for accepting information from informants when any doubt arises concerning the proper implementation of medical safety management after consultation with the relevant organizer, in accordance with the following:
 1. specifying the scope of information to be provided to the contact point, measures to prevent individuals who provide information from being identified, and other necessary particulars for the establishment of the contact point; and
 2. disseminating the contact point and how to use it to employees;
 - (v) having the clinical review board provided for in Article 23, paragraph (5), item (ii) of the Clinical Trials Act, and ensuring a review system for specified clinical trials;
 - (vi) ensuring a review system concerning the methods of receiving and managing money and other benefits related to specified clinical trials as follows:
 - (a) establishing a committee for reviewing whether the methods of receiving and managing money and other benefits related to specified clinical trials are appropriate;
 - (b) assigning a person who performs affairs related to the committee provided for in (a); and
 - (c) establishing rules and procedures for reviews to be conducted by the committee provided for in (a);
 - (vii) ensuring a system for promoting the appropriate management of intellectual property and the transfer of technology related to specified clinical trials as follows:
 - (a) assigning a full-time person who performs operations related to the management of intellectual property and the transfer of technology; and
 - (b) establishing rules and procedures for operations related to the management of intellectual property and the transfer of technology;
 - (viii) ensuring a system for public relations and enlightenment, and for responding to consultations from subjects of specified clinical trials and others as follows:
 - (a) ensuring a system for carrying out activities relevant to public relations and enlightenment concerning clinical research;
 - (b) establishing and publicizing clinical research guidelines;
 - (c) publicizing materials concerning the implementation status of specified clinical trials; and
 - (d) ensuring a system for appropriately responding to consultations from

trial subjects or their families with respect to specified clinical trials to be conducted by the relevant hospital;

- (ix) ensuring a system for providing evaluation treatment (meaning the evaluation treatment provided for in Article 63, paragraph (2), item (iii) of the Health Insurance Act (Act No. 70 of 1922); hereinafter the same applies in this item) and patient requested treatment (meaning the patient requested treatment provided for in Article 63, paragraph (2), item (iv) of the Health Insurance Act; hereinafter the same applies in this item), responding to consultations related to evaluation treatment, and stating opinions related to requests for patient requested treatment (meaning opinions related to the statements provided for in Article 63, paragraph (4) of the Health Insurance Act; hereinafter the same applies in this item) as follows:
 - (a) assigning persons to perform the operations of providing evaluation treatment and patient requested treatment, responding to consultations related to evaluation treatment, and stating opinions related to requests for patient requested treatment; and
 - (b) establishing rules and procedures for the operations of providing evaluation treatment and patient requested treatment, responding to consultations related to evaluation treatment, and stating opinions related to requests for patient requested treatment.

Article 10 The administrator of a hospital, clinic, or birthing center, when allowing patients, pregnant women, women in labor, or women resting after childbirth to be hospitalized or admitted, must comply with the following particulars; provided, however, that the particulars set forth in items (i) through (iv) do not apply to temporary and emergency hospitalization or admission:

- (i) not allowing patients, pregnant women, women in labor, or women resting after childbirth to be hospitalized or admitted in excess of the capacity of each sickroom or each room for admitting pregnant women, women in labor, or women resting after childbirth (hereinafter referred to as a "room for admission");
- (ii) not allowing patients, pregnant women, women in labor, or women resting after childbirth to be hospitalized or admitted in any area other than a sickroom or a room for admission;
- (iii) when allowing persons with psychiatric disorders requiring hospital treatment (excluding those with physical disorders requiring hospital treatment in a sickroom other than a psychiatric room) to be hospitalized, hospitalizing them in psychiatric rooms;
- (iv) not hospitalizing patients with infectious diseases in any sickroom other than an infectious disease room;

- (v) not hospitalizing patients at risk of infecting others in the same room and other types of patients in the same room;
- (vi) not hospitalizing patients in a room in which other patients at risk of infecting others have been hospitalized, unless disinfecting the room beforehand; and
- (vii) not providing patients with clothing, bedding, tableware or the like that has been provided to other patients at risk of infecting others and is or may be infected with viruses, unless disinfecting it beforehand.

Article 11 The provisions of Article 9-20-2, paragraph (1), item (xiv) apply mutatis mutandis to the administrator of a hospital which falls under any of the following items and which is not an advanced treatment hospital (hereinafter referred to as an "accident reporting hospital"):

- (i) a national Hansen's disease sanatorium;
- (ii) a hospital established by the National Hospital Organization, National Cancer Center Japan, National Cerebral and Cardiovascular Center, National Center of Neurology and Psychiatry, Research Institute National Center for Global Health and Medicine, National Center for Child Health and Development, or National Center for Geriatrics and Gerontology; or
- (iii) a hospital (other than a branch hospital) which is a facility attached to a university based on the School Education Act (Act No. 26 of 1947) (hereinafter simply referred to as a "university").

Article 12 If an accident, etc. has occurred, the administrator of an advanced treatment hospital or an accident reporting hospital must submit a written accident report related to the accident, etc., within two weeks from the day of the accident, etc. in principle, to a person that conducts an accident analysis business (meaning a business which collects and analyzes information and materials on accidents, etc., or otherwise conducts scientific research and studies thereon, and provides the results of the analysis or those of the research and studies; the same applies hereinafter) and that has been registered by the Minister of Health, Labour and Welfare (hereinafter referred to as a "registered analytical laboratory").

Article 12-2 (1) The registration referred to in the preceding Article is made upon application by a person that intends to conduct an accident analysis business.

(2) A person that intends to obtain the registration referred to in the preceding Article must submit to the Minister of Health, Labour and Welfare an application form containing the following information:

- (i) the name of the applicant and, when the applicant is a corporation, the

- name of its representative;
 - (ii) the name and location of the principal office where the accident analysis business is intended to be conducted; and
 - (iii) the date on which the accident analysis business is intended to be commenced.
- (3) The following documents must be attached to the application form referred to in the preceding paragraph:
- (i) when the applicant is an individual, a copy of their resident record;
 - (ii) when the applicant is a corporation, its articles of incorporation or articles of endowment and certificate of registered information;
 - (iii) a document explaining that the applicant does not fall under the items of the following Article;
 - (iv) the names and brief biographical outlines of the committee members provided for in Article 12-4, paragraph (1), item (viii);
 - (v) when the applicant is a corporation, a document stating the names and brief biographical outlines of its officers; and
 - (vi) when the applicant conducts operations other than the accident analysis business, a document stating the type and outline of the operations.

Article 12-3 Any person that falls under any of the following items may not obtain the registration referred to in Article 12:

- (i) a person that has been sentenced to a fine or heavier punishment for violating the Act or any order based on the Act, if two years have not passed since the day on which that person finished serving the sentence or ceased to be subject to its enforcement;
- (ii) a person whose registration under Article 12 has been rescinded pursuant to the provisions of Article 12-13, if two years have not passed since the day of the rescission; or
- (iii) a corporation any of whose executive officers falls under either of the preceding two items.

Article 12-4 (1) The Minister of Health, Labour and Welfare must register a person that has applied for the registration pursuant to the provisions of Article 12-2 if the person conforms to all of the following requirements:

- (i) the person does not intend to make profit;
- (ii) when the person is a corporation, part of its purpose is to analyze or evaluate safety management related to medical care and other functions of medical institutions, and to support the improvement thereof;
- (iii) the person has the ability to perform the analysis or evaluation of safety management related to medical care and other functions of medical institutions on a nationwide basis, and has sufficient achievements;

- (iv) the person has a financial accounting basis necessary for properly and smoothly conducting an accident analysis business on a nationwide basis;
 - (v) the person does not have any interest in conducting the accident analysis business;
 - (vi) when the person conducts operations other than the accident analysis business, there is no risk that the implementation of the operations decreases the fairness of the operation of the accident analysis business;
 - (vii) when the person is a corporation, there is no risk that the composition of its officers impedes the fair operation of the accident analysis business;
 - (viii) the person has a committee consisting of committee members with expert knowledge or insight on the analysis of accidents, etc.;
 - (ix) the committee members provided for in the preceding item do not have any interest in conducting the accident analysis business; and
 - (x) the person has established procedures that ensure the fair and proper implementation of the accident analysis business.
- (2) The registration is to be made by entering the following information in the registry of registered analytical laboratories:
- (i) the date of registration and the registration number;
 - (ii) the name and address of the registered analytical laboratory and, when it is a corporation, the name of its representative; and
 - (iii) the name and location of the principal place of business where the registered analytical laboratory conducts the accident analysis business.

Article 12-5 (1) The registration referred to in Article 12, unless it is renewed every five years, ceases to be effective upon the passage of the period.

(2) The provisions of the preceding three Articles apply mutatis mutandis to the renewal of registration referred to in the preceding paragraph.

Article 12-6 (1) A registered analytical laboratory, when receiving a written accident report submitted by an advanced treatment hospital or an accident reporting hospital pursuant to the provisions of Article 12, must conduct the accident analysis business without delay unless there are reasonable grounds for not doing so.

(2) A registered analytical laboratory must conduct the accident analysis business in a fair manner.

Article 12-7 A registered analytical laboratory must notify the Minister of Health, Labour and Welfare of any change in the particulars set forth in Article 12-2, paragraph (2), items (i) and (ii) at least two weeks prior to the scheduled date of the change.

Article 12-8 A registered analytical laboratory must establish rules for the accident analysis business which contain the following particulars and notify the Minister of Health, Labour and Welfare of the rules before commencing operations of the accident analysis business; the same applies in the case of any change in the rules:

- (i) the method of conducting the accident analysis business;
- (ii) particulars concerning the preservation of documents and books on the accident analysis business;
- (iii) particulars concerning costs related to the requests referred to in Article 12-10, paragraph (2), items (ii) and (iv); and
- (iv) beyond what is set forth in the preceding items, particulars necessary for the implementation of the accident analysis business.

Article 12-9 A registered analytical laboratory, when intending to suspend or discontinue whole or part of its accident analysis business, must notify the Minister of Health, Labour and Welfare of the following matters at least two weeks prior to the scheduled date of the suspension or discontinuance:

- (i) the reason for the suspension or discontinuance, and the scheduled date thereof; and
- (ii) when suspension is intended, the scheduled period of the suspension.

Article 12-10 (1) A registered analytical laboratory, within three months from the passage of each business year, must prepare an inventory of assets, a balance sheet and a profit and loss statement or an income and expenditure statement, as well as a business report (if, in lieu of the preparation thereof, an electronic or magnetic record has been prepared, including the electronic or magnetic record; referred to as "financial statements, etc." in the following paragraph) for the business year, and keep them in its office for five years.

(2) An advanced treatment hospital, accident reporting hospital, or any other interested party may make the following requests at any time during the business hours of the relevant registered analytical laboratory; provided, however, that it must pay the cost fixed by the registered analytical laboratory for the request referred to in item (ii) or (iv):

- (i) when financial statements, etc. are prepared as written documents, a request for inspection or copy of the documents;
- (ii) a request for a transcript or extract of the documents referred to in the preceding item;
- (iii) when financial statements, etc. are prepared as electronic or magnetic records, a request for inspection or copy of the particulars that are recorded on the electronic or magnetic records and indicated on paper or on the screen of an output device;

(iv) a request for the provision of the particulars recorded on the electronic or magnetic records referred to in the preceding item by either of the following electronic or magnetic means, or for the issuance of a written document stating the particulars:

(a) means of using an electronic data processing system that connects the computer used by the sender and the computer used by the receiver through a telecommunications line, by which information is transmitted via that telecommunications line and recorded in a file on the computer used by the receiver; or

(b) means of delivering a file containing information that is prepared using a magnetic disk or the like;

Article 12-11 The Minister of Health, Labour and Welfare, when finding that a registered analytical laboratory no longer conforms to any of the items of Article 12-4, paragraph (1), may order the registered analytical laboratory to take necessary measures to conform to these provisions.

Article 12-12 The Minister of Health, Labour and Welfare, when finding that a registered analytical laboratory violates the provisions of Article 12-6, may order the registered analytical laboratory to conduct the accident analysis business, or to take necessary measures to improve the method of conducting the accident analysis business or other methods of operations.

Article 12-13 When a registered analytical laboratory falls under any of the following items, the Minister of Health, Labour and Welfare may rescind the registration of the registered analytical laboratory or order the registered analytical laboratory to suspend whole or part of its accident analysis business for a fixed period of time:

(i) it comes to fall under Article 12-3, item (i) or (iii);

(ii) it violates the provisions of Articles 12-7 through 12-9, Article 12-10, paragraph (1), or the following Article;

(iii) it refuses requests under the items of Article 12-10, paragraph (2) without reasonable grounds;

(iv) it violates an order under Article 12-11 or 12-12; or

(v) it obtains the registration referred to in Article 12 by wrongful means.

Article 12-14 A registered analytical laboratory, when conducting the accident analysis business, must keep books stating the following particulars and preserve the books for three years from the date of the final entry.

(i) the date on which a written accident report is received from an advanced treatment hospital or an accident reporting hospital pursuant to the

- provisions of Article 12;
- (ii) the outline of the accident, etc. related to the written accident report referred to in the preceding item; and
 - (iii) the outline of the results of analysis of the accident, etc. related to the written accident report referred to in item (i).

Article 12-15 The Minister of Health, Labour and Welfare may have a registered analytical laboratory report on the administrative or accounting status of its accident analysis business, to the extent necessary to conduct the accident analysis business.

Article 12-16 The Minister of Health, Labour and Welfare, in the following cases, must publicly notify them:

- (i) when the Minister grants the registration referred to in Article 12;
- (ii) when the Minister receives a notification under Article 12-7;
- (iii) when the Minister receives a notification under Article 12-9; and
- (iv) when the Minister rescinds the registration referred to in Article 12 or orders the suspension of an accident analysis business pursuant to the provisions of Article 12-13.

Article 13 (1) The submission of a hospital report under Article 4-8, paragraphs (1) and (2) of the Order is to be made in Appended Form 1, and the submission of a hospital report prepared using Appended Form 1 is to be made to the director of the health center that has jurisdiction over the location of the relevant hospital by the fifth day of each month (in the case of a suspended or discontinued hospital, within five days of the date of suspension or discontinuation).

(2) The sending of a hospital report under Article 4-8, paragraph (3) of the Order is to be made within five days from the date on which the hospital report is submitted.

(3) The sending of a hospital report under Article 4-8, paragraph (5) of the Order is to be made within ten days from the date on which the hospital report is submitted.

Article 13-2 The written report prepared using Appended Form 1 provided for in paragraph (1) of the preceding Article may be substituted with an electronic or magnetic record when the particulars set forth in the columns of the written report are recorded thereon in a manner clearly recognizable by computers (including input-output devices) used by the Ministry of Health, Labour and Welfare.

Article 13-3 A document stating the following particulars must be affixed to the magnetic disk or the like on which the electronic or magnetic record referred to in the preceding Article is kept:

- (i) the fact that it is a hospital report;
- (ii) the date of the report;
- (iii) the name and location of the relevant hospital or clinic; and
- (iv) the name of the health center that has jurisdiction over the location of the relevant hospital or clinic and the name of the prefecture where the health center is located.

Article 14 The administrator of a hospital or clinic must pay necessary attention to ensure that pharmaceuticals, regenerative medical products, and tools existing in the hospital or clinic do not violate the provisions of the Act on Pharmaceuticals and Medical Devices.

Article 15 (1) The administrator of a hospital, clinic, or birthing center, when finding it necessary for observing the provisions of the Act and this Ministerial Order, must request the organizer of the hospital, clinic, or birthing center to improve the buildings or equipment thereof.

(2) When receiving a request under the preceding paragraph, the organizer of a hospital, clinic, or birthing center is to immediately take necessary measures.

Article 15-2 (1) The organizer of a birthing center that handles delivery, in order to respond to abnormalities during delivery and the like, must designate physicians who take charge of the department of obstetrics or obstetrics and gynaecology at a hospital or a clinic as contract physicians pursuant to the provisions of Article 19 of the Act.

(2) Notwithstanding the provisions of the preceding paragraph, when the organizer of a birthing center commissions a hospital or a clinic which has the department of obstetrics or obstetrics and gynaecology to have any of the physicians who take charge of the department of obstetrics or obstetrics and gynaecology at the hospital or clinic provide the response referred to in the preceding paragraph, it may be deemed that contract physicians have been designated.

(3) The organizer of a birthing center, in case it is difficult for its contract physicians to provide the response referred to in paragraph (1), may designate a hospital or clinic which has the department of obstetrics or obstetrics and gynaecology and the department of pediatrics, and is capable of providing medical care for newborns (limited to that having facilities for the hospitalization of patients) as a contract hospital or clinic.

Article 15-3 A birthing assistant who engages in operations solely through out-calls, when promising to provide birthing assistance for a pregnant woman, must designate a hospital or clinic which has the department of obstetrics or obstetrics and gynaecology and the department of pediatrics, and is capable of providing medical care for newborns (limited to that having facilities for the hospitalization of patients) as a hospital or clinic that is to respond to abnormalities in the pregnant woman pursuant to the provisions of Article 19, paragraph (2) of the Act.

Article 15-4 The organizer of an advanced treatment hospital must take the measures provided for in the items of Article 19-2 of the Act in accordance with the following items:

- (i) clarifying the personnel affairs and budget implementation authority necessary for the management and operation of the hospital held by the administrator;
- (ii) establishing an audit committee for ensuring medical safety that meets the following requirements, and submitting to the Minister of Health, Labour and Welfare and publicizing documents containing the list of committee members and the reasons for selecting the committee members:
 - (a) the number of committee members is three or more, and the chairperson and more than half of the committee members are appointed from persons who have no interest in the relevant hospital; and
 - (b) the persons who have no interest provided for in (a) include the following persons:
 - 1. persons with insight on safety management or laws related to medical care, or those with other relevant expertise; and
 - 2. persons other than medical care professionals, such as a recipient of medical care (excluding the persons set forth in 1.);
 - (c) meetings are held at least twice a year;
 - (d) the following operations are conducted:
 - 1. requesting reports from the administrator or the like on the status of operations performed by the person responsible for medical safety management, a medical safety management division, a medical safety management committee, a person responsible for pharmaceutical safety management, a person responsible for medical device safety management, and others, or checking the status thereof personally as necessary;
 - 2. if necessary, expressing an opinion that the organizer or administrator of the relevant hospital should take rectification measures for safety management related to medical care; and
 - 3. publicizing the results of the operations set forth in 1. and 2.;

- (iii) establishing the following systems provided for in Article 19-2, item (iii) of the Act:
 - (a) a system for ensuring that the operations of the administrator of the advanced treatment hospital conform to laws and regulations; and
 - (b) a system related to the supervision of the operations of the advanced treatment hospital by the organizer, council, etc. thereof;
- (iv) establishing a contact point for accepting information when any doubt arises concerning the proper implementation of medical safety management in accordance with the following:
 - (a) specifying the scope of information to be provided to the contact point, measures to prevent individuals who provide information from being identified, and other necessary particulars for the establishment of the contact point; and
 - (b) inform the employees about the contact point and how to use it.

Chapter III Buildings and Equipment of Hospitals, Clinics, and Birthing Centers

Article 16 (1) The standards for the buildings and equipment of a hospital or clinic under Article 23, paragraph (1) of the Act are as follows; provided, however, that the provisions of items (ix) and (xi) do not apply to clinics without facilities for the hospitalization of patients or those with facilities for the hospitalization of not more than nine patients (excluding those with long-term care beds).

- (i) necessary measures are taken for buildings and equipment concerning electricity, light, heat, steam, or gas provided for medical care in order to prevent dangers, and buildings and equipment concerning radiation conform to the provisions of Chapter IV.
- (ii) sickrooms are not located on the basement floor or on the third or higher floor; provided, however, that the sickroom provided for in Article 30-12 may be located on the basement and, if the main structural part (meaning the main structural part provided for in Article 2, item (v) of the Building Standards Act (Act No. 201 of 1950); the same applies hereinafter) is a fireproof structure (meaning a fireproof structure provided for in Article 2, item (vii) of the Building Standards Act; the same applies hereinafter), sickrooms may be located on the third or higher floor;
- (ii)-2 the number of long-term care beds per sickroom is four or less;
- (iii) the floor area of a sickroom is as follows:
 - (a) the internal floor area of a sickroom of a hospital or a sickroom with long-term care beds of a clinic is 6.4 square meters or more per patient; or
 - (b) the internal floor area of a room other than that referred to in (a) is 6.3

- square meters or more when the room accommodates one patient, or 4.3 square meters or more per patient when it accommodates two or more patients;
- (iv) the floor area of a room that accommodates only children may be two-thirds or more of the floor area of the room provided for in the preceding item; provided, however, that the floor area of a room must not be 6.3 square meters or less;
 - (v) mechanical ventilation equipment is designed to prevent the air of infectious disease rooms, tuberculosis rooms, or bacterial pathology laboratories from entering the other parts of the hospital or clinic through air ducts;
 - (vi) necessary measures are taken for equipment in psychiatric rooms in order to provide appropriate medical care and protect patients based on the characteristics of psychiatric diseases;
 - (vii) blocking and other necessary measures are taken for infectious disease rooms and tuberculosis rooms in order to prevent infection to the other parts of the hospital or clinic and to the outside;
 - (viii) when there are sickrooms on the second or higher floor, two or more direct staircases for patients are installed indoors; provided, however, that when an elevator for patients is installed or when the total floor area of sickrooms on each of the second and higher floors is 50 square meters (or 100 square meters for a building whose main structural part is a fireproof structure or is made of non-combustible materials (meaning the non-combustible materials provided for in Article 2, item (ix) of the Building Standards Act; the same applies hereinafter)) or less, the number of indoor direct staircases for patients may be one;
 - (ix) the structure of the direct staircases provided for in the preceding item is as follows:
 - (a) the inner width of stairs and landings is 1.2 meters or more;
 - (b) a rise is 0.2 meters or less, and a run is 0.24 meters or more; and
 - (c) appropriate handrails are installed;
 - (x) when there are sickrooms on the third or higher floors, two or more evacuation staircases are installed so as not to impede evacuation; provided, however, that when one or two of the direct staircases provided for in item (viii) are constructed as the evacuation staircases provided for in Article 123, paragraph (1) of the Order for Enforcement of the Building Standards Act (Cabinet Order No. 338 of 1950), the direct staircases may be included in the number of evacuation staircases;
 - (xi) the width of corridors for patients is as follows:
 - (a) the inner width of a corridor adjacent to sickrooms with psychiatric beds or long-term care beds is 1.8 meters or more; provided, however, that the

- inner width of a corridor with living rooms on both sides must be 2.7 meters or more;
- (b) the inner width of a corridor other than that referred to in (a) (limited to a corridor of a hospital) is 1.8 meters or more; provided, however, that the inner width of a corridor (limited to that of a hospital) with living rooms on both sides must be 2.1 meters or more;
 - (c) the inner width of a corridor other than that referred to in (a) (limited to a corridor of a clinic) is 1.2 meters or more; provided, however, that the inner width of a corridor (limited to that of a clinic) with living rooms on both sides must be 1.6 meters or more;
 - (xii) necessary disinfection equipment is installed in a hospital or clinic that has an infectious disease room or a tuberculosis room;
 - (xiii) dustproof equipment and other necessary equipment are installed in a dental laboratory;
 - (xiv) the buildings and equipment of a dispensary comply with the following:
 - (a) sufficient lighting and ventilation are provided, and cleanliness is maintained;
 - (b) a cool and dark place is installed; and
 - (c) a balance with a reciprocal sensibility of 10 milligrams, an even balance with a reciprocal sensibility of 500 milligrams, and other tools necessary for dispensing are provided;
 - (xv) equipment necessary for fire prevention is installed in a place where fire is used; and
 - (xvi) a fire extinguishing machine or tools are provided.
- (2) Beyond what is prescribed in the preceding paragraph, the standards for the buildings and equipment of a hospital or clinic are governed by Cabinet Order based on the provisions of the Building Standards Act.

Article 17 (1) The standards for the buildings and equipment of a birthing center under Article 23, paragraph (1) of the Act are as follows:

- (i) a room for admission is not located on the basement or on the third or higher floor; provided, however, that it may be located on the third or higher floor when the main structural part is a fireproof structure;
- (ii) the internal floor area of a room for admission is 6.3 square meters or more when the room accommodates one pair of mother and child, or 4.3 square meters or more per pair of mother and child when it accommodates two or more pairs thereof;
- (iii) when there is a room for admission on the second or higher floor, a direct staircase for admitted mothers and children is installed indoors;
- (iv) when there is a room for admission on the third or higher floor, two or more evacuation staircases are installed so as not to impede evacuation;

provided, however, that when the direct staircase provided for in the preceding item is constructed as the evacuation staircase provided for in Article 123, paragraph (1) of the Order for Enforcement of the Building Standards Act, the direct staircase may be included in the number of evacuation staircases;

- (v) for a birthing center with facilities for admission, a delivery room with a floor area of 9 square meters or more is installed; provided, however, that this does not apply to birthing centers which do not handle delivery;
 - (vi) equipment necessary for fire prevention is installed in a place where fire is used; and
 - (vii) a fire extinguishing machine or tools are provided.
- (2) Beyond what is prescribed in the preceding paragraph, the standards for the buildings and equipment of a birthing center are governed by Cabinet Order based on the provisions of the Building Standards Act.

Article 18 (Deletion)

(Order of the Ministry of Health and Welfare No. 13 of 1954)

Article 19 (1) The standards for the numbers of physicians and dentists a hospital should have under Article 21, paragraph (1), items (i) of the Act are as follows:

- (i) physicians: when the sum of the number obtained by dividing the number of patients hospitalized in sickrooms with psychiatric beds or long-term care beds by 3, the number of patients hospitalized in sickrooms other than those with psychiatric beds or long-term care beds (excluding dental, orthodontic, pediatric dental, and dental surgery inpatients), and the number obtained by dividing the number of outpatients (excluding dental, orthodontic, pediatric dental, and dental surgery outpatients) by 2.5 (or 5 for the department of psychiatry, otorhinolaryngology, or ophthalmology) (hereinafter referred to as the "specific number" in this item) is 52 or less, three; or when the specific number exceeds 52, the number obtained by adding 3 to the number obtained by dividing the number obtained by subtracting 52 from the specific number by 16;
- (ii) dentists:
 - (a) for a hospital whose clinical departments are limited to those concerning dental practices, when the number of inpatients is 52 or less, three; or when the number thereof exceeds 52, 3 plus the number obtained by dividing the number obtained by subtracting 52 from the number of the inpatients by 16 (any fraction is rounded up), plus the number deemed necessary according to the circumstances of the hospital with regard to its outpatients; or

- (b) for a hospital other than that referred to in (a), when the number of dental, orthodontic, pediatric dental, and dental surgery inpatients is 16 or less, one; or when the number thereof exceeds 16, 1 plus the number obtained by dividing the number obtained by subtracting 16 from the number of the inpatients by 16 (any fraction is rounded up), plus the number deemed necessary according to the circumstances of the hospital with regard to its dental, orthodontic, pediatric dental, and dental surgery outpatients.
- (2) The standards prescribed by Order of the Ministry of Health, Labour and Welfare referred to in Article 21, paragraph (3) of the Act (limited to those pertaining to hospital employees and the number thereof; the same applies in the following paragraph) which a prefecture should follow in enacting Prefectural Ordinances are as follows:
- (i) pharmacists: the sum of the number obtained by dividing the number of patients hospitalized in sickrooms with psychiatric beds or long-term care beds by 150, the number obtained by dividing the number of patients hospitalized in sickrooms other than those with psychiatric beds or long-term care beds by 70, and the number obtained by dividing the number of handled prescriptions pertaining to outpatients by 75 (if the number is less than one, it is counted as one; or if the number includes a fraction of less than one, the fraction is counted as one);
 - (ii) nurses and assistant nurses: the sum of the number obtained by dividing the number of patients hospitalized in sickrooms with long-term care beds, psychiatric beds, or tuberculosis beds by 4 and the number obtained by dividing the number of patients hospitalized in sickrooms with infectious disease beds or general beds (including hospitalized newborns) by 3 (if the number is less than one, it is counted as one; or if the number includes a fraction of less than one, the fraction is counted as one), plus the number obtained by dividing the number of outpatients by 30 (any fraction is rounded up); provided, however, that for the department of obstetrics and gynaecology or obstetrics, an appropriate number of nurses and assistant nurses are to be replaced with birthing assistants, and for the department of dentistry, orthodontics, pediatric dentistry, or dental surgery, an appropriate number thereof may be replaced with dental hygienists;
 - (iii) nursing aids: the number dividing the number of patients hospitalized in sickrooms with long-term care beds by 4 (any fraction is rounded up); and
 - (iv) dietitians: for a hospital with 100 or more beds, one.
- (3) The standards prescribed by the Ministry of Health, Labour and Welfare referred to in Article 21, paragraph (3) of the Act which a prefecture should take into consideration in enacting Prefectural Ordinances are as follows:
- (i) medical radiology technicians, clerks, and other employees: appropriate

- numbers according to the circumstances of the hospital; and
 - (ii) physical therapists and occupational therapists: for a hospital with long-term care beds, appropriate numbers according to the circumstances of the hospital.
- (4) The facilities provided for in Article 11, paragraph (1) of the Ordinance for Enforcement of the Medical Practitioners Act (Order of the Ministry of Welfare No. 47 of 1948) or Article 11 of the Order for Enforcement of the Dental Practitioners Act (Order of the Ministry of Welfare No. 48 of 1948) are to have an appropriate number of persons who intend to receive practical training on medical care or practical training on medical care and oral health at the facilities.
- (5) The numbers of inpatients, outpatients, and handled prescriptions referred to in paragraphs (1) and (2) are the respective averages for the previous business year; provided, however, that in the case of new establishment or resumption, the numbers are based on presumptions.

Article 20 The facilities and records under Article 21, paragraph (1), items (ii) through (vi), (viii), (ix), and (xi) of the Act are as follows:

- (i) a consultation room for each clinical department may be used as a room for two or more clinical departments when a physician performs medical care of two or more clinical departments at the same time, or when there are other special circumstances;
- (ii) an operating room must be provided in a hospital which has any of the departments of surgery, orthopedics, plastic surgery, cosmetic surgery, neurosurgery, respiratory surgery, cardiovascular surgery, pediatric surgery, dermatology, urology, obstetrics and gynecology, obstetrics, gynecology, ophthalmology, and otorhinolaryngology, or in a hospital whose clinical departments are limited to those concerning dental practices;
- (iii) an operating room must be provided with an adjacent preparation room as far as possible so as not to allow dust to enter, have inner walls all of which are covered with impermeable material, have appropriate heating and lighting equipment, and be provided with attached and clean hand-washing equipment;
- (iv) a treatment room is installed for each department as far as possible; provided, however, that it may be used by two or more departments or used as an examination room according to circumstances;
- (v) a diagnostic laboratory must be capable of performing routine laboratory testing of sputum, blood, urine, feces, and others;
- (vi) notwithstanding the provisions of the preceding item, when the operations of specimen examination are entrusted to others pursuant to the provisions of Article 15-3, paragraph (1) of the Act, the installation of equipment for the

- examination may be omitted in the relevant diagnostic laboratory;
- (vii) an X-ray unit must be installed in a hospital which has any of the departments of internal medicine, psychosomatic medicine, rheumatology, pediatrics, surgery, orthopedics, plastic surgery, cosmetic surgery, neurosurgery, respiratory surgery, cardiovascular surgery, pediatric surgery, urology, rehabilitation, and radiology, or in a hospital whose clinical departments are limited to those concerning dental practices;
 - (viii) food service facilities are to be capable of providing meals to all inpatients, and the floor of a cooking room must be constructed with waterproof material to facilitate washing and drainage or cleaning, and disinfection equipment for tableware must be installed;
 - (ix) notwithstanding the provisions of the preceding item, when cooking operations or washing operations are entrusted to others pursuant to the provisions of Article 15-3, paragraph (2) of the Act, the installation of equipment for the operations may be omitted in the relevant food service facilities;
 - (x) records concerning medical care consist of hospital diaries, medical care diaries of each department, prescriptions, operative notes, nursing notes, records of examination findings, x-ray photographs, books clarifying the numbers of inpatients and outpatients, and hospitalization and medical care plans for the last two years; and
 - (xi) at least one of the functional training rooms of a hospital with long-term care beds must have an internal floor area of 40 square meters or more and must be equipped with necessary equipment and tools.

Article 21 The standards prescribed by Order of the Ministry of Health, Labour and Welfare referred to in Article 21, paragraph (3) of the Act (limited to those pertaining to the facilities of a hospital and its buildings and equipment) which a prefecture should take into consideration in enacting Prefectural Ordinances are to have the buildings and equipment prescribed in the following items according to the categories of facilities set forth respectively in those items:

- (i) disinfection facilities and laundry facilities (when the operations of sterilizing and disinfecting textile products or those of washing bedding, etc. are entrusted to others pursuant to the provisions of Article 15-3, paragraph (2) of the Act, excluding equipment related to the entrusted operations) that are capable of disinfecting clothing, bedding, etc. of inpatients and employees using steam, gas, or chemicals, or by other means (limited to hospitals with disinfection facilities);
- (ii) a lounge that has a space enough for patients hospitalized in long-term care beds to enjoy conversation with other inpatients or with their families (limited to hospitals with long-term care beds);

- (iii) a dining room that has an internal space of 1 square meter or more per patient hospitalized in a long-term care bed (limited to hospitals with long-term care beds); and
- (iv) a bathroom that is suitable for physically handicapped persons to bathe (limited to hospitals with long-term care beds).

Article 21-2 (1) The standard number of physicians to be placed in a clinic with long-term care beds pursuant to the provisions of Article 21, paragraph 2, item (i) of the Act is one.

(2) The standards prescribed by the Ministry of Health, Labour and Welfare referred to in Article 21, paragraph (3) of the Act (limited to those pertaining to employees of a clinic with long-term care beds and the number thereof; the same applies in the following paragraph) which a prefecture should follow in enacting Prefectural Ordinances are as follows:

(i) nurses and assistant nurses: the number obtained by dividing the number of patients hospitalized in sickrooms with long-term care beds by 4 (any fraction is rounded up); and

(ii) nursing aids: the number dividing the number of patients hospitalized in sickrooms with long-term care beds by 4 (any fraction is rounded up).

(3) The standards prescribed by Order of the Ministry of Health, Labour and Welfare referred to in Article 21, paragraph (3) of the Act which a prefecture should take into consideration in enacting Prefectural Ordinances are to have an appropriate number of clerks and other employees according to the circumstances of each clinic with long-term care beds.

(4) The provisions of Article 19, paragraph (5) apply mutatis mutandis to the particulars set forth in the items of paragraph (2).

Article 21-3 The functional training room provided for in Article 21, paragraph (2), item (ii) of the Act must be large enough and equipped with necessary equipment and tools for conducting functional training.

Article 21-4 The provisions of Article 21, items (ii) through (iv) apply mutatis mutandis to the standards prescribed by Order of the Ministry of Health, Labour and Welfare referred to in Article 21, paragraph (3) of the Act (limited to those pertaining to the facilities of a clinic with long-term care beds and its buildings and equipment) which a prefecture should take into consideration in enacting Prefectural Ordinances.

Article 21-5 The facilities and records under Article 22, items (i) through (viii) of the Act are as follows:

- (i) an intensive care unit, examination facilities for chemistry, bacteria, and

- pathology, and a pathological anatomy room must have appropriate buildings and equipment according to the circumstances of the relevant hospital;
- (ii) records concerning medical care consist of hospital diaries, medical care diaries of each department, prescriptions, operative notes, nursing notes, records of examination findings, x-ray photographs, letters of referral, summaries of medical care progress during hospitalization related to discharged patients, and hospitalization and medical care plans for the last two years; and
 - (iii) records concerning the management and operation of a hospital consist of books that clarify the results of shared use, the results of provision of emergency medical care, the results of training for enhancing the qualities of local medical care professionals, the results of inspections, and the results of provision of medical care to referral patients and referral of patients to other hospitals or clinics.

Article 22 The facilities under Article 22, item (ix) of the Act are an ambulance or an automobile for transporting patients and a drug information management room (meaning a room for collecting, classifying, evaluating, and providing information on drugs; the same applies in Article 22-4).

Article 22-2 (1) The number of physicians, dentists, pharmacists, nurses, and other employees an advanced treatment hospital should have under Article 22-2, item (i) of the Act are as follows:

- (i) physicians: the number obtained by dividing the sum of the number of inpatients (excluding dental, orthodontic, pediatric dental, and dental surgery inpatients) and the number obtained by dividing the number of outpatients (excluding dental, orthodontic, pediatric dental, and dental surgery outpatients) by 2.5 by 8 (referred to as the "standard number of physicians assigned" in paragraph (3));
- (ii) dentists: at least the number obtained by dividing the number of dental, orthodontic, pediatric dental, and dental surgery inpatients by 8 (any fraction is rounded up), plus the number deemed necessary according to the circumstances of the hospital with regard to its dental, orthodontic, pediatric dental, and dental surgery outpatients;
- (iii) pharmacists: at least the number obtained by dividing the number of inpatients by 30 (any fraction is rounded up) or, as a standard, the number obtained by dividing the number of dispensed prescriptions by 80 (any fraction is rounded up);
- (iv) nurses and assistant nurses: at least the sum of the number obtained by dividing the number of inpatients (including hospitalized newborns) by 2 (any fraction is rounded up) and the number obtained by dividing the

number of outpatients by 30 (any fraction is rounded up); provided, however, that for the department of obstetrics and gynaecology or obstetrics, an appropriate number of nurses and assistant nurses are to be replaced with birthing assistants, and for the department of dentistry, orthodontics, pediatric dentistry, or dental surgery, an appropriate number thereof may be replaced with dental hygienists;

(v) registered dietitian: one or more; and

(vi) medical radiology technicians, clerks, and other employees: appropriate numbers according to the circumstances of the hospital.

(2) The numbers of inpatients and outpatients referred to in the preceding paragraph are the respective averages for the previous business year; provided, however, that in the case of resumption, the numbers are based on presumptions.

(3) With regard to physicians an advanced treatment hospital should have referred to in paragraph (1), at least half of the standard number of physicians assigned under item (i) of the same paragraph must be physicians specializing in internal medicine, surgery, psychiatry, pediatrics, dermatology, urology, obstetrics and gynecology, ophthalmology, otorhinolaryngology, radiology, emergency medicine, neurosurgery, orthopedics, or anesthesiology.

Article 22-3 The facilities and records under Article 22-2, items (ii) through (iv) of the Act are as follows:

(i) an intensive care unit must be large enough to provide intensive care management and be equipped with a respirator and other devices required for intensive care;

(ii) records concerning medical care consist of hospital diaries, medical care diaries of each department, prescriptions, operative notes, nursing notes, records of examination findings, x-ray photographs, letters of referral, summaries of medical care progress during hospitalization related to discharged patients, and hospitalization and medical care plans for the last two years; and

(iii) records concerning the management and operation of a hospital consist of books that clarify the number of employees, and books that clarify the results of provision of advanced medical care, the results of development and evaluation of advanced medical technology, the results of training on advanced medical care, the results of inspection, the results of provision of medical care to referral patients and referral of patients to other hospitals or clinics, the numbers of inpatients, outpatients, and dispensed prescriptions, as well as the status of the matters set forth in Article 9-20-2, paragraph (1), items (i) through (xiii) and the items of Article 15-4, and the status of ensuring the system provided for in Article 1-11, paragraph (1) and of the

measures provided for in paragraph (2) of the same Article for the last two years.

Article 22-4 The facilities under Article 22-2, item (vi) of the Act are a sickroom where aseptic conditions are maintained and a drug information management room.

Article 22-4-2 The cases prescribed by Order of the Ministry of Health, Labour and Welfare as cases that cause a significant impediment to the suitable provision of medical care provided for in Article 23-2 of the Act are cases in which the number of physicians, dentists, nurses, or other employees is half or less of the standard for the number provided for in Article 19 or Article 21-2, or the number prescribed by Prefectural Ordinance for more than two years, and in which the Prefectural Council on Medical Service Facilities finds it appropriate for the prefectural governor to take measures pursuant to the provision of Article 23-2 of the Act.

Article 22-5 (1) The notice concerning clinics under Article 25-2 of the Act is to be given in writing by October 31 of each year, describing the following information as of October 1 of the year:

- (i) the name;
- (ii) the location;
- (iii) the address and name of the organizer (if the organizer is a corporation, its name and the location of its principal office);
- (iv) the names of clinical departments; and
- (v) the number of beds.

(2) The notice concerning birthing centers under Article 25-2 of the Act is to be given in writing by October 31 of each year, describing the following information as of October 1 of the year:

- (i) the name;
- (ii) the location;
- (iii) the address and name of the organizer (if the organizer is a corporation, its name and the location of its principal office); and
- (iv) the capacity of rooms for admitting pregnant women, women in labor, or women resting after childbirth.

Article 22-6 (1) The numbers of physicians, dentists, pharmacists, nurses, and other employees engaged in clinical research under Article 22-3, item (i) of the Act are as follows:

- (i) physicians or dentists: five or more;
- (ii) pharmacists: five or more;

- (iii) nurses: ten or more;
 - (iv) full-time persons with considerable experience and insight in the operations of providing support for the implementation of clinical research: twenty-four or more;
 - (v) full-time persons with considerable experience and insight in the management of data concerning clinical research: three or more;
 - (vi) full-time persons with considerable experience and insight in biostatistics: two or more; and
 - (vii) full-time persons with considerable experience and insight in pharmaceutical examinations: one or more.
- (2) For the purpose of application of the provisions of item (iv) of the preceding paragraph to core clinical research hospitals that play a central role in conducting clinical research on pediatric diseases, neurological diseases, and other diseases requiring the establishment of systems appropriate to the diseases for conducting clinical research, the term "twenty-four" in the same item is replaced with "twelve."

Article 22-7 The facilities and records under Article 22-3, items (ii) through (iv) of the Act are as follows:

- (i) an intensive care unit is large enough to provide intensive care management and be equipped with a respirator and other devices required for intensive care;
- (ii) records concerning medical care and clinical research consist of hospital diaries, medical care diaries of each department, prescriptions, operative notes, nursing notes, records of examination findings, x-ray photographs, and data and other records obtained through the administration of pharmaceuticals and others to research subjects and the provision of medical care thereto for the last two years.
- (iii) records concerning the management and operation of a hospital consist of books that clarify the number of employees, and books that clarify the results of the planning and implementation of specified clinical trials, the results of playing a leading role in conducting specific clinical trials when the specific clinical trials are conducted jointly with other hospitals or clinics, the results of providing other hospitals or clinics with consultation on the implementation of specified clinical trials, necessary information, advice, and other appropriate support, the results of training on specified clinical trials, and the status of ensuring the systems provided for in the items of Article 1-11, paragraph (1) and the items of Article 9-25 for the last two years.

Article 22-8 The facilities under Article 22-3, item (vi) of the Act are a diagnostic laboratory that has equipment for ensuring the accuracy of examinations.

Article 23 A prefectural governor, when receiving an offer from the organizer of a hospital, clinic, or birthing center that wishes to undergo the inspection under Article 27 of the Act, must perform the inspection referred to in the same Article within ten days from the day of receiving the offer, unless there are special circumstances for not doing so.

Chapter IV Protection from Medical Radiation

Section 1 Notification

(Cases Prescribed by Order of the Ministry of Health, Labour and Welfare
Referred to in Article 15, Paragraph (3) of the Act)

Article 24 The cases prescribed by Order of the Ministry of Health, Labour and Welfare referred to in Article 15, paragraph (3) of the Act are as follows:

- (i) when a hospital or clinic is intended to be equipped with an electron beam or X-ray generator with an energy of 1 megaelectron volt or more to be provided for medical care (hereinafter referred to as a "medical high-energy radiation generator");
- (ii) when a hospital or clinic is intended to be equipped with an apparatus to be provided for medical care which irradiates proton beams or heavy ion beams (hereinafter referred to as a "medical particle beam irradiation apparatus");
- (iii) case where a hospital or clinic is intended to be equipped with an irradiation device to be provided for medical care which is equipped with sealed radiation-emitting isotopes or their compounds, or materials containing thereof, whose quantity and concentration of radiation-emitting isotopes exceed the quantity (hereinafter referred to as the "lower limit quantity") and the concentration prescribed in Appended Table 2 (hereinafter referred to as "radioisotopes"), if the quantity of the radioisotopes mounted on the irradiation device exceeds the quantity obtained by multiplying the lower limit quantity by 1000 (excluding the device prescribed in item (vii); hereinafter referred to as a "medical irradiation apparatus");
- (iv) when a hospital or clinic is intended to be equipped with an irradiation device to be provided for medical care which is equipped with sealed radioisotopes whose quantity does not exceed the quantity obtained by multiplying the lower limit quantity by 1000 (excluding the device prescribed in item (vii); hereinafter referred to as a "medical irradiation tool");
- (v) when a hospital or clinic is intended to be equipped with a medical irradiation tool equipped with radioisotopes with a half-life of thirty days or less;
- (vi) when a hospital or clinic has been equipped with the medical irradiation tool provided for in the preceding item;

- (vii) when a hospital or clinic is intended to be equipped with a device to be provided for medical care which is equipped with sealed radioisotopes and which is prescribed by the Minister of Health, Labour and Welfare (hereinafter referred to as a "radioisotope-equipped medical device");
- (viii) when a hospital or clinic is intended to be equipped with the following unsealed radioisotopes that are used in diagnostic imaging by positron emission tomography scanners (hereinafter referred to as "radioisotopes for positron tomography examination"):
 - (a) the pharmaceuticals provided for in Article 1-11, paragraph (2), item (ii), (c), 2.;
 - (b) in-vitro diagnostics that have obtained the approval referred to in Article 23-2-5, paragraph (1) or Article 23-2-17, paragraph (1) of the Act on Pharmaceuticals and Medical Devices (including the approval for changes referred to in Article 23-2-5, paragraph (15) of the Act on Pharmaceuticals and Medical Devices (including as applied mutatis mutandis pursuant to Article 23-2-17, paragraph (5) thereof)) or that have obtained the certification referred to in Article 23-2-23, paragraph (1) of the Act on Pharmaceuticals and Medical Devices (including the certification for changes referred to in paragraph (7) of the same Article), or in-vitro diagnostics for which the notification under Article 23-2-12, paragraph (1) of the Act on Pharmaceuticals and Medical Devices (including the notification of changes under paragraph (2) of the same Article) has been made;
 - (c) those provided for in Article 1-11, paragraph (2), item (ii), (c), 1. and set forth below:
 - 1. those used in a clinical trial (meaning the clinical trial provided for in Article 2, paragraph (17) of the Act on Pharmaceuticals and Medical Devices; the same applies in Article 30-32-2, paragraph (1), item (xiii) and Appended Table 1);
 - 2. those used in the specified clinical trials provided for in Article 2, paragraph (2) of the Clinical Trials Act;
 - 3. those used in the regenerative medicine provided for in Article 2, paragraph (1) of the Act on Securing Safety of Regenerative Medicine (Act No. 85 of 2013); or
 - 4. those used in the advanced medical care set forth in the items of No. 2 or the items of No. 3, or the patient requested treatment set forth in No. 4 of the Standards for Advanced Medical Care, Patient Requested Treatment, and Facilities Prescribed by the Minister of Health, Labour and Welfare (Public Notice of Ministry of Health, Labour and Welfare No. 129 of 2008); or
- (d) pharmaceuticals which are administered to recipients of medical care for

- the purpose of care or diagnosis after being dispensed at a hospital or clinic where the care or diagnosis is provided (excluding those falling under (a) through (c));
- (viii)-2 when a hospital or a clinic is intended to be equipped with unsealed radioisotopes that are not used in diagnostic imaging by positron emission tomography scanners and that are set forth in (a) through (c) of the preceding item (hereinafter referred to as "medical radioisotopes");
 - (ix) when a hospital or clinic has been equipped with medical radioisotopes or radioisotopes for positron tomography examination;
 - (x) when there is any change in the particulars set forth in Article 24-2, items (ii) through (v);
 - (xi) when any of the following is intended to be changed: the particulars set forth in Article 25, items (ii) through (v) (including as applied mutatis mutandis pursuant to the provision of Article 25-2), the particulars set forth in Article 26, items (ii) through (iv), the particulars set forth in Article 27, paragraph (1), items (ii) through (iv), the particulars set forth in Article 27, paragraph (1), items (iii) and (iv), and paragraph (2), item (ii) of the same Article in cases that fall under item (v), the particulars set forth in Article 27-2, items (ii) through (iv), or the particulars set forth in Article 28, paragraph (1), items (iii) through (v);
 - (xii) when a hospital or a clinic is no longer equipped with an X-ray unit, medical high-energy radiation generator, medical particle beam irradiation apparatus, medical irradiation apparatus, medical irradiation tool, or radioisotope-equipped medical device; and
 - (xiii) when a hospital or clinic is no longer equipped with medical radioisotopes or radioisotopes for positron tomography examination.

(Notification of X-ray Units)

Article 24-2 When a hospital or a clinic is equipped with X-ray units to be provided for medical care (limited to those with a rated output tube voltage (measured at its peak value; the same applies hereinafter) of 10 kilovolts or more and with an energy less than 1 megaelectron volt; hereinafter referred to as "X-ray units"), the notification under Article 15, paragraph (3) of the Act is to be made by submitting a written notification stating the following particulars within ten days:

- (i) the name and location of the hospital or clinic;
- (ii) the manufacturer's name, type, and number of the X-ray units;
- (iii) the rated output of the X-ray high voltage generators;
- (iv) buildings and equipment concerning the prevention of X-ray damage consisting of the X-ray units and the X-ray examination room, and the outline of the preventive measures; and

- (v) the names of physicians, dentists, medical radiology technicians, or medical X-ray technicians who are engaged in X-ray examination, and their backgrounds concerning X-ray examination.

(Notification of Medical High-energy Radiation Generators)

Article 25 The notification under Article 15, paragraph (3) of the Act in cases falling under Article 24, item (i) is to be made by submitting a written notification stating the following information in advance:

- (i) the name and location of the hospital or clinic;
- (ii) the manufacturer's name, type, and number of the medical high-energy radiation generators;
- (iii) the rated output of the medical high-energy radiation generators;
- (iv) buildings and equipment concerning the prevention of radiation damage consisting of the medical high-energy radiation generators and the room for using medical high-energy radiation generators, and the outline of the preventive measures;
- (v) the names of physicians, dentists, or medical radiology technicians who use the medical high-energy radiation generators, and their backgrounds concerning radiology examination; and
- (vi) the scheduled time of commencing use.

(Notification of Medical Particle Beam Irradiation Apparatuses)

Article 25-2 The provisions of the preceding Article apply mutatis mutandis to medical particle beam irradiation apparatuses.

(Notification of Medical Irradiation Apparatuses)

Article 26 The notification under Article 15, paragraph (3) of the Act in cases falling under Article 24, item (iii) is to be made by submitting a written notification stating the following particulars in advance:

- (i) the name and location of the hospital or clinic;
- (ii) the manufacturer's name, type, and number of the medical irradiation apparatuses, and the type and quantity expressed in becquerel units of the radioisotopes which are mounted on the medical irradiation apparatuses;
- (iii) buildings and equipment concerning the prevention of radiation damage consisting of the medical irradiation apparatuses, the room for use, storage facilities, and transportation containers of medical irradiation apparatuses, and sickrooms in which patients getting treated with medical irradiation apparatuses are hospitalized, and the outline of the preventive measures;
- (iv) the names of physicians, dentists, or medical radiology technicians who use the medical irradiation apparatuses, and their backgrounds concerning radiology examination; and

(v) the scheduled time of commencing use.

(Notification of Medical Irradiation Tools)

Article 27 (1) The notification under Article 15, paragraph (3) of the Act in cases falling under Article 24, item (iv) is to be made by submitting a written notification stating the following particulars in advance:

- (i) the name and location of the hospital or clinic;
- (ii) the type and number of the medical irradiation tools, and the type and quantity expressed in becquerel units of the radioisotopes which are mounted on the medical irradiation tools;
- (iii) buildings and equipment concerning the prevention of radiation damage consisting of the room for use, storage facilities, and transportation containers of medical irradiation tools, and sickrooms in which patients getting treated with medical irradiation tools are hospitalized, and the outline of the preventive measures;
- (iv) the names of physicians, dentists, or medical radiology technicians who use the medical irradiation tools, and their backgrounds concerning radiology examination; and
- (v) the scheduled time of commencing use.

(2) Notwithstanding the provisions of the preceding paragraph, the notification under Article 15, paragraph (3) of the Act in cases falling under Article 24, item (v) is to be made by submitting a written notification stating the following particulars beyond the particulars set forth in items (i), (iii), and (iv) of the preceding paragraph in advance:

- (i) the type and number of the medical irradiation tools planned to be used in the year, and the type and quantity expressed in becquerel units of the radioisotopes which are mounted on the medical irradiation tools; and
- (ii) the maximum quantity scheduled to be stored and the maximum quantity scheduled to be used per day for each type of radioisotope expressed in becquerel units.

(3) The notification under Article 15, paragraph (3) of the Act in cases falling under Article 24, item (vi) is to be made by submitting a written notification stating the particulars set forth in paragraph (1), item (i) and item (i) of the preceding paragraph, by December 20 of each year, with regard to the medical irradiation tools planned to be used in the following year.

(Notification of Radioisotope-Equipped Medical Devices)

Article 27-2 The notification under Article 15, paragraph (3) of the Act in cases falling under Article 24, item (vii) is to be made by submitting a written notification stating the following information in advance:

- (i) the name and location of the hospital or clinic;

- (ii) the manufacturer's name, type, and number of the radioisotope-equipped medical devices, and the type and quantity expressed in becquerel units of the radioisotopes which are mounted on the radioisotope-equipped medical devices;
- (iii) buildings and equipment concerning the prevention of radiation damage consisting of the room for using the radioisotope-equipped medical devices, and the outline of the preventive measures;
- (iv) for radioisotope-equipped medical devices for irradiating the human body, the names of physicians, dentists, or medical radiology technicians who use the devices, and their backgrounds concerning radiology examination; and
- (v) the scheduled time of commencing use.

(Notification of Medical Radioisotopes or Radioisotopes for Positron Tomography Examination)

Article 28 (1) The notification under Article 15, paragraph (3) of the Act in cases falling under Article 24, item (viii) or (viii)-2 is to be made by submitting a written notification stating the following information in advance:

- (i) the name and location of the hospital or clinic;
 - (ii) the type, shape, and quantity expressed in becquerel units of the medical radioisotopes or radioisotopes for positron tomography examination planned to be used in the year;
 - (iii) the maximum quantity scheduled to be stored, the maximum quantity scheduled to be used per day, and the maximum quantity scheduled to be used for three months for each type of medical radioisotopes or radioisotopes for positron tomography examination expressed in becquerel units;
 - (iv) buildings and equipment concerning the prevention of radiation damage consisting of the room for use, storage facilities, transportation containers, and disposal facilities of the medical radioisotopes or the radioisotopes for positron tomography examination, and sickrooms in which patients getting treated with medical radioisotopes or radioisotopes for positron tomography examination are hospitalized, and the outline of the preventive measures; and
 - (v) the names of physicians or dentists who use the medical radioisotopes or radioisotopes for positron tomography examination, and their backgrounds concerning radiology examination.
- (2) The notification under Article 15, paragraph (3) of the Act in cases falling under Article 24, item (ix) is to be made by submitting a written notification stating the information set forth in items (i) and (ii) of the preceding paragraph, by December 20 of every year, with regard to the medical radioisotopes or radioisotopes for positron tomography examination planned to be used in the following year.

(Notification of Changes)

Article 29 (1) The notification under Article 15, paragraph (3) of the Act in cases falling under Article 24, item (x) or (xii) is to be made by submitting a written notification stating to that effect within ten days.

(2) The notification under Article 15, paragraph (3) of the Act in cases falling under Article 24, item (xi) is to be made by submitting a written notification stating to that effect in advance.

(3) The notification under Article 15, paragraph (3) of the Act in cases falling under Article 24, item (xiii) is to be made by submitting a written notification stating to that effect within ten days and submitting a written notification stating the outline of the measures set forth in the items of Article 30-24 within thirty days.

Section 2 Protection of X-ray Units

(Protection of X-ray Units)

Article 30 (1) An X-ray unit must be that for which the following damage prevention measures have been taken:

(i) shielding the container of the X-ray tube and the irradiation cylinder so that the quantity of X-rays other than the usable beams becomes equal to the following air kerma rate in free air (hereinafter referred to as the "air kerma rate"):

(a) for a therapeutic X-ray unit with a rated tube voltage of 50 kilovolts or less, 1.0 milligray or less per hour at a distance of 5 centimeters from the accessible surface of the X-ray unit;

(b) for a therapeutic X-ray unit with a rated tube voltage exceeding 50 kilovolts, 10 milligray or less per hour at a distance of 1 meter from the focal spot of the X-ray tube, and 300 milligray or less per hour at a distance of 5 centimeters from the accessible surface of the X-ray unit;

(c) for an intraoral X-ray unit with a rated tube voltage of 125 kilovolts or less, 0.25 milligray or less per hour at a distance of 1 meter from the focal spot of the X-ray tube;

(d) for an X-ray unit other than those set forth in (a) through (c), 1.0 milligray or less per hour at a distance of 1 meter from the focal spot of the X-ray tube; and

(e) for a capacitor discharge high-voltage generator, 20 microgray or less per hour at a distance of 5 centimeters from the accessible surface in a charged state other than at the time of irradiation;

(ii) attaching a supplemental filter to the X-ray unit so that the total filtration of usable beams becomes equal to that set forth below:

- (a) for an intraoral X-ray unit with a rated tube voltage of 70 kilovolts or less, 1.5 millimeters or more of aluminum equivalent;
 - (b) for a mammographic X-ray unit with a rated tube voltage of 50 kilovolts or less, 0.5 millimeters or more of aluminum equivalent or 0.03 millimeters or more of molybdenum equivalent; and
 - (c) for an X-ray unit for irradiating blood supply, therapeutic X-ray unit, or X-ray unit other than those set forth in (a) and (b), 2.5 millimeters or more of aluminum equivalent;
- (2) Beyond what is provided for in the preceding paragraph, a fluoroscopic X-ray unit must be that for which the following damage prevention measures have been taken:
- (i) with respect to the entrance dose rate to the patient during fluoroscopy, keeping the air kerma rate at the center of the usable beams on the patient's entrance surface at or below 50 milligray per minute; provided, however, that for a unit equipped with a high-dose-rate fluoroscopic control which operates only by continuous manual operation of an operator and which emits continuous warning beeps or the like during operation, keeping the rate at or below 125 milligray per minute;
 - (ii) installing a timer capable of integrating fluoroscopic times and emitting warning beeps or the like when a certain time elapses during fluoroscopy;
 - (iii) installing an apparatus which ensures that the distance between the focal spot of the X-ray tube and the skin is 30 centimeters or more, or an interlock which prevents irradiation at a distance less than the skin to focal spot distance; provided, however, that for an X-ray unit which is used during surgery, the distance between the focal spot of the X-ray tube and the skin may be 20 centimeters or more;
 - (iv) providing an apparatus which narrows down the X-ray irradiation field so that it will not exceed the image reception area over the distance between the focal spot of the X-ray tube and the image receptor used; provided, however, that an X-ray irradiation field exceeding the image reception area is to be permitted in the following cases:
 - (a) when the image reception area is circular and the X-ray irradiation field is rectangular, and the X-ray irradiation field does not exceed the size at the time of circumscribing the image reception area; and
 - (b) when two straight lines intersecting at right angles on an image reception area perpendicular to the irradiation direction are assumed, if each sum of the distance between the point of intersection of each straight line and the edge of the X-ray irradiation field and the distance between the point of intersection of each straight line and the edge of the image reception area (hereinafter referred to as the "distances between the points of intersection" in this Article) does not exceed 3 percent of the focal spot to

- image receptor distance, and the total sum of the distances between these points of intersection does not exceed 4 percent of the focal spot to image receptor distance;
- (v) keeping the air kerma rate of X-rays that pass through the image receptor, such as a fluorescent screen or image intensifier, in usable beams at or below 150 microgray per hour at a distance of 10 centimeters from the accessible surface of the image receptor, such as a fluorescent screen or image intensifier, in usable beams;
 - (vi) keeping the air kerma rate of X-rays that pass through any section exceeding 3.0 centimeters from the maximum image reception area during fluoroscopy at or below 150 microgray per hour at a distance of 10 centimeters from the accessible surface of the section;
 - (vii) taking appropriate measures to effectively shield X-rays other than usable beams;
- (3) Beyond what is provided for in paragraph (1), a radiographic X-ray unit (other than a photofluorographic X-ray unit for chest mass surveys) must be that for which the following damage prevention measures (excluding those set forth in item (i) for a CT X-ray unit, and those set forth in item (ii) for an X-ray unit for bone mineral quantitative analysis) have been taken:
- (i) providing an apparatus which narrows down the X-ray irradiation field so that it will not exceed the image reception area over the distance between the focal spot of the X-ray tube and the image receptor used; provided, however, that an X-ray irradiation field exceeding the image reception area is to be permitted in the following cases; or for an intraoral X-ray unit, keeping the diameter of the X-ray irradiation field at the end of the irradiation cylinder at or below 6.0 centimeters; or for a mammographic X-ray unit, keeping the spread of the X-ray irradiation field beyond the edge of the patient support near the patient's chest wall at or below 5 millimeters, and keeping the spread of the X-ray irradiation field beyond the edge of the image reception area at or below 2 percent of the focal spot to image receptor distance:
 - (a) when the image reception area is circular and the X-ray irradiation field is rectangular, and the X-ray irradiation field does not exceed the size at the time of circumscribing the image reception area; and
 - (b) when two straight lines intersecting at right angles on an image reception area perpendicular to the irradiation direction are assumed, if the sum of the distances between the points of intersection of each straight line does not exceed 3 percent of the focal spot to image receptor distance, and the total sum of these distances between the points of intersection does not exceed 4 percent of the focal spot to image receptor distance;
 - (ii) maintaining the distance between the focal spot of the X-ray tube and the

- skin as follows; provided, however, that this does not apply in the case of magnification radiography (excluding the case set forth in (f)):
- (a) for an intraoral X-ray unit with a rated tube voltage of 70 kilovolts or less, 15 centimeters or more;
 - (b) for an intraoral X-ray unit with a rated tube voltage exceeding 70 kilovolts, 20 centimeters or more;
 - (c) for a dental panoramic tomography unit, 15 centimeters or more;
 - (d) for a mobile or portable X-ray unit, 20 centimeters or more;
 - (e) for a CT X-ray unit, 15 centimeters or more;
 - (f) for a mammographic X-ray unit (limited to the case of magnification radiography), 20 centimeters or more; and
 - (g) for an X-ray unit other than those set forth in (a) through (f), 45 centimeters or more;
- (iii) for a mobile or portable X-ray unit or an X-ray unit which is used during surgery, constructing the unit so that it can be operated at a position 2 meters or more away from the focal spot of the X-ray tube and the patient.
- (4) Beyond what is provided for in paragraph (1), a photofluorographic X-ray unit for chest mass surveys must be that for which the following damage prevention measures have been taken:
- (i) providing an apparatus which narrows down the X-ray irradiation field so that usable beams will become pyramidal in shape and the X-ray irradiation field will not exceed the image reception area over the distance between the focal spot of the X-ray tube and the image receptor used; provided, however, that an X-ray irradiation field exceeding the image reception area is to be permitted when two straight lines intersecting at right angles on an image reception area perpendicular to the irradiation direction are assumed, if the sum of the distances between the points of intersection of each straight line does not exceed 3 percent of the focal spot to image receptor distance, and the total sum of these distances between the points of intersection does not exceed 4 percent of the focal spot to image receptor distance;
 - (ii) keeping the air kerma in free air (hereinafter referred to as the "air kerma") in the primary protection shielding of the image receptor at a distance of 10 centimeters from the accessible surface of the unit at or below 1.0 microgray per exposure; and
 - (iii) installing box-shaped shielding around the irradiated object, and keeping the air kerma at a distance of 10 centimeters from the shielding at or below 1.0 microgray per exposure; provided, however, that this does not apply when persons engaging in the operation of an X-ray unit or other operations can easily evacuate outside the room at the time of irradiation.
- (5) A therapeutic X-ray unit (excluding brachytherapy unit) must be that for which the damage prevention measures provided for in paragraph (1) have

been taken and that equipped with an interlock which blocks the generation of X-rays when the filter is removed.

(Protection of Medical High-energy Radiation Generators)

Article 30-2 A medical high-energy radiation generator must be that for which the following damage prevention measures have been taken:

- (i) shielding the container of the generator tube so that the radiation dose other than that of usable beams will be one-thousandth or less of the radiation dose of usable beams;
- (ii) taking appropriate protective measures to reduce exposure to unnecessary radiation immediately after irradiation ends;
- (iii) installing an apparatus which automatically indicates the generation of radiation at the time thereof; and
- (iv) when the entrance to the room for using medical high-energy radiation generators is open, installing an interlock which blocks the generation of radiation.

(Protection of Medical Particle Beam Irradiation Apparatuses)

Article 30-2-2 The provisions of the preceding Article apply mutatis mutandis to medical particle beam irradiation apparatuses. In this case, the term "generator tube" in item (i) of the same Article is replaced with "irradiation tube," the term "the generation of radiation" in item (iii) of the same Article is replaced with "irradiation," and the terms "the room for using medical high-energy radiation generators" and "the generation of radiation" in item (iv) of the same Article is replaced with "the room for using medical particle beam irradiation apparatuses" and "irradiation," respectively.

(Protection of Medical Irradiation Apparatuses)

Article 30-3 A medical irradiation apparatus must be that for which the following damage prevention measures have been taken:

- (i) shielding the housing of the radiation source so that the air kerma rate at a distance of 1 meter will be 70 microgray or less per hour when the irradiation port is closed;
- (ii) if necessary to prevent radiation damage, installing an appropriate secondary electron filter at the irradiation port; and
- (iii) constructing the irradiation port so that it can be opened and closed remotely from outside the room for using medical irradiation apparatuses; provided, however, that this does not apply when an appropriate apparatus which protects persons engaging in the operation of a medical irradiation apparatus or other operations is provided.

Section 3 Buildings and Equipment of X-ray Examination Rooms

(X-ray Examination Room)

Article 30-4 The standards for the buildings and equipment of an X-ray examination room are as follows:

- (i) the ceiling, floor, and surrounding walls (hereinafter referred to as "walls, etc.") are to be capable of reducing the effective dose outside the walls, etc. to 1 millisievert or less per week; provided, however, that this does not apply to walls, etc. whose outside is a place which no person passes through or stays at;
- (ii) no place to operate an X-ray unit is installed inside the X-ray examination room; provided, however, that this does not apply when the box-shaped shielding provided for in Article 30, paragraph (4), item (iii) is installed, or when proximity fluoroscopy or mammography is performed after a necessary protection is installed; and
- (iii) a sign is attached to indicate that the room is an X-ray examination room.

(Room for Using Medical High-energy Radiation Generators)

Article 30-5 The standards for the buildings and equipment of a room for using medical high-energy radiation generators are as follows:

- (i) the walls, etc. are to be capable of reducing the effective dose outside the walls, etc. to 1 millisievert or less per week; provided, however, that this does not apply to walls, etc. which outside the walls is a place which no person passes through or stays at;
- (ii) a single entrance through which persons regularly enter and leave is provided, and an apparatus which automatically indicates the generation of radiation at the time thereof is installed in the entrance; and
- (iii) a sign is attached to indicate that the room is that for using medical high-energy radiation generators.

(Room for Using Medical Particle Beam Irradiation Apparatuses)

Article 30-5-2 The provisions of the preceding Article apply mutatis mutandis to a room for using medical particle beam irradiation apparatuses. In this case, the term "the generation of radiation" in item (ii) of the same Article is deemed to be replaced with "irradiation."

(Room for Using Medical Irradiation Apparatuses)

Article 30-6 The standards for the buildings and equipment of a room for using medical irradiation apparatuses are as follows:

- (i) the main structural part, etc. (meaning the main structural part, and the walls and pillars dividing the place thereof; the same applies hereinafter) are

- fireproof structures or are constructed with non-combustible materials;
- (ii) the walls, etc. are to be capable of reducing the effective dose outside the walls, etc. to 1 millisievert or less per week; provided, however, that this does not apply to walls, etc. whose outside is a place which no person passes through or stays at;
- (iii) a single entrance through which persons regularly enter and leave is provided, and an apparatus which automatically indicates the generation of radiation at the time thereof is installed in the entrance; and
- (iv) a sign is attached to indicate that the room is that for using medical irradiation apparatuses.

(Room for Using Medical Irradiation Tools)

Article 30-7 The standards for the buildings and equipment of a room for using medical irradiation tools are as follows:

- (i) the walls, etc. are to be capable of reducing the effective dose outside the walls, etc. to 1 millisievert or less per week; provided, however, that this does not apply to walls, etc. whose outside is a place which no person passes through or stays at;
- (ii) a single entrance through which persons regularly enter and leave is provided; and
- (iii) a sign is attached to indicate that the room is that for using medical irradiation tools.

(Room for Using Radioisotope-equipped Medical Devices)

Article 30-7-2 The standards for the buildings and equipment of a room for using radioisotope-equipped medical devices are as follows:

- (i) the main structural part, etc. are fireproof structures or are constructed with non-combustible materials;
- (ii) locks or other equipment or tools for closing are installed in areas connected to the outside, such as doors;
- (iii) a sign is attached to indicate that the room is that for using radioisotope-equipped medical devices; and
- (iv) appropriate preventive measures, such as installing partitions, are taken against radiation damage.

(Room for Using Medical Radioisotopes)

Article 30-8 The standards for the buildings and equipment of a room for using medical radioisotopes are as follows:

- (i) the main structural part, etc. are fireproof structures or are constructed with non-combustible materials;
- (ii) the room is divided into a room where medical radioisotopes are dispensed

- (hereinafter referred to as the "preparation room") and a room where medical care is carried out using the radioisotopes:
- (iii) the walls, etc. are to be capable of reducing the effective dose outside the walls, etc. to 1 millisievert or less per week; provided, however, that this does not apply to walls, etc. which outside the walls is a place where no person passes through or stays at;
 - (iv) a single entrance through which persons regularly enter and leave is provided;
 - (v) a sign is attached to indicate that the room is that for using medical radioisotopes;
 - (vi) the walls, floor, and other parts inside the room which are likely to be contaminated with radioisotopes are those with few protrusions, dimples, and gaps such as joints of finishing materials;
 - (vii) the surfaces of the walls, floor and other parts inside the room that are likely be contaminated with radioisotopes are finished using smooth and corrosion-inhibiting materials impermeable to gas or liquid;
 - (viii) a radiation meter necessary to inspect contamination with radioisotopes, instruments and cleaning equipment necessary to remove contamination with radioisotopes, and dressing equipment are installed near the entrance;
 - (ix) cleaning equipment is installed in the preparation room;
 - (x) the cleaning equipment provided for in the preceding two items is connected to the drainage equipment installed pursuant to the provisions of Article 30-11, paragraph (1), item (ii); and
 - (xi) if any apparatus, such as a hood or glove box, has been installed in the preparation room to prevent the spread of gaseous radioisotopes or objects contaminated with radioisotopes, the apparatus is connected to the exhaust equipment installed pursuant to the provisions of Article 30-11, paragraph (1), item (iii).

(Room for Using Radioisotopes for Positron Tomography Examination)

Article 30-8-2 The standards for the buildings and equipment of a room for using radioisotopes for positron tomography examination are as follows:

- (i) the main structural part, etc. are fireproof structures or are constructed with non-combustible materials;
- (ii) the room is divided into a room where radioisotopes for positron tomography examination are dispensed (hereinafter referred to as the "positron preparation room"), a room where medical care is carried out using the radioisotopes, and a room where patients to whom radioisotopes for positron tomography examination have been administered wait;
- (iii) the walls, etc. are to be capable of reducing the effective dose outside the walls, etc. to 1 millisievert or less per week; provided, however, that this

- does not apply to walls, etc. which outside the walls is a place where no person passes through or stays at;
- (iv) a single entrance through which persons regularly enter and leave is provided;
 - (v) a sign is attached to indicate that the room is that for using radioisotopes for positron tomography examination;
 - (vi) no place to operate a positron emission tomography scanner is installed inside the room for using radioisotopes for positron tomography examination;
 - (vii) the walls, floor, and other parts inside the room which are likely to be contaminated with radioisotopes are those with few protrusions, dimples, and gaps such as joints of finishing materials;
 - (viii) the surfaces of the walls, floor and other parts inside the room that are likely be contaminated with radioisotopes are finished using smooth and corrosion-inhibiting materials impermeable to gas or liquid;
 - (ix) a radiation meter necessary to inspect contamination with radioisotopes, instruments and cleaning equipment necessary to remove contamination with radioisotopes, and dressing equipment are installed near the entrance;
 - (x) cleaning equipment is installed in the positron preparation room;
 - (xi) the cleaning equipment provided for in the preceding two items is connected to the drainage equipment installed pursuant to the provisions of Article 30-11, paragraph (1), item (ii); and
 - (xii) if any apparatus, such as a hood or glove box, has been installed in the positron preparation room to prevent the spread of gaseous radioisotopes or objects contaminated with radioisotopes, the apparatus is connected to the exhaust equipment installed pursuant to the provisions of Article 30-11, paragraph (1), item (iii).

(Storage Facilities)

Article 30-9 The standards for the buildings and equipment of facilities for storing medical irradiation apparatuses, medical irradiation tools, medical radioisotopes, or radioisotopes for positron tomography examination (hereinafter referred to as the "storage facilities") are as follows:

- (i) the storage facilities are structurally separated from the outside, such as storage rooms and storage boxes;
- (ii) the storage facilities are to be capable of reducing the effective dose outside them to 1 millisievert or less per week; provided, however, that this does not apply to storage facilities whose outside is a place which no person passes through or stays at;
- (iii) the main structural part, etc. of a storage room are fireproof structures, and a fire door falling under the category of specified fire prevention equipment provided for in Article 112, paragraph (1) of the Order for

- Enforcement of the Building Standards Act is installed in its opening; provided, however, that this does not apply when medical irradiation apparatuses or medical irradiation tools are stored in containers that are fireproof structures;
- (iv) a storage box or the like is a fireproof structure; provided, however, that this does not apply when medical irradiation apparatuses or medical irradiation tools are stored in containers that are fireproof structures;
 - (v) a single entrance through which persons regularly enter and leave is provided;
 - (vi) locks or other equipment or tools for closing are installed in areas connected to the outside, such as doors and covers;
 - (vii) a sign is attached to indicate that the facilities are storage facilities;
 - (viii) the storage facilities are equipped with storage containers conforming the following; provided, however, that this does not apply when medical radiation apparatuses or medical irradiation tools are stored in a storage box or the like that is shielded so that the effective dose rate at a distance of 1 meter from its door or cover opened will be 100 microsievert or less per hour:
 - (a) a storage container is capable of reducing the effective dose rate at a distance of 1 meter to 100 microsievert or less per hour during storage;
 - (b) a storage container for containing medical radioisotopes or radioisotopes for positron tomography examination that are likely to contaminate air outside the container is an airtight structure;
 - (c) a storage container for containing liquid medical radioisotopes or radioisotopes for positron tomography examination is structurally unlikely to cause leakage and is made of materials impermeable to liquid; and
 - (d) a sign is attached to indicate that it is a storage container, and the type and the quantity expressed in becquerel units of radioisotopes to be stored and mounted on medical irradiation apparatuses or medical irradiation tools, or of medical radioisotopes or radioisotopes for positron tomography examination to be stored are indicated;
 - (ix) trays, absorbent, or other equipment or tools for preventing the spread of contamination with radioisotopes are installed.

(Transportation Containers)

Article 30-10 The provisions of item (viii), (a) through (d) of the preceding Article apply mutatis mutandis to the structural standards of a container for transporting medical irradiation apparatuses, medical irradiation tools, medical radioisotopes, or radioisotopes for positron tomography examination (hereinafter referred to as a "transportation container").

(Disposal Facilities)

Article 30-11 (1) The standards for the buildings and equipment of facilities where medical radioisotopes, radioisotopes for positron tomography examination, or objects contaminated with radioisotopes (hereinafter referred to as "medical radioactive contaminants") are disposed of (hereinafter referred to as the "disposal facilities") are as follows:

- (i) the disposal facilities are to be capable of reducing the effective dose outside them to 1 millisievert or less per week; provided, however, that this does not apply to disposal facilities where outside the facility is a place where no person passes through or stays at;
- (ii) when liquid medical radioactive contaminants are drained or purified, drainage equipment (meaning a series of equipment for draining or purifying liquid medical radioactive contaminants, such as drain pipes and waste liquid treatment tanks; the same applies hereinafter) is installed pursuant to the following provisions:
 - (a) the equipment has the ability to keep the concentration of radioisotopes in waste liquid at its drainage outlets at or below the concentration limit prescribed in Article 30-26, paragraph (1), or to keep the concentration of radioisotopes in waste water at the boundary of the hospital or clinic (when measures have been taken to prevent persons from entering an area adjacent to the boundary of the hospital or clinic without good reason, the boundary of the area; the same applies hereinafter) at or below the concentration limit prescribed in Article 30-26, paragraph (1) by installing waste water monitoring equipment and monitoring the concentration of radioisotopes in waste water;
 - (b) the equipment is structurally unlikely to cause the leakage of waste liquid and is made of corrosion-inhibiting materials impermeable to waste liquid;
 - (c) a waste liquid treatment tank is structurally capable of collecting waste liquid or capable of measuring the concentration of radioisotopes in waste liquid, and is provided with an apparatus for controlling the outflow of waste liquid;
 - (d) the opening of the upper part of a waste liquid treatment tank is structurally capable of being closed with a cover, or fences or other equipment (hereinafter referred to as "fences, etc. ") are installed around the tank to prevent persons from entering without good reason; and
 - (e) a sign is attached to each drain pipe and waste liquid treatment tank in order to indicate that it is a drainage equipment;
- (iii) when gaseous medical radioactive contaminants are exhausted or purified, exhaust equipment (meaning a series of equipment for exhausting or purifying gaseous medical radioactive contaminants, such as exhausters, exhaust gas purifiers, exhaust pipes, and exhaust ports; the same applies

hereinafter) is installed pursuant to the following provisions; provided, however, that this does not apply when it is extremely difficult to install exhaust equipment due to the nature of the work and there is no risk of generating gaseous radioisotopes or contaminating the air with radioisotopes:

- (a) the equipment has the ability to keep the concentration of radioisotopes in exhaust gas at its exhaust ports at or below the concentration limit prescribed in Article 30-26, paragraph (1), or to keep the concentration of radioisotopes in air outside the boundary of the hospitals or clinic at or below the concentration limit prescribed in Article 30-26, paragraph (1) by installing exhaust gas monitoring equipment and monitoring the concentration of radioisotopes in exhaust gas;
 - (b) the equipment has the ability to keep the concentration of radioisotopes in the air at places where persons regularly enter at or below the concentration limit prescribed in Article 30-26, paragraph (2);
 - (c) the equipment is structurally unlikely to cause the leakage of gas and is made of corrosion-inhibiting materials;
 - (d) the equipment is provided with an apparatus which is capable of rapidly preventing the spread of objects contaminated with radioisotopes when any trouble occurs; and
 - (e) a sign is attached to each exhaust gas purifier, exhaust pipe, and exhaust port in order to indicate that it is exhaust equipment;
- (iv) when medical radioactive contaminants are incinerated, the following equipment is installed:
- (a) an incinerator satisfying the following requirements:
 - 1. the incinerator is structurally unlikely to cause the leakage of gas and the scattering of ash;
 - 2. the incinerator is structurally connected to the exhaust equipment;
 - 3. the outlet of the incinerator from which incinerated residues are taken out is connected to a waste work room (meaning a room in which the residues of incinerated medical radioactive contaminants are taken out from the incinerator or is solidified (or processed for solidification) with concrete or other solidifying materials; hereinafter the same applies in this item).
 - (b) a waste work room satisfying the following requirements:
 - 1. the walls, floor and other parts inside of the waste work room that are likely to be contaminated with radioisotopes are structures with few protrusions, dimples, and gaps such as joints of finishing materials;
 - 2. the surfaces of the walls, floor and other parts inside the waste work room that are likely be contaminated with radioisotopes are finished using smooth and corrosion-inhibiting materials impermeable to gas or

- liquid;
3. if any apparatus, such as a hood or glove box, has been installed in the waste work room to prevent the spread of gaseous medical radioactive contaminants, the apparatus is connected to the exhaust equipment; and
 4. a sign is attached to indicate that the room is a waste work room;
- (c) a contamination inspection room (meaning a room in which the surface of a human body or an article worn by a human body, such as work clothing, footwear, or personal protective equipment, is inspected for contamination with radioisotopes) satisfying the following requirements:
1. the room is installed near the entrance of the disposal facilities through which persons regularly enter and leave or in any other optimal place to conduct inspections for contamination with radioisotopes;
 2. the walls, floor and other parts inside the contamination inspection room that are likely be contaminated with radioisotopes satisfy the requirements set forth in (b), 1. and 2.;
 3. cleaning equipment and dressing equipment are installed, and a radiation meter for contamination inspections and instruments necessary to remove contamination are provided;
 4. the drain pipes of the cleaning equipment referred to in 3. are connected to the drainage equipment; and
 5. a sign is attached to indicate that the room is a contamination inspection room;
- (v) when medical radioactive contaminants are disposed of by storage (excluding the case prescribed in the following item), disposal-by-storage equipment is installed pursuant to the following provisions:
- (a) the equipment is structurally separated from the outside;
 - (b) locks or other equipment or tools for closing are installed in areas connected to the outside, such as doors and covers of the disposal-by-storage equipment;
 - (c) the disposal-by-storage equipment is equipped with a container that is a fireproof structure pursuant to the provisions of Article 30-9, item (viii), (b) and (c), and a sign is attached to the surface of the container to indicate that the container is a disposal-by-storage container; and
 - (d) a sign is attached to indicate that the equipment is disposal-by-storage equipment;
- (vi) when radioisotopes for positron tomography examination (limited to those whose maximum quantity to be used per day is not more than the quantity prescribed by the Minister of Health, Labour and Welfare for each type prescribed by the Minister of Health, Labour and Welfare; hereinafter the same applies in this item) or objects contaminated with radioisotopes for

positron tomography examination are disposed of by storage, that is carried out within the controlled area beyond the period specified by the Minister of Health, Labour and Welfare as a period for which the number of atoms of the radioisotopes for positron tomography examination will certainly fall below one by sealing the radioisotopes for positron tomography examination or objects contaminated therewith and indicating to that effect in order to prevent contamination or adhesion by other objects.

- (2) The provisions of item (ii), (a) or item (iii), (a) of the preceding paragraph do not apply when it is extremely difficult to install drainage equipment or exhaust equipment having the ability provided for in item (ii), (a) or item (iii), (a) of the same paragraph, if the Minister of Health, Labour and Welfare has approved the ability of the relevant drainage equipment or exhaust equipment to keep the effective dose outside the boundary of the hospital or clinic at or below 1 millisievert per year. In this case, the effective dose outside the boundary of the hospital or clinic must be kept at or below 1 millisievert per year by monitoring the quantity and concentration of radioisotopes in waste water at the drainage outlets or the place where waste water monitoring equipment is located, or by monitoring the quantity and concentration of radioisotopes in exhaust gas at the exhaust ports or the place where exhaust gas monitoring equipment is located.
- (3) When it is found that drainage equipment or exhaust equipment for which the approval referred to in the preceding paragraph has been granted no longer has the approved ability, the Minister of Health, Labour and Welfare may rescind the approval.
- (4) Radioisotopes for positron tomography examination or the objects contaminated with radioisotopes for positron tomography examination that are disposed of by storage pursuant to the provisions of paragraph (1), item (vi) are no longer to be radioisotopes for positron tomography examination or objects contaminated with radioisotopes after the expiration of the period specified by the Minister of Health, Labour and Welfare referred to in the same item.

(Radiation Therapy Sickrooms)

Article 30-12 Standards for the structure and equipment of a sickroom to hospitalize patients under treatment using an irradiation appliance for medical care, irradiation implement for medical care, radioisotopes for medical care, or radioisotopes for positron computerized tomography examination (hereinafter referred to as "radiation therapy sickroom") is as follows:

- (i) the room is to be equipped with walls, etc. or other necessary screens so that the effective dose outside the walls, etc. will be not more than 1 millisievert per week; provided, however, that this does not apply to walls, etc. whose outside is a place which no person passes through or stays at or a radiation

- therapy sickroom;
- (ii) a sign which shows that it is a radiation therapy sickroom is to be attached to the room; and
 - (iii) the room must conform to the provisions of Article 30-8, items (vi) through (viii); provided, however, that the provisions of Article 30-8, item (viii) do not apply to radiation therapy sickrooms to hospitalize only patients under treatment with an irradiation appliance for medical care or irradiation implement for medical care.

Section 4 Obligations of Managers

(Posting of Precautions)

Article 30-13 The manager of a hospital or clinic must post necessary precautions to prevent radiation damage at a conspicuous place of an X-ray examination room, room for using high-energy radiation generators for medical care, room for using particle beam irradiation appliances for medical care, room for using irradiation appliances for medical care, room for using irradiation implements for medical care, room for using medical examination appliances equipped with radioisotopes, room for using radioisotopes for medical care, room for using radioisotopes for positron computerized tomography examination, storage facility, disposal facility, and radiation therapy sickroom (hereinafter referred to as "radiation handling facilities").

(Restriction of Places for Use)

Article 30-14 The manager of a hospital or clinic must carry out the operations set forth in the left columns of the table below in the rooms or facilities set forth respectively in the middle columns of the relevant table or with the implements set forth respectively in the relevant columns; provided, however, that this does not apply to the case falling under the cases set forth in the right columns of the table below.

(Entrustment of Disposal of Radioisotopes for Medical Care)

Article 30-14-2 (1) Notwithstanding the provisions of the preceding Article, the manager of a hospital or clinic may entrust the disposal of radioactive contaminants for medical care to a facility for repacking radioactive contaminants for medical care which conforms to technical standards for positions, structure and equipment as specified in the following Article (hereinafter referred to as "waste repacking facility"), a facility for storing radioactive contaminants for medical care (hereinafter referred to as "waste storage facility") or a person who has a disposal facility and is separately designated by Order of the Ministry of Health, Labour and Welfare.

- (2) A person who intends to receive the designation referred to in the preceding paragraph must submit to the Minister of Health, Labour and Welfare an application form stating the following information:
 - (i) the name and address of the person as well as the name of its representative when the person is a corporation;
 - (ii) the location of the disposal place of business;
 - (iii) the method of disposal;
 - (iv) the position, structure and equipment of the waste repacking facility;
 - (v) the position, structure, equipment and storage capacity of the waste storage facility; and
 - (vi) the position, structure and equipment of the disposal facility.
- (3) Conditions may be set to the designation referred to in paragraph (1).
- (4) The conditions referred to in the preceding paragraph must be limited to the minimum necessary ones to prevent radiation damage and must be those pursuant to which unreasonable obligations are not imposed on a person who receives the designation.
- (5) If a person who has received the designation referred to in paragraph (1) breaches a condition for designation as referred to in paragraph (3) or if the waste repacking facility, waste storage facility or disposal facility which the person owns ceases to conform to the technical standards referred to in paragraph (1), the Minister of Health, Labour and Welfare may rescind the designation.

Article 30-14-3 (1) Technical standards for the positions, structure and equipment of waste repacking facilities are to be as follows:

- (i) the facility is to be established at a place where there is little risk of a landslide and flooding occurring;
- (ii) when the facility has a building prescribed in Article 2, item (i) of the Building Standards Act or a room prescribed in item (iv) of the relevant Article, the main structural part, etc. of it is to be fireproof structure or a structure using non-inflammable materials;
- (iii) the facility is to be equipped with shields, such as shielding walls, which are needed to keep the effective doses set forth in the left columns of the table below not more than the limits of the effective doses as set forth respectively in the right columns of the relevant table;
- (iv) in the case of repacking unsealed radioactive contaminants for medical care, the facility is to have a repacking work room which meets the necessary conditions set forth in Article 30-11, paragraph (1), item (iv), (b) and a contamination test room which meets the necessary conditions set forth in (c) of the relevant item;
- (v) fences or the like are to be placed at the boundary of the controlled zone

- (which means a place in which the dose of external radiation, the concentration of radioisotopes in the air, or the density of radioisotopes on the surface of a thing contaminated with radioisotopes is liable to exceed the dose, contamination or density specified in Article 30-26, paragraph (3); the same applies hereinafter), and a sign showing that it is the controlled zone is to be attached by that boundary; and
- (vi) a sign showing that eating, drinking, or smoking is prohibited in a place in which persons are at risk of orally ingesting radioisotopes is to be attached.
- (2) Technical standards for the positions, structure and equipment of waste storage facilities are to be as follows:
- (i) the facility is to be established at a place where there is little risk of a landslide and flooding occurring;
- (ii) the facility is to be provided with a storage room which meets the necessary conditions set forth in the main clause of Article 30-9, item (iii) or a storage box which meets the necessary conditions set forth in the main clause of item (iv) of the relevant Article, to which a sign showing that it is a storage room or storage box is to be attached;
- (iii) the facility is to be equipped with walls, such as shielding walls, which meet the necessary conditions set forth in item (iii) of the preceding paragraph;
- (iv) the facility is to be provided with storage containers for radioactive contaminants for medical care which meet the following necessary conditions:
- (a) a storage container for radioactive contaminants for medical care which are liable to contaminate the air outside the container is to be structurally airtight;
- (b) a storage container for liquid radioactive contaminants for medical care is to be a structure that prevents the liquid from spilling, and materials which liquid does not easily penetrate;
- (c) a storage container for liquid or solid radioactive contaminants for medical care to which an accident, such as a crack or break, is liable to occur is to be equipped with a saucer, absorber or other equipment or other measures for preventing the spread of contamination through radioactive contaminants; and
- (d) a sign showing that it is a storage container is to be attached;
- (v) the part of a storage room or storage box which lead to the outside, such as its door or lid, is to be equipped with equipment or an implement for closing, such as a lock;
- (vi) at the boundary of the controlled zone, fences or the like and a sign showing that it is the controlled zone is to be attached; and
- (vii) a sign showing that eating, drinking, or smoking is prohibited in a place in

which persons are at risk of orally ingesting radioisotopes is to be be attached.

- (3) Technical standards for the positions, structure and equipment of the disposal facilities set forth in paragraph (1) of the preceding Article is to be as follows:
- (i) the facility is to be established at a place where there is little risk of a landslide and flooding occurring;
 - (ii) the main structural part and the like is to have fireproof structure or structure using non-inflammable materials;
 - (iii) the facility is to be equipped with walls, such as shielding walls, which meet the necessary conditions set forth in item (iii) of paragraph (1);
 - (iv) when liquid or gaseous radioactive contaminants for medical care are disposed of, the facility is to be equipped with drainage which meets the necessary conditions set forth in Article 30-11, paragraph (1), item (ii) or exhaust equipment which meets the necessary conditions set forth in item (iii) of the relevant paragraph;
 - (v) when radioactive contaminants for medical care are incinerated, the facility is to be equipped with exhaust equipment which meets the necessary conditions set forth in Article 30-11, paragraph (1), item (iii), an incinerator which meets the necessary conditions set forth in item (iv), (a) of the relevant paragraph, a disposal work room which meets the necessary conditions set forth in (b) of the relevant item, and a contamination test room which meets the necessary conditions set forth in (c) of the relevant item;
 - (vi) when radioactive contaminants for medical care are solidified with a solidifying material, such as concrete, the facility is to be equipped with solidification treatment equipment (which means equipment for solidifying radioactive contaminants for medical care with a solidifying material, such as concrete, including crushing apparatus, compressors, mixers, and packing apparatus) which meets the following necessary conditions as well as being equipped with exhaust equipment which meets the necessary conditions set forth in Article 30-11, paragraph (1), item (iii) and is to have a disposal work room which meets the necessary conditions set forth in item (iv), (b) of the relevant paragraph and a contamination test room which meets the necessary conditions set forth in (c) of the relevant item:
 - (a) the equipment is to have structure in which radioactive contaminants for medical care do not easily leak or spill and the particulates do not scatter easily; and
 - (b) materials that are resistant to liquid penetration and corrosion are to be used for the equipment;
 - (vii) when radioactive contaminants for medical care are stored and disposed of, the facility is to be equipped with storage and disposal equipment that meets the following necessary conditions:

- (a) the equipment is to be separated from the outside;
 - (b) the part leading to the outside, such as its door or lid, is to be equipped with equipment or an implement for closing, such as a lock;
 - (c) the equipment is to be provided with a storage and disposal container which has fireproof structure and meets the necessary conditions set forth in item (iv) of the preceding paragraph; provided, however, that this does not apply to the case where an object contaminated with radioisotopes is a large machine or the like and it is extremely difficult to enclose the object in the container, when special measures are taken to prevent the spread of contamination; and
 - (d) a sign is attached to indicate that the equipment is disposal-by-storage equipment;
 - (viii) at the boundary of the controlled zone, fences or the like and a sign showing that it is the controlled zone is to be attached; and
 - (ix) a sign showing that eating, drinking, or smoking is prohibited in a place in which persons are at risk of orally ingesting radioisotopes is to be attached at the facility.
- (4) The provisions of Article 30-11, paragraphs (2) and (3) apply mutatis mutandis to the drainage or exhaust equipment referred to in items (iv) through (vi) of the preceding paragraph. In this case, in paragraph (2) of the relevant Article, the term "item (ii), (a) of the preceding paragraph" is replaced with "Article 30-11, paragraph (1), item (ii), (a) regarding the drainage or exhaust equipment set forth in items (iv) through (vi) of the preceding paragraph," and the term "hospital or clinic" with "disposal facility."

(Restriction of Patients' Hospitalization)

- Article 30-15 (1) The manager of a hospital or clinic must not permit a patient under treatment into whom an irradiation appliance for medical care or irradiation implement for medical care is continuously inserted or a patient who is treated with radioisotopes for medical care or radioisotopes for positron computerized tomography examination to be hospitalized in other sickroom than radiation therapy sickrooms; provided, however, that this does not apply to the case where appropriate protective measures and contamination control measures are taken.
- (2) The manager of a hospital or clinic must not permit other patient than the patient prescribed in the preceding paragraph to be hospitalized in a radiation therapy sickroom.

(Controlled Zones)

- Article 30-16 (1) The manager of a hospital or clinic must place a sign showing that it is a controlled zone to a controlled zone in the hospital or clinic.

- (2) The manager of a hospital or clinic must take measures to prevent persons from entering the controlled zone referred to in the preceding paragraph without reason.

(Protection at Boundary of Site)

Article 30-17 The manager of a hospital or clinic must keep the dose in a zone in the hospital or clinic in which persons reside and at the boundary of the site of the hospital or clinic not more than the dose limit specified in Article 30-26, paragraph (4) by taking such measures as installing suitable shields at or around the radiation handling facility.

(Prevention of Care Workers' Exposure to Radiation)

Article 30-18 (1) The manager of a hospital or clinic is to take any of the measures set forth in items (i) through (iii) and the measures set forth in items (iv) through (vi) and must keep a dose at which a radiation care worker, etc. (which means a person who is involved in handling or management of an X-ray unit, high-energy radiation generator for medical care, particle beam irradiation appliance for medical care, irradiation appliance for medical care, irradiation implement for medical care, medical appliance equipped with radioisotopes, radioisotopes for medical care, or radioisotopes for positron computerized tomography examination (hereinafter referred to as "X-ray unit, etc." in this paragraph) or in operations incidental thereto and enters the controlled zone; the same applies hereinafter) not exceeding the effective dose limit and the equivalent dose limit specified in Article 30-27:

- (i) shielding radiation by using walls, such as shielding walls;
- (ii) keeping an adequate distance between an X-ray unit, etc. and a human body in such a way as using a remote controller or forceps;
- (iii) shortening time during which a human body is exposed to radiation;
- (iv) keeping the concentration of radioisotopes contained in air which a radiation care worker, etc. breathes in a room for using radioisotopes for medical care, room for using radioisotopes for positron computerized tomography examination, storage facility, disposal facility, or radiation therapy sickroom not exceeding the concentration limit specified in Article 30-26, paragraph (2);
- (v) keeping the surface density of radioisotopes on an object which a person touches in a room for using radioisotopes for medical care, room for using radioisotopes for positron computerized tomography examination, storage facility, disposal facility, or radiation therapy sickroom not exceeding the surface density limit specified in Article 30-26, paragraph (6); and
- (vi) prohibiting eating, drinking, or smoking in a place where a person is at risk of ingesting radioisotopes orally.

- (2) The effective dose and the equivalent dose referred to in the preceding paragraph is calculated as specified by the Minister of Health, Labour and Welfare based on the results of the measurement of a dose through being exposed to external radiation (hereinafter referred to as "external exposure") and a dose through being exposed to radiation from radioisotopes ingested inside the human body (hereinafter referred to as "internal exposure") under the following provisions:
- (i) a dose through external exposure is measured by measuring a 1-centimeter dose equivalent and a 70-micrometer dose equivalent (or 1-centimeter dose equivalent for neutron beams) with a radiation meter; provided, however, that, if it is extremely difficult to measure them with a radiation meter, the values of them may be computed by calculation;
 - (ii) a dose through external exposure is measured on the chest (or the abdomen for a woman (except for those who have been diagnosed as there being no possibility of their becoming pregnant and those who have notified the manager of a hospital or clinic in writing that they have no intention of becoming pregnant; hereinafter the same applies in this item)); provided, however, that, when the trunk (which means the head, neck, chest, upper arm, abdomen and thigh of the human body parts; the same applies hereinafter) is classified into three sections, namely the section of the head and neck, that of the chest and upper arms, and that of the abdomen and thigh, if the section on which an exposure dose is liable to be the maximum is a section other than that of the chest and upper arms (or that of the abdomen and thigh for women), a dose is measured on that section and that, if a human body part which may be exposed to the maximum does is a part other than the trunk, a dose is also to be measured on that part;
 - (iii) notwithstanding the provisions of item (i), when a dose is measured on a part other than the trunk, pursuant to the proviso of the preceding item, it is sufficient to measure a 70-micrometer dose equivalent (or 1-centimeter dose equivalent for neutron beams);
 - (iv) a dose through external exposure is measured continuously while a worker is in the controlled zone; and
 - (v) a dose through internal exposure is measured whenever a worker inhales or orally ingests radioisotopes by mistake or once in each period of less than three months when a worker enters a room for using radioisotopes for medical care, room for using radioisotopes for positron computerized tomography examination or other place in which the worker is at risk of inhaling or orally ingesting radioisotopes (or once in each period of less than one month for a pregnant woman during a period from the time when the manager of a hospital or clinic learns the fact of pregnancy through a report or the like from the woman to the time of childbirth) as specified by the

Minister of Health, Labour and Welfare.

(Prevention of Patients' Exposure to Radiation)

Article 30-19 The manager of a hospital or clinic must keep the effective dose of radiation (except for radiation to which a patient is exposed in medical care) to which a patient hospitalized in a sickroom of the hospital or clinic is exposed not exceeding 1.3 millisievert per three months by taking such measures as using walls, such as shielding walls.

(Particulars to be Observed When Handling Persons)

Article 30-20 (1) The manager of a hospital or clinic must have a person handling radioactive contaminants for medical care observe the following particulars:

- (i) the handling person is to wear work clothes or the like in a room for using radioisotopes for medical care, room for using radioisotopes for positron computerized tomography examination, or disposal facility and is not go out of that room or facility in the clothes without due cause;
- (ii) the handling person is not take an object contaminated with radioisotopes on whose surface has a radioisotopes density exceeding the surface density limit specified in Article 30-26, paragraph (6) out of a room for using radioisotopes for medical care, room for using radioisotopes for positron computerized tomography examination, disposal facility, or radiation therapy sickroom without due cause; and
- (iii) the handling person is not take an objected contaminated with radioisotopes on whose surface has a radioisotopes density exceeding one-tenth of the surface density limit specified in Article 30-26, paragraph (6) out of the controlled zone without reason.

(2) The manager of a hospital or clinic must have a physician or dentist who gives a radiation treatment observe the following particulars:

- (i) when they use an X-ray unit, the doctor or dentist is to indicate that fact at the doorway of the X-ray examination room; and
- (ii) the doctor or dentist is to put an appropriate sign to a patient who has treatment with an irradiation appliance for medical care, irradiation implement for medical care, radioisotopes for medical care, or radioisotopes for positron computerized tomography examination.

(Measurement of X-ray Units)

Article 30-21 The manager of a hospital or clinic is to measure the radiological dosage of a therapeutic X-ray unit, high-energy radiation generator for medical care, particle beam irradiation appliance for medical care, and irradiation appliance for medical care once or more in each period of less than six months

with a dosimeter and must store the record of the results for five years.

(Measurement of Places Where There Is a Risk of Radiation Damage)

Article 30-22 (1) The manager of a hospital or clinic is to measure a radiation quantity and the state of contamination through radioisotopes once before the beginning of medical care and once in each period of less than one month after the beginning of medical care (or once in each period of less than six months, in the case of the measurement set forth in item (i), or each time drainage or exhaust is carried out in the case of the measurement set forth in item (ii) (or in succession when drainage or exhaust is carried out in succession)) at a place in which radiation damage is liable to occur and must keep the record of the results for five years:

- (i) the measurement of a radiation quantity in an X-ray examination room, room for using high-energy radiation generators for medical care, room for using particle beam irradiation appliances for medical care, room for using irradiation appliances for medical care, and room for using medical appliances equipped with radioisotopes, at the boundary of the controlled zone, in the zone in the hospital or clinic in which persons reside, and at the boundary of the site of the hospital or clinic in the case where an X-ray unit, high-energy radiation generator for medical care, particle beam irradiation appliance for medical care, irradiation appliance for medical care, or medical appliance equipped with radioisotopes is fixed and handled, if the method of handling it and the positions of walls, such as shielding walls, are fixed; and
 - (ii) the measurement of the state of contamination through radioisotopes at a place at which the drain of drainage, the vent of exhaust equipment or drainage monitoring equipment is located and at a place at which exhaust monitoring equipment is located.
- (2) The radiation quantity and the state of contamination through radioisotopes under the provisions of the preceding paragraph is measured pursuant to the provisions of the following items:
- (i) radiation quantity is measured for a 1-centimeter dose equivalent rate or 1-centimeter dose equivalent; provided, however, that that quantity is measured for a 70-micrometer dose equivalent rate or 70-micrometer dose equivalent, respectively, at a place at which a 70-micrometer dose equivalent rate is likely to be over ten times the value of 1-centimeter dose equivalent rate or at a place at which a 70-micrometer dose equivalent is likely to be over ten times of the value of the 1-centimeter dose equivalent;
 - (ii) a radiation quantity and the state of contamination through radioisotopes is measured with a radiation meter at the most suitable position for measuring them; provided, however, that, if it is extremely difficult to measure them with a radiation meter, their values may be computed by

calculation; and

- (iii) the measurement referred to in the preceding two items are carried out at the places set forth in the right columns of the table below according to the items set forth in the left columns of the relevant table.

(Registration)

Article 30-23 (1) The manager of a hospital or clinic must keep books, enter the total hours of use per week regarding the appliances or implements set forth in the middle columns of the table below for each of the rooms set forth in the left columns of the relevant table, close the books annually, and keep the books for two years after their closure; provided, however, that this does not apply to a room shielded off so that the effective dose rate outside the walls or the like of that room is not more than the dose rate set forth respectively in the right columns of the relevant table.

(2) The manager of a hospital or clinic must keep books, enter the following particulars concerning the acquisition, use, and disposal of irradiation appliances for medical care, irradiation implements for medical care, radioisotopes for medical care, or radioisotopes for positron computerized tomography examination as well as the disposal of things contaminated with radioisotopes, close the books annually, and keep the books for five years after their closure:

- (i) the date of acquisition, use or disposal;
- (ii) the model and the number of irradiation appliances for medical care or irradiation implements for medical care pertaining to the acquisition, use or disposal;
- (iii) the class and the quantity in becquerels of radioisotopes provided to irradiation appliances for medical care or irradiation appliances for medical care pertaining to the acquisition, use or disposal;
- (iv) the class and the quantity in becquerels of radioactive contaminants for medical care pertaining to the acquisition, use or disposal; and
- (v) the name of a person having used them or the name of a person involved in the disposal as well as the method and place of the disposal.

(Measures After Discontinuance)

Article 30-24 When a hospital or clinic ceases to be provided with radioisotopes for medical care or radioisotopes for positron computerized tomography examination, the manager of the hospital or clinic must take the following measures within thirty days:

- (i) the manager is to remove contamination through radioisotopes; and
- (ii) the manager is to transfer or dispose of things contaminated with radioisotopes.

(Measures in Case of Accidents)

Article 30-25 If radiation damage arises or is liable to arise due to a disaster, such as an earthquake or fire, or an accident, such as a theft or loss, the manager of a hospital or clinic must immediately make a report to that effect to the health center, police station, fire station and other related organizations having jurisdiction over the location of the hospital or clinic and must endeavor to prevent radiation damage.

Section 5 Limits

(Concentration Limits)

Article 30-26 (1) With regard to the concentration limits prescribed in Article 30-11, paragraph (1), item (ii), (a) and item (iii), (a), the average concentrations for three months of radioisotopes in drainage or effluent or exhaust gas or the air are to be as follows:

- (i) when the class (which means those set forth in Appended Table 3; the same applies in the following item and item (iii)) of radioisotopes is known and one, according to the classes of radioisotopes as set forth in Column 1 of Appended Table 3, the concentration set forth in Column 3 for that in drainage or effluent or the concentration set forth in Column 4 for that in exhaust gas or the air;
 - (ii) when the classes of radioisotopes are known, if two or more classes of radioisotopes are in drainage or effluent or in exhaust gas or the air, the concentration of radioisotopes in which the sum of the proportions of the concentrations of those radioisotopes respectively to the concentrations of them as referred to in the preceding item is one;
 - (iii) when the classes of radioisotopes are unknown, the concentrations in drainage or effluent or the concentrations in exhaust gas or the air as set forth in Column 3 or 4 of Appended Table 3 (except for those pertaining to the classes of radioisotopes for which it is clear that those classes are not contained in that drainage or effluent or in that exhaust gas or air), whichever the lowest; and
 - (iv) when the class of radioisotopes is known, if that class is not set forth in Column 3 of Appended Table 3, according to the categories of radioisotopes as set forth in Column 1 of Appended Table 4, the concentration set forth in Column 3 for that in drainage or effluent or the concentration set forth in Column 4 for that in exhaust gas or the air.
- (2) With regard to the concentration limits on radioisotopes in the air as prescribed in Article 30-11, paragraph (1), item (iii), (b) and Article 30-18, paragraph (1), item (iv), the average concentrations for one week is to be the

following concentrations:

- (i) when the class (which means those set forth in Appended Table 3; the same applies in the following item and item (iii)) of radioisotopes is known and one, according to the classes of radioisotopes as set forth in Column 1 of Appended Table 3, the concentrations set forth in Column 2;
 - (ii) when the classes of radioisotopes are known, if two or more classes of radioisotopes are in the air, the concentration of radioisotopes in which the sum of the proportions of the concentrations of those radioisotopes respectively to the concentrations of them as referred to in the preceding item is one;
 - (iii) when the classes of radioisotopes are unknown, the concentrations set forth in Column 2 of Appended Table 3 (except for those pertaining to the classes of radioactive substances for which it is clear that those classes are not contained in that air), whichever the lowest; and
 - (iv) when the class of radioisotopes is known, if that class is not set forth in Appended Table 3, according to the categories of radioisotopes as set forth in Column 1 of Appended Table 4, the concentration set forth in Column 2.
- (3) A dose of external radiation pertaining to the controlled zone, the concentration of radioisotopes in the air, and the density of radioisotopes on the surface of a thing contaminated with radioisotopes is as follows:
- (i) regarding a dose of external radiation, an effective dose is to be 1.3 millisieverts per three months;
 - (ii) regarding the concentration of radioisotopes in the air, the average concentration for three months is to be one-tenth of the concentration prescribed in the preceding paragraph;
 - (iii) the density of radioisotopes on the surface of a thing contaminated with radioisotopes is to be one-tenth of the density prescribed in paragraph (6); and
 - (iv) notwithstanding the provisions of items (i) and (ii), when there is a risk of being exposed to external radiation, if there is a risk of inhaling radioisotopes in the air, the effective dose and the concentration of radioisotopes in the air for which the sum of the proportion of the effective dose to the dose prescribed in item (i) and the proportion of the concentration of radioisotopes in the air to the concentration prescribed in item (ii) is one.
- (4) With regard to the dose limit prescribed in Article 30-17, an effective dose is to be 250 microsieverts per three months.
- (5) With regard to the provisions of paragraph (1) and the preceding paragraph, if there is a risk of being exposed to external radiation simultaneously or if there is a risk of inhaling radioisotopes in the air or of orally ingesting radioisotopes in the water simultaneously, the concentration limit or dose limit is to be the concentration or dose for which the sum of the proportions of the

concentrations or doses in the air or water respectively to the concentration limit or dose limit is one.

- (6) The surface density limits prescribed in Article 30-18, paragraph (1), item (v) and Article 30-20, paragraph (1), items (ii) and (iii), according to the categories set forth in the left columns of Appended Table 5, is the density set forth respectively in the right columns.

(Dose Limits)

Article 30-27 (1) The effective dose limits for radiation care workers, etc. as prescribed in Article 30-18, paragraph (1) is as follows; provided, however, that the effective dose limit for a radiation care worker, etc. involved in urgent work to prevent radiation damage (limited to those who have been diagnosed as there being no possibility of their becoming pregnant and those who have notified the manager of a hospital or clinic in writing that they have no intention of becoming pregnant, for women; referred to as "urgent radiation care worker, etc." in the following paragraph) is 100 millisieverts:

- (i) 100 millisieverts for each of periods of five years on and after April 1, 2001;
- (ii) 50 millisieverts for a period of one year commencing on April 1;
- (iii) regarding women (except for those who have been diagnosed as there being no possibility of them becoming pregnant, those who have notified the manager of a hospital or clinic in writing that they have no intention of becoming pregnant, and those prescribed in the following item), beyond as prescribed in the preceding two items, 5 millisieverts for each of periods of three months commencing on April 1, July 1, October 1, and January 1; and
- (iv) for a pregnant woman, beyond as prescribed in items (i) and (ii), 1 millisievert for internal exposure for a period from the time when the manager of a hospital or clinic learns the fact of pregnancy from a report from that woman to the time of childbirth.

(2) The equivalent dose limits for radiation care workers, etc. as prescribed in Article 30-18, paragraph (1) is as follows:

- (i) 150 millisieverts for a period of one year commencing on April 1 for the lens of the eyes (the equivalent dose limit for the lens of the eyes for urgent radiation care workers, etc. is 300 millisieverts);
- (ii) 500 millisieverts for a period of one year commencing on April 1 for skin (the equivalent dose limit for skin for urgent radiation care workers, etc. is 1 sievert); and
- (iii) 2 millisieverts for the period prescribed in item (iv) of the preceding paragraph for the surface of the abdomen of a pregnant woman.

Chapter IV-2 Basic Policy

(Request by Minister of Health, Labour and Welfare to Provide Information)
Article 30-27-2 The Minister of Health, Labour and Welfare is to request the establisher or manager of a sickbed function reporting hospital, etc. as prescribed in Article 30-13, paragraph (1) of the Act to provide information reported to an entrustee prescribed in Article 30-33-6, paragraph (2) (hereinafter referred to as "entrustee" in this Article) through the entrustee by the method of recording it in a file, etc. as prescribed in the relevant paragraph or by means of receipt information as prescribed in paragraph (iii) of the relevant Article, pursuant to the provisions of Article 30-3-2 of the Act.

Chapter IV-2-2 Medical Care Plans

(Diseases Specified by Order of the Ministry of Health, Labour and Welfare as Referred to in Article 30-4, Paragraph (2), Item (iv) of the Act)
Article 30-28 Diseases specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 30-4, paragraph (2), item (iv) of the Act are cancer, strokes, cardiovascular diseases, such as myocardial infarction, diabetes, and mental diseases.

(Standards specified by Order of the Ministry of Health, Labour and Welfare as Prescribed in Article 30-4, Paragraph (2), Item (vii) of the Act)
Article 30-28-2 Standards specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 30-4, paragraph (2), item (vii) of the Act are set by the zone in which it is found appropriate to promote the specialization and coordination of sickbed functions in an area as a united zone in consideration of the trend of demand for medical care, including predictions for changes in population structures, and other circumstances, including predictions for the states of posting of medical workers and of establishment of medical institutions, by considering the zone prescribed in item (xiv) of the relevant paragraph as a basis.

(Calculation of Future Sickbed ed Requirements)
Article 30-28-3 (1) The necessary number of future sickbeds in the design zone is to be the number calculated using the expression set forth in row 1 of Appended Table 6 for categories of bed functions. In this case, the sum of those numbers in the same prefecture is not be over the sum of numbers calculated using the expression set forth in row 2 of the relevant Table for categories of bed functions in the same prefecture.
(2) After a medical care plan for a prefecture is publicly notified pursuant to the provisions of Article 30-4, paragraph (18) of the Act, if it becomes extremely difficult to attain the necessary number of future beds with chronic stage

functions in the design zone (limited to those recognized by the Minister of Health, Labour and Welfare) as calculated pursuant to the provisions of the preceding paragraph and specified in that medical care plan due to special circumstances, the prefectural governor may specify a correction rate as prescribed in Remarks of Appended Table 6 for the necessary number of those future beds in the manner recognized by the Minister of Health, Labour and Welfare.

(Particulars Specified by Order of the Ministry of Health, Labour and Welfare as Referred to in Article 30-4, Paragraph (2), Item (vii), (b) of the Act)

Article 30-28-4 Particulars specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 30-4, paragraph (2), item (vii), (b) of the Act are as follows:

- (i) the necessary amount of medical care in homes, etc. (which means the homes, etc. prescribed in Article 1-2, paragraph (2) of the Act; the same applies in Appended Table 7) in the design zone; and
- (ii) other particulars which the Minister of Health, Labour and Welfare finds necessary.

(Method of Calculating the Index for the Number of Physicians)

Article 30-28-5 A method specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 30-4, paragraph (2), item (xi), (b) of the Act is, after elements such as medical examination rates by sex and age class regarding persons who have their address in the zone prescribed in item (xiv) of the relevant paragraph, are taken into account, a method of calculation by dividing the number of physicians engaged in medical care in that zone by the number of persons who have their address in the zone.

Article 30-28-6 A method specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 30-4, paragraph (2), item (xi), (c) of the Act is, after elements, such as medical examination rates by sex and age class regarding persons who have their address in the zone prescribed in item (xv) of the relevant paragraph, are taken into account, a method of calculation by dividing the number of physicians engaged in medical care in that zone by the number of persons who have their address in the zone.

(Special Medical Care)

Article 30-28-7 The special medical care prescribed in Article 30-4, paragraph (2), item (xv) of the Act is medical care which requires a special diagnosis or treatment and falls under any of the following items:

- (i) medical care which require advanced skills;

- (ii) medical care which require the use of a special medical instrument;
- (iii) medical care relating to a disease which occurs infrequently; and
- (iv) especially highly-specialized emergency medical care.

(Those Specified by Order of the Ministry of Health, Labour and Welfare as Referred to in Article 30-4, Paragraph (6) of the Act)

Article 30-28-8 Those specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 30-4, paragraph (6) of the Act are those set forth in the following items:

- (i) the entire medical care provided; and
- (ii) clinical departments.

(Standards for Setting Zones in Which the Number of Physicians are Considered Low)

Article 30-28-9 A standard specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 30-4, paragraph (6) of the Act for the zones prescribed in the the relevant paragraph are those of the value of the index prescribed in paragraph (2), item (xi), (b) of the relevant Article is not more than the value of the index pertaining to the zone prescribed in the relevant item based on which the value of a ranking, when the values of the indices pertaining to the zones prescribed in item (xiv) of the relevant paragraph in Japan are ranked in ascending order, is a value obtained by dividing the total number of the zones prescribed in the relevant item in Japan by 3 (any fraction less than one is rounded off to a whole number).

(Those Specified by Order of the Ministry of Health, Labour and Welfare as Referred to in Article 30-4, Paragraph (7) of the Act)

Article 30-28-10 Those specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 30-4, paragraph (7) of the Act are those set forth in the following items:

- (i) the entire medical care provided; and
- (ii) clinical departments.

(Standards for Setting Zones in Which the Number of Physicians Are Considered High)

Article 30-28-11 A standard specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 30-4, paragraph (7) of the Act for the zones prescribed in the relevant paragraph are those that the value of the index prescribed in paragraph (2), item (xi), (b) of the relevant Article is not less than the value of that index pertaining to the zone prescribed in the relevant item based on which the value of a ranking, when the values of the

indices pertaining to the zones prescribed in item (xiv) of the relevant paragraph in Japan are ranked in descending order, is a value obtained by dividing the total number of the zones prescribed in the relevant item in Japan by 3 (any fraction less than one is rounded off to a whole number).

(Standards for Setting Zones)

Article 30-29 Standards for setting zones as prescribed in Article 30-4, paragraph (8) of the Act are as follows:

- (i) the zones prescribed in Article 30-4, paragraph (2), item (xiv) of the Act is to be set by the zone in which it is considered appropriate with the aim to secure a system of providing medical care pertaining to hospitalization in hospitals and clinics (except for the special medical care prescribed in Article 30-28-7 and medical care pertaining to other sickbeds than long-term care beds and general beds) as a united zone in consideration of natural conditions, such as geographical conditions, and social conditions, such as the state of meeting demand in daily life and traffic conditions; and
- (ii) the zones prescribed in Article 30-4, paragraph (2), item (xv) of the Act is to be set by the district of a prefecture; provide, however, that, when the district of that prefecture is extremely large or when there are other special circumstances, two or more of those zones may be set in the district of the prefecture, and a zone may be set over two or more districts of prefectures according to the actual situation of supply of and demand for medical care in an area around the boundary of the prefecture.

(Calculation of the Standard Numbers of Sickbeds)

Article 30-30 The standard numbers of sickbeds as prescribed in Article 30-4, paragraph (2), item (xvii) of the Act (hereinafter referred to as "standard numbers of sickbeds") is the number specified in the following items for the category specified respectively in those items:

- (i) long-term care beds and general beds: the sum of numbers calculated using the expressions set forth in row 1 of Appended Table 7 for each of the zones prescribed in item (i) of the preceding Article according to the classes of sickbeds; in this case, the sum of those numbers in the same prefecture is not to be over a value obtained by subtracting the expected number of patients to treat outside prefecture (which means the number specified by the prefectural governor through consultation with the governors of related prefectures as the number of patients to whom medical care is expected to be provided in other zones than those of the prefecture with the limit of the number of inpatients who have their address in other zone than those of the prefecture, of the inpatients of hospitals and clinics located in the zones of the prefecture, of the inpatients of hospitals and clinics located in the zones of the prefecture; the same applies hereinafter) from a value obtained by adding

the expected number of patients to treat in prefecture (which means the number specified by the prefectural governor through consultation with the governors of related prefectures as the number of patients to whom medical care is expected to be provided in the zones of the prefecture with the limit of the number of inpatients who have their address in the zones of the prefecture, of the inpatients of hospitals and clinics located in other zones than those of the prefecture; the same applies hereinafter) to the sum of numbers calculated using the expression set forth in row 2 of the relevant Table in that same prefecture;

- (ii) psychiatric hospital beds: a number calculated using the expression set forth in row 3 of Appended Table 7 for each of the zones of a prefecture;
- (iii) tuberculosis hospital beds: the number specified by the prefectural governor as necessary to aim to prevent tuberculosis and to provide proper medical care to tuberculous patients for each of the zones of a prefecture; and
- (iv) infectious disease hospital beds: the number specified by the prefectural governor on the basis of the sum of the number of the infectious disease hospital beds of designated medical institutions for specified infectious diseases which are designated by the Minister of Health, Labour and Welfare pursuant to the provisions of Article 38, paragraph (1) of the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (Act No. 114 of 1998) for each of the zones of a prefecture and that of the infectious disease hospital beds of designated medical institutions for Class I infectious diseases and designated medical institutions for Class II infectious diseases which are designated by a prefectural governor pursuant to the provisions of paragraph (2) of the the relevant Article.

Article 30-31 (1) Circumstances specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 5-2, paragraph (1), item (iii) of the Order are as follows:

- (i) concentration of hospitals capable of providing advanced medical care; and
 - (ii) there are other circumstances recognized by the Minister of Health, Labour and Welfare as those equivalent to the preceding item.
- (2) The standard number of sickbeds in the case where the number of sickbeds is not according to the standards for calculation as prescribed in Article 5-2, paragraph (2) of the Order is to be the numbers specified in the following items according to the categories of the cases set forth in the following items:
- (i) the cases referred to in Article 5-2, paragraph (1), items (i) and (ii) of the Order: a value obtained by adding a number to which consent is obtained from the Minister of Health, Labour and Welfare after consultation with that Minister to the number calculated pursuant to the provisions of the

- preceding Article; and
- (ii) the case referred to in the preceding paragraph: a number to which consent is obtained from the Minister of Health, Labour and Welfare after consultation with that Minister.

(Special Provisions for Specific Sickbeds)

Article 30-32 Circumstances specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 5-3, paragraph (1), item (iii) of the Order are as follows:

- (i) it becomes necessary to secure the sickbeds of hospitals or long-term care beds of clinics in an area which is not favored by traffic conditions, such as a mountainous area or an isolated island; and
- (ii) there are other circumstances recognized by the Minister of Health, Labour and Welfare as those equivalent to the preceding item.

Article 30-32-2 (1) Sickbeds specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 30-4, paragraph (11) of the Act are to be the following sickbeds:

- (i) the sickbeds of hospitals or clinics which make diagnoses, give treatment, conduct research and study and provide training for medical personnel solely regarding malignant neoplasms, such as cancer, or circulatory disease and of hospitals or clinics with functions and nature equivalent thereto (limited to, of the sickbeds of hospitals or clinics which give advanced cancer medical care or circulatory disease medical care in areas in which there is a shortage of advanced cancer care facilities or circulatory disease care facilities, those pertaining to those functions);
- (ii) of the sickbeds of hospitals or clinics which make diagnoses, give treatment, conduct research and study and provide training for medical personnel solely regarding infantile disease and of hospitals or clinics with functions and nature equivalent thereto, those pertaining to those functions;
- (iii) of the sickbeds of hospitals or clinics which make diagnoses, give treatment, conduct research and study and provide training for medical personnel solely regarding perinatal disease and of hospitals or clinics with functions and nature equivalent thereto, those pertaining to those functions;
- (iv) of the sickbeds of hospitals or clinics which make diagnoses, give treatment, conduct research and study and provide training for medical personnel solely regarding rehabilitation and of hospitals or clinics with functions and nature equivalent thereto, those pertaining to those functions (limited to those pertaining to special rehabilitation such as early rehabilitation for children with developmental disabilities);
- (v) of the sickbeds of hospitals or clinics with medical care functions

- indispensable to an emergency medical care system, those pertaining to those functions;
- (vi) of the sickbeds of hospitals with special medical care functions regarding a toxic mental disease due to a drug, such as alcohol, senile mental disease, infantile mental disease and other diseases specified by the Minister of Health, Labour and Welfare, those pertaining to those functions;
 - (vii) of the sickbeds of hospitals or clinics which hospitalize persons with intractable neurological disease and conducts diagnoses, treatment and research and research on that disease, those pertaining to those functions;
 - (viii) of the sickbeds of hospitals or clinics which solely hospitalize patients with terminal malignant neoplasm, such as cancer, to provide the patients with palliative care, those pertaining to those functions;
 - (ix) of the sickbeds of hospitals or clinics which have the whole or any part of their buildings as well as their equipment, instruments and implements used for medical care, study or training by and for physicians or dentists not working for the hospitals or clinics, those pertaining to those functions;
 - (x) of the sickbeds of hospitals or clinics which make diagnoses, give treatment, conduct research and study and provide training for medical personnel regarding acquired immunodeficiency syndrome, those pertaining to those functions;
 - (xi) of the sickbeds of hospitals which make diagnoses, give treatment, conduct research and study and provide training for medical personnel regarding emerging infectious disease or re-emerging infectious disease, those pertaining to those functions;
 - (xii) deleted;
 - (xiii) of the sickbeds of hospitals or clinics which conduct clinical trials, those pertaining to those functions; and
 - (xiv) the long-term care beds of clinics which are changed from the sickbeds (limited to those which have actually existed on March 31, 1998 (including sickbeds pertaining to applications for permission to establish a clinic or for permission to change the number of sickbeds of a clinic which have been made by the relevant date or the sickbeds of clinics which pertain to applications for confirmation which have been made by the date pursuant to the provisions of Article 6, paragraph (1) of the Building Standards Act)) of the clinics.
- (2) When an application under the provisions of Article 5-4, paragraph (1) of the Order which pertains to the sickbeds referred to in item (xiv) of the preceding paragraph is made, the provisions of Article 30-4, paragraph (11) of the Act is to be applied only when the number of the sickbeds pertaining to the provision of the long-term care beds of a clinic or to an increase in the number of the sickbeds of a clinic which pertains to that application is not over a value

calculated through a discussion by the prefectural council on medical service facilities pursuant to the provisions of Article 30-32-2, paragraph (2) of the Regulations for Enforcement of the Medical Care Act prior to amendment by the Ministerial Order Partially Amending the Regulations for Enforcement of the Medical Care Act (Order of the Ministry of Health, Labour and Welfare No. 8 of 2001; hereinafter referred to as "2001 Amendment Ministerial Order").

Article 30-32-3 The requirements specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 30-4, paragraph (12) of the Act are to be that it falls under all of the following items:

- (i) an application under the provisions of Article 30-4, paragraph (12) of the Act (hereinafter simply referred to as "application" in this Article) is needed to promote the achievement of a regional medical care design prescribed in Article 30-4, paragraph (2), item (vii) of the Act (hereinafter simply referred to as "regional medical care design" in Article 30-33-14) which is specified in a medical care plan (which means that publicly notified pursuant to the provisions of Article 30-4, paragraph (18) of the Act by the prefecture including a medical coordination promotion zone prescribed in Article 70, paragraph (1) of the Act (hereinafter simply referred to as "medical coordination promotion zone") which is specified in its articles of incorporation by a regional medical coordination promoting corporation prescribed in Article 70-5, paragraph (1) of the Act (hereinafter simply referred to as "regional medical coordination promoting corporation") a member of which is the participating corporation (which means the participating corporation prescribed in Article 70, paragraph (1) of the Act; hereinafter the same applies in this Article and Chapter VI) which has made the application);
- (ii) the sum of the numbers of the sickbeds of hospitals and clinics established by a participating corporation of the regional medical coordination promoting corporation one of whose members is the participating corporation which has been made that application does not increase before or after the application;
- (iii) when the sum of the numbers of the sickbeds of hospitals and clinics established by a participating corporation of the regional medical coordination promoting corporation one of whose members is the participating corporation which has made the application decreases before or after the application, securing a medical care delivery system in the medical coordination promotion zone pertaining to the application is not to be hindered; and
- (iv) the application is to be made after opinions in advance are heard from the council on regional medical care promotion prescribed in Article 70-3, paragraph (1), item (xvi) of the Act (hereinafter simply referred to as "council

on regional medical care coordination promotion") which is established in the regional medical coordination promoting corporation one of whose members is the participating corporation which has made the application.

(Particulars Specified by Order of the Ministry of Health, Labour and Welfare as Referred to in Article 30-6, Paragraph (1) of the Act)

Article 30-32-4 Particulars specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 30-6, paragraph (1) of the Act are the particulars set forth in Article 30-4, paragraph (2), item (x).

(Revision of Number of Existing Sickbeds and Number of Applied Sickbeds)

Article 30-33 (1) When an application is made for permission to establish a hospital, permission to increase the number of the sickbeds of a hospital or to change of the class of the sickbeds of a hospital or permission to provide sickbeds in a clinic or permission to increase the number of the sickbeds of a clinic or to change the class of the sickbeds of a clinic or when an order under the provisions of Article 7-2, paragraph (3) of the Act or a request under the provisions of Article 7-2, paragraph (3) of the Act, as applied mutatis mutandis pursuant to Article 30-12, paragraph (1) of the Act following the deemed replacement of terms (hereinafter referred to as "order, etc." in this paragraph and the following paragraph) is to be made, standards for revision which a prefectural governor has to make in calculating the number of existing sickbeds and the number of the sickbeds pertaining to the application according to the classes of sickbeds pertaining to that application or order, etc. in the zone prescribed in Article 30-30 are as follows:

(i) regarding the sickbeds of hospitals or clinics established by the State and under the jurisdiction of the Imperial Household Agency, Ministry of Justice or Ministry of Defense, hospitals or clinics established by the Japan Organization of Occupational Health and Safety which give medical care only to workers who are employed in business for which insurance relation has been established for industrial accident compensation insurance and have a disaster in the course of business, hospitals or clinics which give medical care only to the employees of specific offices or places of business or their family members, hospitals which are a medical care facility for children with disabilities as prescribed in Article 42, item (ii) of the Child Welfare Act (Act No. 164 of 1947) or a facility which gives the long-term nursing care prescribed in Article 5, paragraph (6) of the Act on the Comprehensive Support for the Daily and Social Life of Persons with Disabilities (Act No. 123 of 2005) or hospitals or clinics which are a facility prescribed in Article 13, item (iii) of the Act on the National Agency for Automotive Safety & Victims' Aid, Independent Administrative Agency (Act No. 183 of 2002), a

value obtained by multiplying the numbers of existing sickbeds or the numbers of the sickbeds pertaining to the application for each of the classes of sickbeds by a value calculated using the following expression (it is 0 when a value calculated using the following expression is 0.05 or less) is calculated as the number of existing sickbeds and the number of the sickbeds pertaining to the application.

the number of persons other than personnel and their family members, persons other than the members of the Force and their family members, persons other than workers who have had a disaster in the course of business, persons other than employees and their family members, or other persons than inpatients, of the users of those sickbeds / the number of the users of the sickbeds;

(ii) the sickbeds in radiation treatment rooms is not to be counted in the number of existing sickbeds and that of the sickbeds pertaining to the application;

(iii) the sickbeds of hospitals which are a national and non-national leper colony is not to be counted in the number of existing sickbeds; and

(iv) the number of the sickbeds of hospitals which are a designated medical institution for hospitalization which is designated by the Minister of Health, Labour and Welfare pursuant to the provisions of Article 16, paragraph (1) of the Act on Medical Care and Observation for Persons Who Have Caused Serious Harm to Other Person in a State of Insanity (Act No. 110 of 2003) (limited to those pertaining to the medical care by hospitalization under the relevant Act for persons who have received a decision referred to in Article 42, paragraph (1), item (i) or Article 61, paragraph (1), item (i) of the relevant Act) is not to be counted in the number of existing sickbeds.

(2) The number of persons other than personnel and their family members, persons other than the members of the Force and their family members, persons other than employees and their family members, persons other than workers who have had a disaster in the course of business, or persons other than inpatients, of the users of those sickbeds, as referred to in item (i) of the preceding paragraph as well as the number of the users of the sickbeds and the number of the sickbeds of radiation treatment rooms as referred to in item (ii) of the relevant paragraph is based on the number on the most recent 30th of September before an application for permission to establish a hospital, permission to increase the number of the sickbeds or to change the class of sickbeds in a hospital, permission to provide a sickbed in a clinic, or permission to increase the number of sickbeds or to change the class of sickbeds in a clinic is made or before an order, etc. is to be made. In this case, when operations are not carried out on the most recent 30th of September before an application for that permission is made or before that order, etc. is to be made, those numbers

is based on a number estimated by a prefectural governor in consideration of the performance of that hospital or clinic, performance of hospitals or clinics which have the same functions and nature as the hospital or clinic and other considerations.

- (3) Notwithstanding the provisions of the preceding paragraph, regarding the number of the sickbeds pertaining to the application, the number of persons other than personnel and their family members, persons other than employees and their family members, or persons other than inpatients, of the users of the sickbeds, as referred to in paragraph (1), item (i), as well as the number of the users of the sickbeds as well as the number of the sickbeds in radiation treatment rooms as referred to in item (ii) of the relevant paragraph is based on a number estimated by a prefectural governor in consideration of the functions and nature of the hospital pertaining to the application, the performance at the existing sickbeds in the case where the hospital has existing sickbeds whose class is that of the sickbeds pertaining to the application, the performance of hospitals which have the same functions and nature as the hospital and other considerations.

Chapter IV-2-3 Promotion of Specialization and Coordination of Functions of Sickbeds in Areas

(Classification of Functions of Sickbeds)

Article 30-33-2 Classification specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 30-13, paragraph (1) of the Act is set forth in the following items, and their definitions are as specified respectively in those items:

- (i) advanced acute stage function: a function of providing medical care where the density of medical care is especially high to patients at the acute stage to stabilize the condition of those patients early;
- (ii) acute stage function: a function of providing medical care to patients at the acute stage to stabilize the condition of those patients early (except for that falling under the preceding item);
- (iii) convalescent stage function: a function of providing medical care or rehabilitation in order to return home to patients who have proceeded from the acute stage (including a function of intensively providing rehabilitation for the purpose of improving ADL (which means the ability to make basic movements in daily life) with the goal of returning home for those patients with such disease as cerebrovascular disease or femoral neck fracture who have proceeded from the acute stage); and
- (iv) chronic stage function: a function of hospitalizing patients who need medical treatment over a long period (including severely disabled persons

(including persons with severely disturbed consciousness), patients with muscular dystrophy, patients with an intractable disease or other similar disease who need medical treatment over a long time).

(Date specified by Order of the Ministry of Health, Labour and Welfare as Referred to in Article 30-13, Paragraph (1), Item (i) of the Act)

Article 30-33-3 A date specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 30-13, paragraph (1), item (i) of the Act is July 1 of the year including a day on which a report under the provisions of the relevant paragraph (referred to as "sickbed function report" in Article 30-33-6 and Article 30-33-9) is made.

(Period Specified by Order of the Ministry of Health, Labour and Welfare as Referred to in Article 30-13, Paragraph (1), Item (ii) of the Act)

Article 30-33-4 A period specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 30-13, paragraph (1), item (ii) of the Act is a period to June 30, 2025.

(Particulars to Report as Specified by Order of the Ministry of Health, Labour and Welfare as Referred to in Article 30-13, Paragraph (1), Item (iv) of the Act)

Article 30-33-5 Particulars specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 30-13, paragraph (1), item (iv) of the Act is structural equipment and staffing of personnel and other necessary particulars.

(Method of Reporting)

Article 30-33-6 (1) A sickbed function report is made once a year in the period from the 1st to the 31st of October by the following means as specified by the Minister of Health, Labour and Welfare:

- (i) the method of recording it in a file or the like; and
- (ii) the method through receipt information.

(2) The "method of recording it in a file or the like" as referred to in item (i) of the preceding paragraph means a method through a person who is entrusted by the Minister of Health, Labour and Welfare to manage and total necessary data such as the contents of sickbed function reports (hereinafter referred to as "trustee" in this paragraph and the following paragraph) (in this case, a report to the trustee is made by the methods set forth in (a) through (c) below):

- (a) a method of offering to view the contents of data recorded in a file provided in the computer used by a sender to a person who is provided with

- information using a telecommunications line and recording data in the file provided in a computer used by the person who is provided with the relevant information;
- (b) a method of delivering a file prepared with a magnetic disk or the like in which data are recorded; and
 - (c) a method of delivering a document.
- (3) The "method through receipt information" as referred to in paragraph (1), item (ii) means a method through an entrustee (a report to the entrustee in this case is made for data recorded in the receipt computer prescribed in Article 5, paragraph (1) of the Ministerial Order on Medical Treatment Benefits and Claims for Expenses for Medical Care at Public Expense (Order of the Ministry of Health and Welfare No. 36 of 1976) by making use of the method under the provisions of Article 1, paragraph (1) of the relevant Ministerial Order and Article 5, paragraph (3) of the Regulations for Enforcement of the Act on Assurance of Medical Care for Elderly People (Order of the Ministry of Health, Labour and Welfare No. 129 of 2007).

(Change in Particulars Reported)

- Article 30-33-7 (1) A case specified by Order of the Ministry of Health, Labour, and Welfare as referred to in Article 30-13, paragraph (2) of the Act is a case when the manager of a sickbed function reporting hospital, etc. prescribed in paragraph (1) of the relevant Article decides that it is necessary to provide medical care pertaining to the class of sickbed functions which differs from the sickbed function after the base date which has been reported pursuant to the provisions of the relevant paragraph, with a full understanding of the actual situation such as that of demand for medical care in the area.
- (2) The report under the provisions of Article 30-13, paragraph (2) of the Act is made by the method specified by the Minister of Health, Labour and Welfare pursuant to the provisions of paragraph (1) of the preceding Article.

(Public Announcement of Reports)

- Article 30-33-8 Pursuant to the provisions of Article 30-13, paragraph (4) of the Act, a prefectural governor must publicly announce particulars reported pursuant to the provisions of paragraphs (1) and (2) of the relevant Article through the use of the Internet or by other appropriate methods, as specified by the Minister of Health, Labour and Welfare.

(Cases Specified by Order of the Ministry of Health, Labour and Welfare as Referred to in Article 30-15, Paragraph (1) of the Act)

- Article 30-33-9 (1) A case specified by Order of the Ministry of Health, Labour, and Welfare as referred to in Article 30-15, paragraph (1) of the Act is a case

where the bed function on base date pertaining to a sickbed function report is different from the sickbed function after base date pertaining to the same.

- (2) Particulars specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 30-15, paragraph (1) of the Act is the the reason why the sickbed function on base date pertaining to that sickbed function report is different from the sickbed function after base date pertaining to the same and the specific details of that sickbed function after base date.
- (3) Cases specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 30-15, paragraph (4) of the Act are as follows:
- (i) when an agreement has not been reached at the place of consultation provided in Article 30-15, paragraph (2) of the Act; and
 - (ii) when it is found to be difficult for the establisher or manager of a reporting hospital, etc. who has been requested by a prefectural governor pursuant to the provisions of Article 30-15, paragraph (2) of the Act to hold a consultation at the place of consultation do to not participating in the consultation provided in the same paragraph or other reason.

(Cases Specified by Order of the Ministry of Health, Labour and Welfare as Referred to in Article 30-16, Paragraph (1) of the Act)

Article 30-33-10 Cases specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 30-16, paragraph (1) of the Act are as follows:

- (i) when an agreement is not arranged on the occasion for consultation prescribed in Article 30-14, paragraph (1) of the Act (hereinafter referred to as "occasion for consultation" in this Article);
- (ii) when it is found to be difficult to hold a consultation on the occasion for consultation for the reason that the relevant person prescribed in Article 30-14, paragraph (1) of the Act (referred to as "relevant person" in the following item) does not participate in the occasion for consultation or other reasons; and
- (iii) when the relevant person does not fulfill the particulars on which an agreement among the relevant persons has been arranged at the consultation.

Chapter IV-3 Measures to Secure Medical Workers

Article 30-33-11 A person specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 30-21, paragraph (2) of the Act is to be a person who is recognized by a prefectural governor as a person capable of conducting the affairs set forth in the items of paragraph (1) of the relevant Article in an appropriate, fair and neutral manner.

Article 30-33-12 (1) Those specified by Order of the Ministry of Health, Labour

and Welfare as prescribed in Article 30-23, paragraph (1), item (v) of the Act are to be hospitals established by the following persons:

- (i) the State;
 - (ii) an incorporated administrative agency prescribed in Article 2, paragraph (1) of the Act on General Rules for Incorporated Administrative Agencies (Act No. 103 of 1999);
 - (iii) a national university corporation prescribed in Article 2, paragraph (1) of the National University Corporation Act (Act No. 112 of 2003); and
 - (iv) a local incorporated administrative agency prescribed in Article 2, paragraph (1) of the Local Independent Administrative Agency Act (Act No. 118 of 2003).
- (2) Persons specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 30-23, paragraph (1), item (ix) of the Act are to be those set forth in the following items:
- (i) National Hospital Organization, Incorporated Administrative Agency;
 - (ii) Japan Community Health Care Organization, Incorporated Administrative Agency;
 - (iii) local medical care related bodies;
 - (iv) related municipalities; and
 - (v) bodies which represent local residents.
- (3) In having the managers or other relevant persons of the persons set forth in Article 30-23, paragraph (1), item (v) of the Act (referred to as "private hospital" in this paragraph) participate in the council on measures for regional medical care, when a body of the establishers and other relevant persons of private hospitals or a body whose members include the establishers and other relevant persons of private hospitals exists in the zones of a prefecture, the prefecture are to have the establishers and other relevant persons of private hospitals which belong to that body participate in the council preferentially.
- (4) When a prefecture intends to specify particulars concerning staffing in the medical profession (which means having other physician than those belonging to a hospital or clinic engaged in medical care in that hospital or clinic as a staffed worker prescribed in Article 2, item (ii) of the Act for Securing the Proper Operation of Staffing Businesses and Protecting Staffing-Agency Workers (Act No. 88 of 1985; referred to as "Staffing Act in Article 30-33-15) as particulars needed to carry out particulars concerning securing of physicians which are specified in the medical care plan prescribed in Article 30-23, paragraph (1) of the Act, the prefecture is to specify those which the establisher of a hospital or clinic carries out.

Article 30-33-13 (1) A plan specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 30-23, paragraph (2), item (i) of the Act

(hereinafter referred to as "career development program) is to meet the following necessary conditions:

- (i) the plan is one which requires a physician to whom the career development program applies pursuant to the provisions of paragraph (5) or (6) (hereinafter referred to as "target physician") to be engaged in medical care at a medical institution located in the zone of the prefecture, as a rule, in accordance with predetermined conditions for clinical departments and other matters (hereinafter referred to as "course") over a given period including a period during which the target physician receives clinical training (which means the clinical training under the provisions of Article 16-2, paragraph (1) of the Medical Practitioners' Act; the same applies hereinafter);
 - (ii) two or more courses are to be specified in the plan; and
 - (iii) if a prefectural governor receives a request from a target physician to suspend or discontinue the plan, or if the prefectural governor finds it appropriate or otherwise necessary to grant that request, the plan may be suspended or discontinued
- (2) In formulating a career development program pursuant to the provisions of Article 30-25, paragraph (1), item (v) of the Act, a prefecture in advance is to hear opinions from target physicians and persons who are a student majoring in medicine at the medical development of a university and are expected to be a target physician after graduation (hereinafter referred to as "student to be a target"). The same applies to alteration to the career development program.
- (3) When a prefecture hears opinions pursuant to the provisions of the preceding paragraph, the prefecture must endeavor to reflect the details of the opinions in the career development program.
- (4) When a prefecture formulates a career development program pursuant to the provisions of Article 30-25, paragraph (1), item (v) of the Act, the prefecture must apply the career development program to the following persons with the consent of those persons:
- (i) a person who is a physician within regional limits (which means a physician who promises to be engaged in medical care at a medical institution located in the zone of the prefecture over a given period after graduation and graduates a university; the same applies in the following paragraph) to those who have received a loan of study funds for the relevant university by the prefecture;
 - (ii) a physician who has graduated Jichi Medical University and is engaged in medical care at a medical institution located in a zone of the prefecture; and
 - (iii) other physicians wishing to be eligible for a career development program.
- (5) When a prefecture formulates a career development program pursuant to the provisions of Article 30-25, paragraph (1), item (v) of the Act, the prefecture is to endeavor to apply the career development program to physicians within

regional limits (except for those set forth in item (i) of the preceding paragraph) with the consent of those physicians.

- (6) A target student, in advance, is to give the consent referred to in paragraph (4) or the preceding paragraph while the student is attending the medical department of the university.
- (7) A target physician is to select the applicable course to be applied to them at the time specified by a prefectural governor.
- (8) A prefectural governor may change the applicable course of the target physician when the governor receives a request from that target physician, or if the governor finds it appropriate or otherwise finds it necessary.
- (9) A prefecture is to take approaches which contribute to raising awareness of the future work life planning of students majoring in medicine at the medical department of universities with the assistance of the persons set forth in the items of Article 30-23, paragraph (1) of the Act so that students to be a target and target physicians can give the consent referred to in paragraph (6) and make the choice referred to in paragraph (7) appropriately.

Article 30-33-14 Particulars specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 30-23, paragraph (3) of the Act are the following particulars:

- (i) based on the data about the number of physicians shown through the index prescribed in Article 30-4, paragraph (2), item (xi), (b) of the Act;
- (ii) based on the state of securing physicians in the area;
- (iii) based on the wishes of a staffed physician;
- (iv) securing consistency with the regional medical care design; and
- (v) destinations to which physicians are staffed by a prefecture is not concentrated to the public medical institutions prescribed in Article 31 of the Act (simply referred to as "public medical institutions" in Article 31-2) without legitimate grounds.

Article 30-33-15 A person specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 30-25, paragraph (3) of the Act is a person who is recognized by a prefectural governor as a person capable of conducting the regional medical care support affairs prescribed in the relevant paragraph in an appropriate, fair and neutral manner; provided, however, that, when affairs for employment placement business for physicians are entrusted, the person is limited to a person who conducts a staffing business with the permission referred to in Article 30, paragraph (1) or Article 33, paragraph (1) of the Employment Security Act (Act No. 141 of 1947) and that, when affairs for worker staffing services for the medical profession are entrusted, the person is limited to a person who renders a worker staffing service with the

permission referred to in Article 5, paragraph (1) of the Worker Dispatch Act.

Chapter V Medical Corporations

Section 1 General Rules

(Assets of Medical Corporations)

Article 30-34 A medical corporation must have facilities, equipment or funds needed to carry out the operations of a hospital, clinic, long-term care health facility or long-term care home established by it.

(Persons Who Have a Special Connection with the Members of Medical Corporations)

Article 30-35 Persons who have a special relationship specified by Order of the Ministry of Health, Labour and Welfare with the officer, member or councillor prescribed in Article 42-2, paragraph (1), items (i), (ii) and (iii) of the Act (hereinafter referred to as "member, etc.") are the following persons:

- (i) a person in a relationship with the member, etc. where a marital relationship is de facto, though a marriage has not been registered;
- (ii) a person who is an employee of the member, etc. and other person than that employee who earns a livelihood by property, such as money, which is received from that member, etc.; and
- (iii) a relative of any of the persons set forth in the preceding two items who depends on that person for their living.

(Standards Specified by Order of the Ministry of Health, Labour and Welfare as Referred to in Article 42-2, Paragraph (1), Item (iv), (b) of the Act)

Article 30-35-2 Standards specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 42-2, paragraph (1), item (iv), (b) of the Act are as follows:

- (i) the prefecture of the location of a hospital established by the medical corporation and the prefecture of the location of a clinic established by the medical corporation (which means a prefecture other than the prefecture adjacent to the zone prescribed in Article 30-4, paragraph (2), item (xiv) of the Act which is specified in a medical care plan specified by the prefecture of the location of that hospital pursuant to the provisions of paragraph (1) of the relevant Article (hereinafter referred to as "medical care plan" in this item and the following item) is to specify particulars concerning a medical care delivery system in the area including the locations of the hospital and the clinic in each of their medical care plans;
- (ii) all the hospitals, clinics, long-term care health facilities and long-term care homes established by the medical corporation are to be located in the zone

- including the location of the hospitals established by the medical corporation (which means the zone prescribed in Article 30-4, paragraph (2), item (xiv) of the Act which is specified in the medical care plan of the prefecture of the location of the hospital) and in municipalities adjacent to that zone (including special wards) which are in other prefectures than the prefecture (referred to as "adjacent municipalities" in item (iv));
- (iii) all the hospitals, clinics, long-term care health facilities and long-term care homes established by the medical corporation are to be adjacent to each other; and
- (iv) a hospital established by the medical corporation must assume a key role in providing medical care at clinics established by the medical corporation (limited to those located in adjacent municipalities) in light of a system of providing medical care, including its facilities and equipment, and the number of its sickbeds.

(Necessary Conditions for Authorization for Social Medical Corporations)

Article 30-35-3 (1) A necessary condition specified by Order of the Ministry of Health, Labour and Welfare for the public operation as prescribed in Article 42-2, paragraph (1), item (vi) of the Act is that it falls under all of the following items:

- (i) the operation of the medical corporation falls under all of the following:
- (a) the fixed number of the directors of the medical corporation is six or more, and the fixed number of the auditors is two or more;
- (b) when the medical corporation is a medical corporation which is a foundation, the councillors of the medical corporation is commissioned by the president to persons recommended by the council;
- (c) the sum of the numbers of persons who are a director or employee of other identical body (except for public interest incorporated associations or public interest incorporated foundations or other bodies equivalent thereto (hereinafter referred to as "public interest corporations, etc.)) and other directors equivalent thereto who have a close connection with each other is not to exceed one-third of the total number of directors; and the same applies to auditors;
- (d) regarding compensation, etc. to its directors, auditors, and councillors (which means economic benefits received in consideration for the performance of duties, such as compensation and bonuses, and retirement allowances; the same applies hereinafter), standards for payment is set so that the amount of the compensation, etc. will not be unduly high in view of compensation, etc. to the officers of private enterprises and pay to the employees of the same, the state of the accounting of the medical corporation and other circumstances;

- (e) in conducting its business, special benefits are not to be given to the person concerned with the medical corporation, including its members, councillors, directors, auditors, and employees;
- (f) in conducting its business, an act of giving special benefits, such as donations, are not to be carried out to a person who conducts business for profit, such as a stock company, or a person who carries out activities to seek the interest of a specific individual or body; provided, however, that this does not apply to the case where an act of giving special benefits, such as donations, is carried out to a public interest corporation, etc. for business for public interest purpose which is conducted by that public interest corporation, etc.;
- (g) the amount of idle assets on the last day of each fiscal year of the medical corporation is not to exceed the amount of expenses pertaining to business (except for that conducted as the operations set forth in the items of Article 42 of the Act pursuant to the provisions of the relevant Article and as the profit-making operations prescribed in Article 42-2, paragraph (1) of the Act pursuant to the provisions of the relevant paragraph) which are recorded in the profit and loss statement of the fiscal year having ended most recently;
- (h) the medical corporation is not to hold property, such as shares, through which it may participate in decision-making at other body; provided, however, that this does not apply to the case where the medical corporation is not likely to substantially control the business activities by that other body by holding that property; and
- (i) there is to be no fact that the medical corporation is in violation of laws and regulations, no fact that the medical corporation makes records or entries in its books and documents to conceal or disguise all or any of transactions or other facts in conflict with the public interest.
- (ii) the business of the medical corporation falls under all of the following:
 - (a) the amount of expenses pertaining to the operations of hospitals, clinics, long-term care health facilities, and long-term care homes is over sixty-hundredths of the amount of ordinary expenses;
 - (b) the total of the amount of income from social insurance medical care (which means the social insurance medical care prescribed in Article 26, paragraph (2) of the Act on Special Measures concerning Taxation (Act No. 26 of 1957); the same applies hereinafter) (including medical care fees for patients pertaining to the Industrial Accident Compensation Insurance Act (Act No. 50 of 1947) (limited to the case where those medical care fees are according to the same standards as those for social insurance medical fees or the case where the amount of the medical care fees is small (which means the case where that amount is not more than ten-hundredths of the

amount of all income))) (simply referred to as "the amount of income from to social insurance medical care" in Article 57-2, paragraph (1), item (ii), (a)), the amount of income from the health promotion services prescribed in Article 4 of the Health Promotion Act (Act No. 103 of 2002) which are rendered by the health promotion service providers set forth in the items of Article 6 of the relevant Act (limited to those pertaining to health checkups; the same applies hereinafter) (limited to the case where the amount of that income is calculated according to the same standards as those for social insurance medical fees) (simply referred to as "the amount of income from health promotion services" in Article 57-2, paragraph (1), item (ii), (a)), the amount of income from vaccinations (which mean the regular vaccinations, etc. prescribed in Article 2, paragraph (6) of the Immunization Act (Act No. 68 of 1948) and other vaccinations specified by the Minister of Health, Labour and Welfare; the same applies in Article 57-2, paragraph (1), item (ii), (a)), the amount of income from midwifery (except for that pertaining to social insurance medical care and health promotion services) (the limit of that amount is 500,000 yen when the amount of income from midwifery pertaining to one delivery is over 500,000 yen) (simply referred to as "the amount of income from midwifery" in Article 57-2, paragraph (1), item (ii), (a)), the amount of income from the payment of insurance proceeds under the provisions of the Long-Term Care Insurance Act (excluding the amount of income from the service set forth in Article 26, paragraph (2), item (iv) of the Act on Special Measures concerning Taxation) (simply referred to as "the amount of income from the payment of insurance proceeds under the provisions of the Long-Term Care Insurance Act" in Article 57-2, paragraph (1), item (ii), (a)) as well as the amount of income pertaining to the cost of nursing care, special nursing care, training, etc., special training, etc., grants for designated persons with disabilities, special grants for designated persons with disabilities, community consultation support, special community consultation support, planning consultation support, special planning consultation support and appropriate medical care as prescribed in Article 6 of the Act on the Comprehensive Support for the Daily and Social Life of Persons with Disabilities, the community life support service prescribed in Articles 77 and 78 of the relevant Act, the disabled child commuting benefit expenses and the special disabled child commuting benefit expenses as prescribed in Article 21-5-2 of the Child Welfare Act, the disabled child entrance benefit expenses prescribed in Article 24-2 of the relevant Act, the benefits for meal expenses, etc. for specified institutionalized disabled children as prescribed in Article 24-7 of the relevant Act and the disabled child consultation support benefit expenses and the special disabled child

- consultation support benefit expenses prescribed in Article 24-25 of the relevant Act (referred to as "the amount of income from disabled person welfare services, etc." in Article 57-2, paragraph (1), item (ii), (a)) is to be over eighty-hundredths of the amount of all income;
- (c) the sum charged to patients at their own expense (which mean other patients than those pertaining to social insurance medical care or those pertaining to the Industrial Accident Compensation Insurance Act; the same applies hereinafter) is calculated according to the same standards as those for social insurance medical fees; and
- (d) the sum received from medical care for medical service (which means medical care pertaining to social insurance medical care, medical care pertaining to the Industrial Accident Compensation Insurance Act, and medical care pertaining patients at own expense; the same applies hereinafter) is within a sum obtained by multiplying the amount of expenses required directly for patients, including pay for physicians, nurses and the like and expenses required to provide medical service (including administration expenses) by one hundred fifty-hundredths.
- (2) The amount of the idle assets prescribed in item (i), (g) of the preceding paragraph is an amount obtained by multiplying an amount obtained by deducting the total of the book values of assets entered in an itemized account of assets held, of the following assets, from the total amount of assets held by the medical corporation and recorded in the balance sheet of the fiscal year having ended most recently, as the total of the value of assets not actually used for the operations of the medical corporation and not expected to continue to be used, by the proportion of the amount of net assets (which means an amount obtained by deducting the amount of liabilities from the amount of assets on the balance sheet; the same applies hereinafter) to the total amount of assets:
- (i) assets provided for use in the operations of hospitals, clinics, long-term care health facilities or long-term care homes established by the medical corporation;
- (ii) assets provided for use in the operations prescribed in the items of Article 42 of the Act;
- (iii) assets provided for use in the profit-making operations prescribed in Article 42-2, paragraph (1) of the Act;
- (iv) assets held to carry out the operations referred to in the preceding three items (except for the assets set forth in the preceding three items);
- (v) funds held to allocate them for the acquisition or improvement of assets for carrying out the operations specified in items (i) through (iii); and
- (vi) funds held to allocate them for payment pertaining to costs specially paid to conduct specific future business (limited to that specified in the articles of incorporation or articles of endowment).

(Particulars to Apply for Authorization for Social Medical Care Corporations)

Article 30-36 (1) Particulars for a medical corporation which intends to be authorized as a social medical corporation to write in an application form as particulars concerning necessary conditions for social medical corporations pursuant to Article 5-5 of the Order are the following particulars:

- (i) whether, of the operations of the medical corporation, those falling within the necessary conditions referred to in Article 42-2, paragraph (1), item (v) of the Act pertain to any of medical care set forth in Article 30-4, paragraph (2), item (v) of the Act; and
- (ii) the name and location of the hospital or clinic which carries out the operations referred to in the preceding item.

(2) Documents specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 5-5 of the Order are the following documents:

- (i) a copy of the articles of incorporation or articles of endowment;
- (ii) a document explaining that the fiscal year pertaining to the standards specified by the Minister of Health, Labour and Welfare as referred to in Article 42-2, paragraph (1), item (v) of the Act falls within the necessary conditions referred to in the relevant item; and
- (iii) a document explaining that it falls within the necessary conditions set forth in Article 42-2, paragraph (1), items (i) through (iv) and item (vi) of the Act.

(Grounds Specified by Order of the Ministry of Health, Labour and Welfare as Referred to in Article 42-3, Paragraph (1) of the Act)

Article 30-36-2 Grounds specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 42-3, paragraph (1) of the Act are those on which a prefectural governor recognizes that there are unavoidable circumstances not attributable to the medical corporation regarding the fact that it results in lacking the necessary conditions set forth in Article 42-2, paragraph (1), item (v), (c) of the Act, such as a natural disaster or substantial decrease in population.

(Form of Implementation Plans)

Article 30-36-3 The implementation plan prescribed in Article 42-3, paragraph (1) of the Act is to be submitted in the appended form 1-2.

(Particulars specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 5-5-2, paragraph (1), item (iv) of the Order)

Article 30-36-4 Particulars specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 5-5-2, paragraph (1), item (iv) of the Order

are particulars concerning the profit-making operations prescribed in Article 42-2, paragraph (1) of the Act.

(Particulars Specified by Order of the Ministry of Health, Labour and Welfare as Referred to in Article 5-5-2, Paragraph (2) of the Order)

Article 30-36-5 Particulars specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 5-5-2, paragraph (2) of the Order are the following:

- (i) the name of the medical corporation and the location of its principal office as well as the name of its representative; and
- (ii) the reason for the rescission of authorization as referred to in Article 42-2, paragraph (1) of the Act.

(Documents Specified by Order of the Ministry of Health, Labour and Welfare as Referred to in Article 5-5-2, Paragraph (2) of the Order)

Article 30-36-6 A document specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 5-5-2, paragraph (2) of the Order is a copy of the articles of incorporation or articles of endowment.

(Necessary Conditions Specified by Order of the Ministry of Health, Labour and Welfare as Referred to in Article 5-5-3, Item (iii) of the Order)

Article 30-36-7 A necessary condition specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 5-5-3, item (iii) of the Order is that the implementation period referred to in Article 5-5-2, paragraph (1), item (iii) of the Order (simply referred to as "implementation period" in paragraph (2) of the following Article) be not exceeding 12 years (or 18 years when implementing bodies for emergency medical care securing business are extremely scarce in the zone including the location of a hospital or clinic which is established by the medical corporation and carries out the operations pertaining to emergency medical care securing business (which means the emergency medical care securing business prescribed in Article 42-2, paragraph (1), item (iv) of the Act; the same applies hereinafter) (that zone means the zone prescribed in Article 30-4, paragraph (2), item (xiv) of the Act which is specified in the medical care plan of the prefecture of the location of that hospital) or when a prefectural governor finds that there are other special circumstances).

(Change of Implementation Plans)

Article 30-36-8 (1) A person who intends to apply for authorization for a change of implementation plan under the provisions of the main clause of Article 5-5-4, paragraph (1) of the Order must submit to the prefectural governor an

application form stating matters to change and the reasons for change, with the implementation plan changed.

- (2) Minor changes specified by Order of the Ministry of Health, Labour and Welfare as prescribed in the proviso of Article 5-5-4, paragraph (1) of the Order are changes within one year from the initial implementation period.

(Submission of Documents Stating State of Carrying out of Implementation Plans)

Article 30-36-9 (1) A document, etc. stating the state of carrying out of the implementation plan under the provisions of Article 5-5-5, paragraphs (1) and (2) of the Order is submitted in the appended form 1-3.

- (2) A document specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 5-5-5, paragraph (1) of the Order is a document explaining that it falls within the necessary conditions referred to in Article 42-2, paragraph (1), items (i) through (vi) (except for item (v), (c)) of the Act.

(Funds)

Article 30-37 (1) A medical corporation which is an association (except for those which have made provisions for equity interests, the social medical corporations prescribed in Article 42-2, paragraph (1) of the Act, and the specific medical corporations prescribed in Article 67-2, paragraph (1) of the Act on Special Measures concerning Taxation; or a member at incorporation before the establishment of a medical corporation which is an association) may specify in its articles of incorporation that it may solicit a person to accept a fund (which means property, such as money, which is contributed to a medical corporation which is an association and which that medical corporation which is an association has an obligation to return (or an obligation to return money equivalent to the value of the property at contribution for other property than money) to a contributor pursuant to this Article and the following Article as well as an agreement between the medical corporation and that contributor; the same applies hereinafter). In this case, the following particulars are specified in the articles of incorporation:

- (i) provisions for the rights of the contributors of the fund; and
 - (ii) the procedure for returning the fund.
- (2) The claim pertaining to the return of the fund as referred to in the preceding paragraph may not earn interest.

Article 30-38 (1) The fund must be returned according to a resolution of an annual general meeting of members.

- (2) When the amount of net assets on the balance sheet pertaining to a fiscal year is over the total of the following amounts, a medical corporation which is

an association may return the fund with the limit of the amount of that excess as the total amount of the return only in the period to the day before the date of the annual general meeting of members for the fiscal year following that fiscal year:

- (i) the total amount of the fund (including the substitute fund referred to in the following paragraph); and
 - (ii) when assets are evaluated on the basis of the market value, if the aggregate market value of the assets is over the total of the acquisition cost of the same, the amount of net assets on the balance sheet which has increased by valuation on the basis of the market value.
- (3) When it returns its fund, the medical corporation must record a sum equivalent to the fund to return as a substitute fund.
- (4) The substitute fund referred to in the preceding paragraph may not be diverted.

(Changeover from a Medical Corporation with Provisions for Equity Interests to a Medical Corporation without Provisions for Equity Interests)

Article 30-39 (1) A medical corporation which is an association and has made provisions for equity interests may change over to a medical corporation which is an association and does not make provisions for equity interests by modifying its articles of incorporation.

- (2) A medical corporation which is an association and does not make provisions for equity interests may not change over to a medical corporation which is an association and has made provisions for equity interests.

Section 2 Establishment

(Application for Authorization for Establishment)

Article 31 A person who intends to obtain authorization for the establishment of a medical corporation pursuant to the provisions of Article 44, paragraph (1) of the Act must submit to the governor of the prefecture of the location of the principal office of the corporation (hereinafter simply referred to as "prefectural governor") an application form with the following documents:

- (i) the articles of incorporation or articles of endowment;
- (ii) an inventory of assets which have to belong to the medical corporation at the time of establishment;
- (iii) a record of a resolution on establishment;
- (iv) documents certifying belonging of the rights to significant property, such as real property, which are issued by registry offices, banks and the like;
- (v) a document stating the clinical departments, the fixed number of employees, and an outline of the site and building structure and equipment of hospitals,

clinics, long-term care health facilities or long-term care homes prescribed in Article 39, paragraph (1) of the Act which the medical corporation intends to establish;

- (vi) for a medical corporation which intends to carry out the operations set forth in Article 42, item (iv) or (v) of the Act, a document stating the personnel, an outline of the site and building structure and equipment, and the operating method of the facility pertaining to those operations;
- (vii) a business plan for two years after establishment and a budget document incidental thereto;
- (viii) the curriculum vitae of the founder;
- (ix) when a representative founder is appointed, a document certifying the fact that the representative founder has been duly appointed and the power thereof;
- (x) officers' acceptances of assumption of office and their curricula vitae; and
- (xi) a document stating the name of a person to be the manager of a hospital, clinic, long-term care health facility or long-term care home to establish.

(Persons Who May Be a Person to Whom Residual Assets Belong)

Article 31-2 Those specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 44, paragraph (5) of the Act are as follows:

- (i) a person who is recognized by the Minister of Health, Labour and Welfare as an establisher of a public medical institution or person equivalent thereto; and
- (ii) a medical corporation which is a foundation or a medical corporation which is an association and does not make provisions for equity interests.

Section 3 Bodies

Subsection 1 General Meeting of Members

(Cases Specified by Order of the Ministry of Health, Labour and Welfare as Referred to in Article 46-3-4 of the Act)

Article 31-3 Cases specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 46-3-4 of the Act are the following cases:

- (i) a case where explaining a particular for which a member has requested an explanation may substantially harm the common interests of members;
- (ii) a case where it is necessary to conduct an examination to explain a particular for which a member has requested explanation (except for the following cases):
 - (a) a case where that member has notified the medical corporation of that particular before a reasonable period of time of the date of the general meeting of members; and

- (b) a case where an examination needed to explain that particular is extremely easy;
- (iii) a case where explaining a particular for which a member has requested an explanation results in infringing the rights of the medical corporation or other persons (except for that member);
- (iv) a case where a member repeatedly requests an explanation for substantially the same matter at the general meeting of members; and
- (v) beyond the cases set forth in the preceding items, a case where there are legitimate grounds for not explaining the particular for which a member has requested an explanation.

(Minutes of a General Meeting of Members)

- Article 31-3-2 (1) The minutes of a general meeting of members under the provisions of Article 57, paragraph (1) of the Act on General Incorporated Associations and General Incorporated Foundations (Act No. 48 of 2006), as applied mutatis mutandis pursuant to Article 46-3-6 of the Act following the deemed replacement of terms, is prepared pursuant to the provisions of this Article.
- (2) The minutes of a general meeting of members must be prepared in writing or by electronic or magnetic record.
 - (3) The minutes of a general meeting of members must be those whose contents are the following information:
 - (i) the date, time, and place when and where the general meeting of members has been held (when a director, auditor, or member who has not existed at that place has attended the general meeting of members, including the method of that attendance);
 - (ii) the point of the progress of the proceedings of the general meeting of members and the results thereof;
 - (iii) when there is a member who has a special interest in a particular which requires a resolution, the name of that member;
 - (iv) when an opinion or remark is expressed or made at the general meeting of members pursuant to the following clauses, an outline of the contents of that opinion or remark:
 - (a) Article 74, paragraph (1) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 46-5-4 of the Act following the deemed replacement of terms;
 - (b) Article 74, paragraph (2) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 46-5-4 of the Act following the deemed replacement of terms;

- (c) Article 46-8, item (iv) of the Act;
- (d) the second sentence of Article 46-8, item (vii) of the Act; and
- (e) Article 105, paragraph (3) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 46-8-3 of the Act following the deemed replacement of terms;
- (v) the names of directors or auditors present at the general meeting of members;
- (vi) the name of the chairperson of the general meeting of members; and
- (vii) the name of a person who has performed the duty pertaining to drawing up of the minutes.

(Measure Specified by Order of the Ministry of Health, Labour and Welfare as Referred to in Article 57, Paragraph (3) of the Act on General Incorporated Associations and General Incorporated Foundations, as Applied Mutatis Mutandis Pursuant to Article 46-3-6 of the Act Following the Deemed Replacement of Terms)

Article 31-3-3 A measure specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 57, paragraph (3) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 46-3-6 of the Act following the deemed replacement of terms, is a measure taken by a method of using an electronic data processing system to which the computer pertaining to use by a medical corporation is connected with a telecommunications line and of recording the contents of data recorded in a file provided on that computer to a file provided on a computer used in the secondary office of the medical corporation through a telecommunications line.

(Method of Displaying Information Recorded in Electronic or Magnetic Records)

Article 31-3-4 A method specified by Order of the Ministry of Health, Labour and Welfare as prescribed in the following clauses is a method of displaying information recorded in an electronic or magnetic record as referred to in the following clauses on the surface of paper or on a screen:

- (i) Article 57, paragraph (4), item (ii) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 46-3-6 of the Act following the deemed replacement of terms;
- (ii) Article 193, paragraph (4), item (ii) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 46-4-7 of the Act following the deemed

- replacement of terms; and
- (iii) Article 97, paragraph (2), item (ii) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 46-7-2, paragraph (1) of the Act following the deemed replacement of terms.

Subsection 2 Councillors and Board of Councillors

(Person Specified by Order of the Ministry of Health, Labour and Welfare as Referred to in Article 46-4, Paragraph (2), Item (ii) of the Act)

Article 31-3-5 A person specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 46-4, paragraph (2), item (ii) of the Act is a person who is unable to appropriately make recognition, decisions, or communication needed to properly perform the duties of a councillor due to a mental function impediment.

(Minutes of a Board of Councillors)

Article 31-4 (1) The minutes of a meeting of the board of councillors under the provisions of Article 193, paragraph (1) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 46-4-7 of the Act following the deemed replacement of terms, are prepared pursuant to the provisions of this Article.

(2) The minutes of a meeting of the board of councillors must be prepared in writing or by electronic or magnetic record.

(3) The minutes of a meeting of the board of councillors must be those whose contents are the following information:

(i) the date, time, and place when and where the meeting of the board of councillors has been held (when a director, auditor, or councillor who has not existed at that place has attended the meeting of the board of councillors, including the method of that attendance);

(ii) the point of the progress of the proceedings of the meeting of the board of councillors and the results thereof;

(iii) when there is a councillor who has a special interest in a particular which requires a resolution, the name of that councillor;

(iv) when an opinion or remark is expressed or made at the meeting of the board of councillors pursuant to the following clauses, an outline of the contents of that opinion or remark:

(a) Article 74, paragraph (1) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 46-5-4 of the Act following the deemed replacement of terms;

- (b) Article 74, paragraph (2) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 46-5-4 of the Act following the deemed replacement of terms;
- (c) Article 46-8, item (iv) of the Act;
- (d) the second sentence of Article 46-8, item (viii) of the Act; and
- (e) Article 105, paragraph (3) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 46-8-3 of the Act following the deemed replacement of terms;
- (v) the names of councillors, directors or auditors present at the meeting of the board of councillors;
- (vi) the name of the chairperson of the meeting of the board of councillors; and
- (vii) the name of a person who has performed the duty pertaining to drawing up of the minutes.

(Application, Mutatis Mutandis, of Provisions for Minutes of General Meetings of Members)

Article 31-4-2 The provisions of Article 31-3-3 apply mutatis mutandis to a measure specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 193, paragraph (3) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 46-4-7 of the Act following the deemed replacement of terms.

Subsection 3 Officers

(Application, Mutatis Mutandis, of Provisions for Councillors)

Article 31-4-3 The provisions of Article 31-3-5 apply mutatis mutandis to the officers of a medical corporation. In this case, in the relevant Article, the term "Article 46-4, paragraph (2), item (ii)" is deemed to be replaced with "Article 46-4, paragraph (2), item (ii) of the Act, as applied mutatis mutandis pursuant to Article 46-5, paragraph (5)," and the term "councillor" with "officer."

(Application for Authorization for a Case Where a Medical Corporation Has One or Two Directors)

Article 31-5 A person who intends to obtain the authorization under the provisions of the proviso of Article 46-5, paragraph (1) of the Act must submit to a prefectural governor an application form stating the following information:

- (i) the number of hospitals, clinics, long-term care health facilities or long-term care homes established by the medical corporation;

- (ii) the number of physicians or dentists who work full-time; and
- (iii) the reason for having one or two directors.

(Application for Authorization for a Case Where a Medical Corporation Does Not Add Any Managers to Directors)

Article 31-5-2 (1) A person who intends to obtain the authorization under the provisions of the proviso of Article 46-5, paragraph (6) of the Act must submit to a prefectural governor an application form stating the following information:

- (i) the address and name of a manager who is not added to directors;
- (ii) the name and location of a hospital, clinic, long-term care health facility or long-term care home managed by that manager; and
- (iii) the reason for not adding the manager to directors.

(2) When a medical corporation submits an application form for authorization to amend the articles of incorporation or articles of endowment to clarify that hospitals, clinics, long-term care health facilities, or long-term care homes whose manager may not be added to their directors, whoever the manager is, pursuant to the provisions of Article 33-25, paragraph (1), at the time of the submission of the application form prescribed in the preceding paragraph, the particulars referred to in item (i) of the preceding paragraph does not require stating.

(Application for Authorization for a Case Where the President is Elected From Among Directors Who Are Not a Physician or Dentist)

Article 31-5-3 A person who intends to obtain the authorization under the provisions of the proviso of Article 46-6, paragraph (1) of the Act must submit to the prefectural governor an application form stating the following information:

- (i) the addresses and names of those directors; and
- (ii) the reason for electing the president from among directors who are not a physician or dentist;

(Minutes of a Council)

Article 31-5-4 (1) The minutes of a meeting of the council under the provisions of Article 95, paragraph (3) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 46-7-2, paragraph (1) of the Act following the deemed replacement of terms, are prepared pursuant to the provisions of this Article.

(2) The minutes of a meeting of the council must be prepared in writing or by electronic or magnetic record.

(3) The minutes of a meeting of the council must be those whose contents are the following information:

- (i) the date, time, and place when and where a meeting of the council has been held (when a director or auditor who has not existed at that place has attended the meeting of the council, including the method of that attendance);
- (ii) when the meeting of the council falls within any of the following, that effect:
 - (a) a meeting convoked at the request of a director under the provisions of Article 93, paragraph (2) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 46-7-2, paragraph (1) of the Act following the deemed replacement of terms;
 - (b) a meeting convoked by a director pursuant to the provisions of Article 93, paragraph (3) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 46-7-2, paragraph (1) of the Act following the deemed replacement of terms;
 - (c) a meeting convoked at the request of an auditor under the provisions of Article 46-8-2, paragraph (2) of the Act; and
 - (d) a meeting convoked by an auditor pursuant to the provisions of Article 46-8-2, paragraph (3) of the Act;
- (iii) the point of the progress of the proceedings of the meeting of the council and the results thereof;
- (iv) when there is a director who has a special interest in particulars which requires a resolution, the name of that director;
- (v) when an opinion or remark is expressed or made at the meeting of the council pursuant to the following clauses, an outline of the contents of that opinion or remark:
 - (a) Article 92, paragraph (2) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 46-7-2, paragraph (1) of the Act following the deemed replacement of terms;
 - (b) Article 46-8, item (iv) of the Act; and
 - (c) Article 46-8-2, paragraph (1) of the Act;
- (vi) when the medical corporation has made the provisions of its articles of incorporation or articles of endowment as referred to in Article 95, paragraph (3) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 46-7-2, paragraph (1) of the Act following the deemed replacement of terms, the names of other directors than the president who have attended the meeting of the council; and
- (vii) when the chairperson of the council exists, the name of the chairperson.

- (4) In the cases set forth in the following items, the minutes of a meeting of the council are those whose contents are the particulars specified respectively in those items:
- (i) when a resolution of the council is deemed to have been adopted pursuant to the provisions of Article 96 of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 46-7-2, paragraph (1) of the Act following the deemed replacement of terms: the following particulars:
 - (a) the contents of particulars on which a resolution of the council is deemed to have been adopted;
 - (b) The name of the director who has proposed particulars referred to in (a);
 - (c) the date on which a resolution of the council is deemed to have been adopted; and
 - (d) the name of a director who has performed the duty pertaining to drawing up of the minutes;
 - (ii) when it has been decided that a report to the council is not required pursuant to the provisions of Article 98, paragraph (1) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 46-7-2, paragraph (1) of the Act following the deemed replacement of terms: the following particulars:
 - (a) the contents of particulars on which it is decided that a report to the council is not required;
 - (b) the date on which it is decided that a report to the council is not required; and
 - (c) the name of a director who has performed the duty pertaining to drawing up of the minutes.

(Electronic Signatures)

Article 31-5-5 (1) A measure substituting for a signature or affixing the name and seal as specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 95, paragraph (4) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 46-7-2, paragraph (1) of the Act following the deemed replacement of terms, is an electronic signature.

- (2) The term "electronic signature" prescribed in the preceding paragraph means a measure which is taken to data which can be recorded in an electronic or magnetic record and falls within all of the following necessary conditions:
- (i) the measure is for showing that the data is created by the person who has taken those measures; and
 - (ii) the measures allow the capability of checking whether the data has not been altered.

(Objects of Examination by Auditors)

Article 31-5-6 Those specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 46-8, item (vii) of the Act is data such as an electronic or magnetic record.

(Amount Calculated by Method Specified by Order of the Ministry of Health, Labour and Welfare as Referred to in Article 113, Paragraph (1), Item (ii) of the Act on General Incorporated Associations and General Incorporated Foundations, as Applied Mutatis Mutandis Pursuant to Article 47-2, Paragraph (1) of the Act Following the Deemed Replacement of Terms)

Article 32 (1) An amount calculated by a method specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 113, paragraph (1), item (ii) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 47-2, paragraph (1) of the Act following the deemed replacement of terms, are the total of the following amounts:

(i) the totals of the amounts of economic benefits which a director or auditor has received or is to receive from the medical corporation during their tenure in consideration for the performance of their duties, such as compensation and bonuses (including a compensation for the execution of their duties, such as compensation and bonuses, in the case where that director doubles as an employee of the medical corporation) (except for those specified in the following item) in fiscal years (limited to the fiscal year including the dates specified in (a) through (c) below according to categories in the cases set forth in (a) through (c) below and the fiscal years before that fiscal year) (the amount of that total converted into that for one year when the period of that fiscal year is not one year), whichever the highest:

(a) when a resolution of the general meeting of members as referred to in Article 113, paragraph (1) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 47-2, paragraph (1) of the Act following the deemed replacement of terms, is adopted: the date of that resolution of the general meeting of members;

(b) when a resolution of the council on making an exemption from liability pursuant to the provisions of the articles of incorporation under 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) of the Act following the deemed replacement of terms, is adopted: the date on which that resolution has been adopted; and

- (c) when a contract referred to in Article 115, paragraph (1) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 47-2, paragraph (1) of the Act following the deemed replacement of terms, has been executed: the date on which the fact causing liability has arisen (when there are two or more of those dates, the latest date);
- (ii) an amount obtained by dividing the amount set forth in (a) by the number set forth in (b):
- (a) the total of the following amounts:
1. the amount of a retirement bonus which the director or auditor has received from the medical corporation;
 2. the amount of, of a retirement allowance for an employee of the medical corporation in the case where the director has doubled as that employee, part of the retirement allowance in consideration for the execution of their duties in the period during which the employee has doubled as the director; and
 3. the amount of economic benefit which has the nature of that set forth 1. or 2.; and
- (b) the number of years during which the director or auditor has held their post as it (when the number specified below in the case where the director or auditor falls within the following posts is over that number of years, that number):
1. the president: 6;
 2. other director than the president who is an employee of the medical corporation: 4; and
 3. a director (except for those set forth in 1. and 2.) or auditor: 2.
- (2) When the provisions of the preceding paragraph apply to a medical corporation doing business as a foundation, in the relevant paragraph, the term "director or auditor" is replaced with "councillor or director or auditor," and the term "general meeting of members" with "board of councillors," and the term "articles of incorporation" in item (i), (b) of the relevant paragraph with "articles of endowment," and in item (ii), (b) of the relevant paragraph, the term "director" with "councillor or director," and the term "or auditor" with "or auditor."

(Economic Benefits Specified by Order of the Ministry of Health, Labour and Welfare as Referred to in Article 113, Paragraph (4) of the Act on General Incorporated Associations and General Incorporated Foundations, as Applied Mutatis Mutandis Pursuant to Article 47-2, Paragraph (1) of the Act Following the Deemed Replacement of Terms)

Article 32-2 Economic benefits specified by Order of the Ministry of Health,

Labour and Welfare as referred to in Article 113, paragraph (4) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 47-2, paragraph (1) of the Act following the deemed replacement of terms (including as applied mutatis mutandis pursuant to Article 114, paragraph (5) and Article 115, paragraph (5) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 47-2, paragraph (1) of the Act following the deemed replacement of terms), are the following:

- (i) a retirement bonus;
- (ii) when the director has doubled as an employee of the medical corporation, of a retirement allowance for that employee, part of the retirement allowance in consideration for the execution of their duties in the period during which the employee has doubled as the director; and
- (iii) an economic benefit which has any of the natures of those set forth in the preceding two items.

(Method Specified by Order of the Ministry of Health, Labour and Welfare as Referred to in Article 278, Paragraph (1) of the Act on General Incorporated Associations and General Incorporated Foundations, as Applied Mutatis Mutandis Pursuant to Article 49-2 of the Act Following the Deemed Replacement of Terms)

Article 32-3 A method specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 278, paragraph (1) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 49-2 of the Act following the deemed replacement of terms, is the submission of a document stating the following particulars or provision of those matters by electronic or magnetic means:

- (i) a person to be a defendant; and
- (ii) the object of claim and facts needed to specify the claim.

(Method Specified by Order of the Ministry of Health, Labour and Welfare as Referred to in Article 278, Paragraph (3) of the Act on General Incorporated Associations and General Incorporated Foundations, as Applied Mutatis Mutandis Pursuant to Article 49-2 of the Act Following the Deemed Replacement of Terms)

Article 32-4 A method specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 278, paragraph (3) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 49-2 of the Act following the deemed replacement of terms, is the submission of a document stating the following particulars or provision of those particulars by electronic or magnetic means:

- (i) the details of an examination conducted by a medical corporation (including the data which are the basis for the decision referred to in the following item);
- (ii) a decision on whether or not a person subject to demand (which means a person who is a director or auditor and the person set forth in item (i) of the preceding Article who pertains to the demand under the provisions of Article 278, paragraph (1) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 49-2 of the Act following the deemed replacement of terms; the same applies in the following item) has liability or an obligation and the reason therefor; and
- (iii) when it is decided that a person subject to demand has liability or an obligation, if the medical corporation does not institute a liability action (which means the liability action prescribed in Article 278, paragraph (1) of the Act on General Incorporated Associations and General Incorporated Foundations, as applied mutatis mutandis pursuant to Article 49-2 of the Act following the deemed replacement of terms), the reason therefor.

Section 4 Account

(Keeping of Accounting of Books)

Article 32-5 Accounting books to be kept pursuant to the provisions of Article 50-2, paragraph (1) of the Act must be kept in writing or by electronic or magnetic record.

(Special Relationship Specified by Order of the Ministry of Health, Labour and Welfare as Referred to in Article 51, Paragraph (1) of the Act)

Article 32-6 A special relationship specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 51, paragraph (1) of the Act is a relationship in the case where the person set forth in item (i) carries out the transaction set forth in item (ii) with the medical corporation:

- (i) a person falls under any of the following:
 - (a) an officer of the medical corporation or their close relative (which means a spouse or relative within the second degree of kinship; the same applies in (b) and (c);
 - (b) a corporation whose representative is an officer of the medical corporation or their close relative;
 - (c) a corporation in which the officers of the medical corporation or their close relatives are in the majority of voting rights in its shareholders meeting or general meeting of members or board of councillors or board of directors or council;

- (d) other corporation in the case where the officers of that other corporation are in the majority of voting rights in the general meeting of members, board of councillors, or council of the medical corporation; and
- (e) other corporation in the case where the officers of the corporation referred to in (c) are in the majority of voting rights in the shareholders meeting or general meeting of members or board of councillors or board of directors or council of that other corporation (except for the medical corporation);
- (ii) a transaction falling under any of the following:
 - (a) a transaction the amount of whose business profit or business expenses is 10 million yen or more and which accounts for 10% or more of the total amount of business profit from the original operations, business profit from incidental operations and business profit from profit-making operations or the total amount of business expenses for the original operations, business expenses for incidental operations and business expenses for profit-making operations of the medical corporation for the fiscal year;
 - (b) a transaction the amount of whose non-business profit or non-business expenses is 10 million yen or more and which accounts for ten percent or more of the total amount of non-business profit or non-business expenses of the medical corporation for the fiscal year;
 - (c) a transaction the amount of whose special income or extraordinary loss is 10 million yen or more;
 - (d) a transaction the total amount of whose assets or liabilities accounts for one percent or more of the total assets of the medical corporation on the last day of the fiscal year and whose balance is over 10 million yen;
 - (e) trade the total amount of whose transactions, such as borrowing and lending of funds and the sale of tangible fixed assets and securities, is 10 million yen or more and which accounts for one percent or more of the total assets of the medical corporation on the last day of the fiscal year; and
 - (f) in the case of a taking over or transfer of business, a transaction in which the total amount of assets or liabilities, whichever larger, is 10 million yen or more and which accounts for one percent or more of the total assets of the medical corporation on the last day of the fiscal year.

(Documents Specified by Order of the Ministry of Health, Labour and Welfare as Referred to in Article 51, Paragraph (1) of the Act)

Article 33 (1) Documents specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 51, paragraph (1) of the Act are the following documents:

- (i) for a social medical corporation, a document explaining that it falls within the necessary conditions referred to in Article 42-2, paragraph (1), items (i) through (vi) of the Act;

- (ii) for a social medical corporation bond issuing corporation (which means a medical corporation which has issued social medical corporation bonds as prescribed in Article 54-2, paragraph (1) of the Act except for those which have redeemed the total amount of those social medical corporation bonds; the same applies in the following paragraph and item (iii) of the following Article), the following documents:
 - (a) the documents set forth in the preceding item (limited to the case where that social medical corporation bond issuing corporation is a social medical corporation); and
 - (b) a statement of changes in net assets, a cash flow statement, and annexed detailed statements; and
 - (iii) for a medical corporation prescribed in Article 51, paragraph (2) of the Act, a statement of changes in net assets and an annexed detailed statement.
- (2) In preparing the business reports, etc. prescribed in Article 51, paragraph (1) of the Act (hereinafter simply referred to as "business reports, etc."), an inventory of assets, balance sheet, profit and loss statement, and the documents set forth in item (ii), (b) of the preceding paragraph pursuant to the provisions of the relevant paragraph, a social medical corporation bond issuing corporation is to prepare them separately as specified by Order of the Ministry of Health, Labour and Welfare.

(Person Falling Within Standards Specified by Order of the Ministry of Health, Labour and Welfare as Referred to in Article 51, Paragraph (2) of the Act)

Article 33-2 A person who falls within standards specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 51, paragraph (2) of the Act is a person who falls under any of the following items:

- (i) a medical corporation for which the total of the amounts recorded in the liabilities section of the balance sheet pertaining to the last fiscal year (which means the most recent fiscal year for which an approval referred to in Article 51, paragraph (6) of the Act has been received for business reports, etc.; hereinafter the same applies in this item and the following item) is 5 billion yen or more or for which the total of the amounts recorded in the business profit section of the profit and loss statement pertaining to the last fiscal year is 7 billion yen or more;
- (ii) a social medical corporation for which the total of the amounts recorded in the liabilities section of the balance sheet pertaining to the last fiscal year is 2 billion yen or more or for which the total of the amounts recorded in the business profit section of the profit and loss statement pertaining to the last fiscal year is 1 billion yen or more; and
- (iii) a social medical corporation which is a social medical corporation bond issuing corporation.

(Audits by Auditors and Certified Public Accountants)

Article 33-2-2 (1) An audit under the provisions of Article 51, paragraphs (4) and (5) of the Act is pursuant to the provisions of from this Article to Article 33-2-6.

(2) The audit prescribed in the preceding paragraph includes, beyond the audit prescribed in Article 2, paragraph (1) of the Certified Public Accountants Act (Act No. 103 of 1948), the procedure for verifying the degree of consistency between the data shown in a balance sheet and a profit and loss statement and those to be shown in a balance sheet and a profit and loss statement and for conveying the results thereof to the interested persons.

(Contents of Auditor's Audit Report)

Article 33-2-3 When an auditor referred to in Article 51, paragraph (4) of the Act (hereinafter simply referred to as "auditor") receives business reports, etc., the auditor must prepare an auditor's audit report whose contents are the following particulars (which means the auditor's audit report prescribed in Article 51-4, paragraph (1), item (ii) of the Act; hereinafter the same applies in this Article and the following Article):

- (i) the method of the auditor's audit and the details thereof;
- (ii) an opinion about whether the business reports, etc. have been prepared in accordance with laws and regulations;
- (iii) if the auditor has been unable to conduct a necessary examination for the audit, that effect and the reason therefor; and
- (iv) the date of drawing up the auditor's audit report.

(Time Limit for Notice of Auditor's Audit Report)

Article 33-2-4 An auditor must notify the director referred to in Article 51-2, paragraph (1) of the Act (simply referred to as "director" in this Article and Article 33-2-6) of the contents of an auditor's audit report by the following days, whichever later:

- (i) the day on which four weeks have passed since the auditor receives the business reports, etc.; and
- (ii) when that director and the auditor have set a day by mutual agreement, that day.

(Contents of an Audit Report by a Certified Public Accountant)

Article 33-2-5 (1) When a certified public accountant or audit corporation referred to in Article 51, paragraph (5) of the Act (hereinafter referred to as "certified public accountant, etc." in this Article and the following Article) receives an inventory of assets, a balance sheet, and a profit and loss statement, the certified public accountant, etc. must prepare an audit report by

a certified public accountant, etc. (which means the audit report by a certified public accountant, etc. prescribed in Article 51-4, paragraph (2), item (ii) of the Act; hereinafter the same applies in this paragraph and the following Article) whose contents are the following particulars:

- (i) the method of audit by the certified public accountant, etc. and the details thereof;
 - (ii) an opinion about whether the inventory of assets, balance sheet and profit and loss statement have been prepared in accordance with laws and regulations;
 - (iii) if the certified public accountant, etc. has no opinion referred to in the preceding item, that effect and the reason therefor;
 - (iv) added data; and
 - (v) the date of drawing up the audit report by a certified public accountant, etc.
- (2) The term "added data" referred to in item (iv) of the preceding paragraph is, of such particulars as the following particulars, those to which an explanation for the decision of the certified public accountant, etc. needs to be added or, of the contents of the inventory of assets, balance sheet and profit and loss statement, those which need to emphasize:
- (i) a change of the accounting policy on legitimate grounds;
 - (ii) a significant contingency; and
 - (iii) a significant subsequent event.

(Time Limit for Notice of Audit Report by a Certified Public Accountant)

- Article 33-2-6 (1) A certified public accountant, etc. must notify directors and auditors of the contents of an audit report by a certified public accountant, etc. by whichever of the following days, whichever comes later:
- (i) the day on which four weeks have passed since the date of receipt of the inventory of assets, balance sheet, and profit and loss statement; and
 - (ii) when those directors and those auditors and that certified public accountant, etc. have set a day by mutual agreement, that day.
- (2) On the day on which directors and auditors receive a notice of the contents of an audit report by a certified public accountant, etc. under the provisions of the preceding paragraph regarding the inventory of assets, balance sheet, and profit and loss statement, a medical corporation referred to in Article 51, paragraph (2) of the Act is considered to have received an audit by a certified public accountant, etc.
- (3) Notwithstanding the provisions of the preceding paragraph, if a certified public accountant, etc. fails to give a notice of the contents of an audit report by a certified public accountant, etc. under the provisions of paragraph (1) by the day on which the certified public accountant, etc. has to give that notice pursuant to the provisions of the relevant paragraph, the medical corporation

referred to in Article 51, paragraph (2) of the Act is considered to have received an audit of its inventory of assets, balance sheet, and profit and loss statement by the certified public accountant, etc. on that day on which the notice has to be given.

(Method of Providing Business Reports)

Article 33-2-7 (1) When a director of a medical corporation doing business as an association sends to members a notice of convocation of the general meeting of members as referred to in Article 51-2, paragraph (1) of the Act by electronic or magnetic means, the director may provide particulars to state in the business reports, etc. by electronic or magnetic means instead of providing business reports, etc. under the provisions of the relevant paragraph; provided, however, that, in this case, when a member makes a request, the director must also provide that member with the business reports, etc.

(2) The provisions of the preceding paragraph apply mutatis mutandis to a medical corporation doing business as a foundation. In this case, the term "member" in the relevant paragraph is deemed to be replaced with "councillor."

(Person Falling Within Standards Specified by Order of the Ministry of Health, Labour and Welfare as Referred to in Article 51-3 of the Act)

Article 33-2-8 Persons who fall within standards specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 51-3 of the Act are the following persons:

- (i) the medical corporation prescribed in Article 33-2, item (i); and
- (ii) a social medical corporation.

(Method of Public Notice)

Article 33-2-9 A medical corporation prescribed in Article 51-3 of the Act may specify any of the following methods as the method of public notice under the provisions of the relevant Article:

- (i) a method of putting it in the Official Gazette;
- (ii) a method of putting it in a daily newspaper which carries particulars concerning current events; and
- (iii) an electronic public notice (which means, of methods of public notice, a method of taking a measure to put an unspecified and large number of persons in a state where they can be provided with information which is the details to be publicly notified by electronic or magnetic means and to use an automatic public transmission server connected to the Internet; the same applies hereinafter).

(Public Notice Period By Way of an Electronic Public Notice)

Article 33-2-10 When a medical corporation gives a public notice by way of an electronic public notice, the medical corporation must continue to give the public notice by way of an electronic public notice until the day on which three years have passed after the day of the closing of the general meeting of members at which the approval referred to in Article 51-2, paragraph (3) of the Act is given to the balance sheet and profit and loss statement referred to in Article 51-3 of the Act or of a meeting of board of councillors at which the approval referred to in paragraph (3) of the relevant Article, as applied mutatis mutandis pursuant to paragraph (5) of the relevant Article following the deemed replacement of terms, is given to that balance sheet and profit and loss statement.

(Inspection of Documents)

Article 33-2-11 Documents under the provisions of Article 51-4, paragraphs (1) and (2) of the Act is inspected in writing or by means of displaying information recorded in a file, magnetic disk or the like provided in a computer on the surface of paper or on the screen of an input-output unit installed at the principal office.

(Notification of Business Reports)

Article 33-2-12 (1) When a medical corporation makes a notification under the provisions of Article 52, paragraph (1) of the Act, the medical corporation must attach duplicate copies to the documents set forth in the items of the relevant paragraph (regarding the documents prescribed in Article 33, paragraph (1), item (i), limited to a document explaining that it falls within the necessary conditions referred to in Article 42-2, paragraph (1), item (v) of the Act, a document specifying the standards for payment as prescribed in Article 30-35-3, paragraph (1), item (i), (d), and a statement of assets held as prescribed in paragraph (2) of the relevant Article).

(2) An inspection referred to in Article 52, paragraph (2) of the Act is conducted regarding the documents pertaining to the report referred to in paragraph (1) of the relevant Article (regarding the documents prescribed in Article 33, paragraph (1), item (i), limited to a document explaining that it falls within the necessary conditions referred to in Article 42-2, paragraph (1), item (v) of the Act, a document specifying the standards for payment as prescribed in Article 30-35-3, paragraph (1), item (i), (d), and a statement of assets held as prescribed in Article paragraph (2) of the relevant Article) which are reported in the past three years.

Section 5 Social Medical Corporation Bonds

(Subscription Requirements)

Article 33-3 (1) Particulars specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 54-3, paragraph (1), item (xiii) of the Act are the following particulars:

- (i) when money is made to be paid by installments in exchange for social medical corporation bonds for subscription, that effect and the amount to be paid in (which means the amount to be paid in as prescribed in Article 54-3, paragraph (1), item (x) of the Act; the same applies in this Article) on each of the payment dates;
- (ii) when a contract under which property other than money is provided instead of paying money in exchange for social medical corporation bonds for subscription is entered into, the terms of that contract;
- (iii) when power other than that of a social medical corporation bond manager as prescribed in the Act is specified in a contract for the entrustment under the provisions of Article 54-5 of the Act, the details of that power; and
- (iv) when it is prescribed in the main clause of Article 711, paragraph (2) of the Companies Act (Act No. 86 of 2005), as applied mutatis mutandis pursuant to Article 54-7 of the Act, the grounds prescribed in the main clause of the relevant paragraph.

(2) Particulars specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 54-3, paragraph (2) of the Act are the following:

- (i) when a social medical corporation delegates a decision on particulars set forth in the items of Article 54-3, paragraph (1) of the Act which pertain to two or more offerings (which means the offering referred to in the relevant paragraph; the same applies hereinafter), that effect;
- (ii) the limit of the total amount of social medical corporation bonds for subscription (in the case prescribed in the preceding item, the total of the limits of the total amounts of social medical corporation bonds for subscription which pertain to the offerings);
- (iii) an outline of particulars concerning interest rates, including the limit of the interest rate on social medical corporation bonds for subscription; and
- (iv) an outline of particulars concerning the amount to be paid in, including the minimum amount of the total of the amounts to be paid in for social medical corporation bonds for subscription.

(Classes of Social Medical Corporation Bonds)

Article 33-4 Particulars specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 54-4, item (i) of the Act are the following:

- (i) the interest rate on social medical corporation bonds;
- (ii) the method and due date of redemption of social medical corporation bonds;
- (iii) the method and due date of payment of interest;

- (iv) when a social medical corporation issues social medical corporation bond certificates, that effect;
- (v) when it is decided that a social medical corporation creditor may not make the whole or any part of a request under the provisions of Article 698 of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act, that effect;
- (vi) when it is decided that a social medical corporation bond manager may carry out the act set forth in Article 706, paragraph (1), item (ii) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act, not according to a resolution of a meeting of social medical corporation creditors, that effect;
- (vii) when a social medical corporation appoints a social medical corporation bond manager, the name and address of the manager as well as the terms of a contract for the entrustment under the provisions of Article 54-5 of the Act;
- (viii) when a social medical corporation appoints a social medical corporation bond register manager, the name and address of the manager; and
- (ix) when social medical corporation bonds are secured social medical corporation bonds, the matters set forth in Article 19, paragraph (1), items (i), (xi) and (xiii) of the Secured Bond Trust Act (Act No. 52 of 1905), as applied mutatis mutandis pursuant to Article 54-8 of the Act.

(Particulars to State in Social Medical Corporation Bond Registers)

Article 33-5 Particulars specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 54-4, item (vii) of the Act are the following:

- (i) when other property than money has been delivered instead of paying money in exchange for social medical corporation bonds for subscription, the value of that property and the date of delivery; and
- (ii) when a social medical corporation creditor has offset an obligation to pay money in exchange for a social medical corporation bond for subscription by a claim against the social medical corporation, the amount of that claim and the date on which the offsetting has been made.

(Case Where Appointing a Social Medical Corporation Bond Manager Is Not Required)

Article 33-6 A case specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 54-5 of the Act is a case where a value obtained by dividing the total amount of a class (which means the class prescribed in Article 54-4, item (i) of the Act; the same applies in this Article) of social medical corporation bonds by the lowest amounts of that class of social medical corporation bonds is below 50.

(Particulars Requiring Notices to Prospective Subscribers)

Article 33-7 Particulars specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 677, paragraph (1), item (iii) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act following the deemed replacement of terms, are the following particulars:

- (i) when a social medical corporation appoints a social medical corporation bond manager, the name and address of that manager; and
- (ii) when a social medical corporation appoints a social medical corporation bond register manager, the name and address of that manager.

(Electronic or Magnetic Means)

Article 33-8 (1) Methods of using information and communications technology, including a method of using an electronic data processing system, as specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 677, paragraph (3) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act following the deemed replacement of terms, are the following methods:

- (i) among the methods of using an electronic data processing system, those set forth in (a) or (b):
 - (a) a method of transmitting data through a telecommunications line which connects the computer used by a sender to the computer used by a receiver and recording the data in a file provided in the computer used by the receiver; or
 - (b) a method of offering the contents of data recorded in a file to be viewed provided in the computer used by a sender to a person who is provided with information through a telecommunications line and of recording those data in a file provided in the computer used by that person who is provided with information; and
 - (ii) a method of delivering information recorded in a file prepared with a magnetic disk or the like.
- (2) The methods set forth in the items of the preceding paragraph must be those which allows the receiver to prepared a document by outputting a record in a file.

(Cases Where No Notice to Persons Who Intend to Subscribe for Is Required)

Article 33-9 Cases specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 677, paragraph (4) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act following the deemed replacement of terms, are the following cases where a social medical corporation provides a person who intends to subscribe for as referred to in paragraph (1) of the relevant Article with the matters set forth in the items of

the relevant paragraph:

- (i) a case where the relevant social medical corporation provides the particulars to state in a prospectus pursuant to the provisions of the Securities Exchange Act (Act No. 25 of 1948) by electronic or magnetic means (which means the electronic or magnetic means prescribed in Article 677, paragraph (3) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act following the deemed replacement of terms; hereinafter the same applies in this Chapter); and
- (ii) a case where the social medical corporation provides materials, including a prospectus or other document equivalent thereto, pursuant to the laws and regulations of a foreign country.

(Electronic or Magnetic Records)

Article 33-10 The information specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 682, paragraph (1) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act following the deemed replacement of terms, is a file prepared with a magnetic disk or the like in which data are recorded.

(Electronic Signatures)

Article 33-11 (1) A measure substituting for a signature or affixing the name and seal as specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 682, paragraph (3) and Article 695, paragraph (3) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act following the deemed replacement of terms, is an electronic signature.

(2) The "electronic signature" prescribed in the preceding paragraph means a measure which is taken to data which can be recorded in an electronic or magnetic record (which means the electronic or magnetic record prescribed in Article 682, paragraph (1) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act following the deemed replacement of terms; hereinafter the same applies in this Chapter) and falls within all the following necessary conditions:

- (i) the measure is to show that the data was created by the person who has taken that measure; and
- (ii) the measure is capable of checking whether the data have not been altered.

(Holders of Right to Inspect)

Article 33-12 Persons specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 684, paragraph (2) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act following the deemed replacement of terms, is a creditor and a member of a social medical

corporation bond issuing corporation, including a social medical corporation creditor.

(Method of Displaying Particulars Recorded in Electronic or Magnetic Records)
Article 33-13 A method specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 684, paragraph (2), item (ii) and Article 731, paragraph (3), item (ii) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act following the deemed replacement of terms, is a method of displaying the particulars recorded in an electronic or magnetic record as referred to in those clauses on the surface of paper or on a screen.

(Request to State Particulars to State in Social Medical Corporation Bond Registers)

Article 33-14 (1) Cases specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 691, paragraph (2) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act following the deemed replacement of terms, are the following cases:

- (i) a case where a social medical corporation bond acquirer (which means a person who has acquired a social medical corporation bond from other person than social medical corporation bond issuing corporations (except for the social medical corporation bond issuing corporation)) gains a final and binding judgment which orders the acquirer to make a claim under the provisions of Article 691, paragraph (1) of the Companies Act, as applied mutatis mutandis pursuant to the Article 54-7 of the Act, pertaining to the social medical corporation bond which the social medical corporation bond acquirer has acquired against a person entered or recorded as a social medical corporation creditor in the social medical corporation bond register or a general successor thereto, if the acquirer makes the claim providing materials, such as a document certifying the details of that final and binding judgment; and
- (ii) a case where a social medical corporation bond acquirer provides materials, such as a document certifying the details of a thing which has the same effect as the final and binding judgment referred to in the preceding item, and makes a claim;
- (iii) a case where a social medical corporation bond acquirer is a person who has acquired the social medical corporation bond of the medical corporation through general succession, if the acquirer provides materials, such as a document certifying that general succession, and makes a claim; and
- (iv) a case where a social medical corporation bond acquirer is a person who has acquired the social medical corporation bond of the medical corporation through an auction, if the acquirer provides materials, including a document

certifying the fact that the person has so acquired through that auction, and makes a claim.

(2) Notwithstanding the provisions of the preceding paragraph, when a social medical corporation bond acquired by a social medical corporation bond acquirer is that with a provision that a social medical corporation bond certificate is issued, a case specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 691, paragraph (2) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act following the deemed replacement of terms, is a case where a social medical corporation bond acquirer makes a claim presenting the social medical corporation bond certificate.

(Qualification for Social Medical Corporation Bond Managers)

Article 33-15 Persons specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 703, item (iii) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act following the deemed replacement of terms, are the following persons:

- (i) a person who has given a license referred to in Article 3 of the Secured Bond Trust Act;
- (ii) the Shoko Chukin Bank, Ltd.;
- (iii) a federation of agricultural cooperatives which conducts both the businesses referred to in Article 10, paragraph (1), items (ii) and (iii) of the Agricultural Co-operatives Act (Act No. 132 of 1947);
- (iv) a federation of cooperatives which conducts the business referred to in Article 9-9, paragraph (1), item (i) of the Small and Medium-Sized Enterprise Cooperatives Act (Act No. 181 of 1949);
- (v) a credit union or a federation of credit unions;
- (vi) a federation of workers' credit unions;
- (vii) a long-term credit bank prescribed in Article 2 of the Long Term Credit Bank Act (Act No. 187 of 1952);
- (viii) an insurance company prescribed in Article 2, paragraph (2) of the Insurance Business Act (Act No. 105 of 1995); and
- (ix) the Norinchukin Bank.

(Electronic or Magnetic Means for Giving Electronic Public Notice)

Article 33-16 A measure to put an unspecified and large number of persons in a state where those persons can be provided with information whose details to be publicly notified as specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 706, paragraph (3) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act following the deemed replacement of terms, is to be, of the method set forth in Article 33-8,

paragraph (1), item (i), (b), that which uses an automatic public transmission server connected to the Internet.

(Special Relationships)

Article 33-17 (1) Special relationships specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 710, paragraph (2), item (ii) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act following the deemed replacement of terms (including as applied mutatis mutandis pursuant to Article 712 of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act), are to be the following connections:

- (i) a relationship between a person who has voting rights over fifty-hundredths of the voting rights of all members or all shareholders of a corporation (hereinafter referred to as "controlling member" in this Article) and that corporation (hereinafter referred to as "controlled corporation" in this Article); and
 - (ii) a relationship between a controlled corporation and other controlled corporation of its controlling member.
- (2) When a controlling member and its controlled corporation have voting rights over fifty-hundredths of the voting rights of all members or all shareholders of other corporation in all, that other corporation is deemed to be a controlled corporation of that controlling member, and the provisions of the preceding paragraph apply to the other corporation.

(Particulars to Decide Concerning Convocation of a Meeting of Social Medical Corporation Creditors)

Article 33-18 Particulars specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 719, item (iv) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act following the deemed replacement of terms, are the following particulars:

- (i) particulars to state in reference documents for a meeting of social medical corporation creditors pursuant to the provisions of the following Article;
- (ii) a time limit for the exercise of voting rights in writing (limited to a time at and before the date and time of a meeting of social medical corporation creditors and at and after the time at which two weeks have passed from the time when a notice under the provisions of Article 720, paragraph (1) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act has been given);
- (iii) when a social medical corporation creditor exercises a voting right repetitiously regarding the identical proposal pursuant to the provisions of Article 726, paragraph (1) of the Companies Act (when the matter set forth

- in Article 719, item (iii) of the relevant Act is specified, Article 726, paragraph (1) or Article 727, paragraph (1) of the relevant Act), as applied mutatis mutandis pursuant to Article 54-7 of the Act, if a matter concerning handling of the exercise of voting rights by that social medical corporation creditor is specified in the case where the details of the exercises of a voting right regarding that identical proposal are different, that matter;
- (iv) when the handling referred to in Article 33-20, paragraph (1), item (iii) is specified, the details of that handling;
 - (v) when the particulars set forth in Article 719, item (iii) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act are specified, the following particulars:
 - (a) a time limit for the exercise of a voting right by electronic or magnetic means (limited to a time at and before the date and time of a meeting of social medical corporation creditors and at and after the time at which two weeks have passed from the time when a notice under the provisions of Article 720, paragraph (1) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act, has been given); and
 - (b) when it is provided that, when a social medical corporation creditor which has given the consent referred to in Article 720, paragraph (2) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act, makes a request, a voting form under the provisions of Article 721, paragraph (1) of the relevant Act (which means the voting form prescribed in the relevant paragraph; the same applies hereinafter) is delivered (including the provision by electronic or magnetic means under the provisions of paragraph (2) of the relevant Article instead of that delivery) to that social medical corporation creditor, that effect.

(Reference Documents to Meetings of Social Medical Corporation Creditors)

Article 33-19 (1) In a reference document for a meeting of social medical corporation creditors, the following particulars must be stated:

- (i) a proposal;
 - (ii) when the proposal is that regarding the election of a representative social medical corporation creditor, the following matters:
 - (a) the name of a candidate;
 - (b) the brief personal history or history of the candidate; and
 - (c) when the candidate has a special interest in the social medical corporation bond issuing corporation or a social medical corporation creditor, an outline of that fact.
- (2) In a reference document for a meeting of social medical corporation creditors, beyond what is specified in the preceding paragraph, particulars which are found to be helpful for the exercise of voting rights by social medical

corporation creditors may be stated.

- (3) Of the particulars to be stated in a reference document for a meeting of social medical corporation creditors which is provided to social medical corporation creditors regarding the same meeting of social medical corporation creditors, if there are particulars stated in other document or particulars provided by electronic or magnetic means, those particulars are not required to be stated in the reference document for a meeting of social medical corporation creditors.
- (4) Of the particulars to be stated the contents of a convocation notice (which means the notice under the provisions of Article 720, paragraphs (1) or (2) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act; hereinafter the same applies in this Chapter) provided to social medical corporation creditors regarding the same meeting of social medical corporation creditors, some matters are stated in a reference document for a meeting of social medical corporation creditors, those particulars are not required to be stated in the convocation notice.

(Voting Forms)

Article 33-20 (1) Particulars to state in a voting form to be delivered pursuant to the provisions of Article 721, paragraph (1) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act following the deemed replacement of terms, or particulars to state in a voting form to be provided by electronic or magnetic means pursuant to the provisions of Article 722, paragraph (1) or (2) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act following the deemed replacement of terms, are the following particulars:

- (i) columns in which approvals or disapprovals (when abstention columns are included, including abstentions) for proposals are stated;
 - (ii) when the particular set forth in Article 33-18, item (iii), (c) is specified, that particular;
 - (iii) when the particular set forth in Article 33-18, item (iii), (d) is specified, the details of handling by which an intention of being for or against or abstaining from proposals is considered to have been manifested in the case where a voting form in which no entry is made in the columns referred to in item (i) is submitted to the convener (which means the convener prescribed in Article 719 of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act following the deemed replacement of terms; hereinafter the same applies in this Article);
 - (iv) a time limit for the exercise of a voting right; and
 - (v) the name of a social medical corporation creditor to exercise its voting rights and the number of voting rights which the creditor may exercise.
- (2) When a social medical corporation specifies the matter set forth in Article 33-

18, item (v), (b), at the time when a request is made by a social medical corporation creditor which has given the consent referred to in Article 720, paragraph (2) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act, the convener must deliver to that social medical corporation creditor a voting form under the provisions of Article 721, paragraph (1) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act (including the provision by electronic or magnetic means under the provisions of paragraph (2) of the relevant Article instead of that delivery).

- (3) Of the matters to be stated in a voting form provided to social medical corporation creditors (limited to those set forth in paragraph (1), items (ii) through (iv)) regarding the same meeting of social medical corporation creditors, some of the particulars are the contents of a convocation notice, those particulars are not be required to be stated in a voting form provided to social medical corporation creditors.
- (4) Of the particulars to be the contents of a convocation notice provided to social medical corporation creditors regarding the same meeting of social medical corporation creditors that should be included, if the particulars are stated in a voting form, those particulars are not required to be included in the contents of a convocation notice provided to social medical corporation creditors.

(Time Limit for Exercise of Voting Rights in Writing)

Article 33-21 Time specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 726, paragraph (2) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act following the deemed replacement of terms, is the time limit for exercise as referred to in Article 33-18, item (ii).

(Time Limit for Exercise of Voting Rights by Electronic or Magnetic Means)

Article 33-22 Time specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 727, paragraph (1) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act following the deemed replacement of terms, is the time limit for exercise as referred to in Article 33-18, item (v), (a).

(Minutes of Meetings of Social Medical Corporation Creditors)

Article 33-23 (1) The minutes of a meeting of social medical corporation creditors under the provisions of Article 731, paragraph (1) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act following the deemed replacement of terms, are prepared pursuant to the provisions of this Article.

- (2) The minutes of a meeting of social medical corporation creditors are prepared in writing or by electronic or magnetic record.
- (3) The minutes of a meeting of social medical corporation creditors are those whose contents are the following particulars:
 - (i) the date, time and place when and where the meeting of social medical corporation creditors is held;
 - (ii) the point of the progress of the proceedings of the meeting of social medical corporation creditors and the results thereof;
 - (iii) when an opinion is expressed at the meeting of social medical corporation creditors pursuant to the provisions of Article 729, paragraph (1) of the Companies Act, as applied mutatis mutandis pursuant to Article 54-7 of the Act, an outline of the contents of that opinion;
 - (iv) the name of the representative or social medical corporation bond manager of the social medical corporation bond issuing corporation who has attended the meeting of social medical corporation creditors;
 - (v) when the chairperson exists at the meeting of social medical corporation creditors, the name of the chairperson; and
 - (vi) the name of a person who has performed the duty pertaining to drawing up of the minutes.

(Electronic or Magnetic Means Pertaining to Order for Enforcement of the Medical Care Act)

Article 33-24 The classes and details of electronic or magnetic means to be shown pursuant to the provisions of Article 5-7, paragraph (1) and Article 5-8, paragraph (1) of the Order are the following:

- (i) among the following methods, those used by the sender:
 - (a) following methods of using an electronic data processing system:
 1. a method of transmitting data through a telecommunications line which connects the computer used by a sender to the computer used by a receiver and of recording the data in a file provided in the computer used by the receiver; and
 2. a method of offering for viewing the contents of data recorded in a file provided in the computer used by a sender to a person who is provided with information through a telecommunications line and of recording those data in a file provided in the computer used by that person who is provided with information; and
 - (b) a method of delivering a file prepared with a magnetic disk or the like in which data are recorded; and
- (ii) the method of recording information into a file.

Section 6 Amendment to Articles of Incorporation and Articles of

Endowment

(Authorization for Amendment to Articles of Incorporation and Articles of Endowment)

Article 33-25 (1) When a medical corporation intends to obtain authorization for amendment to the articles of incorporation or articles of endowment pursuant to the provisions of Article 54-9, paragraph (3) of the Act, the medical corporation must submit to a prefectural governor an application form with the following documents:

- (i) a document stating the details of the amendment to the articles of incorporation or articles of endowment (a comparative table of old provisions and amended ones are attached to it) and the grounds therefor; and
 - (ii) a document certifying that the medical corporation has gone through the procedure for amendment as specified in the articles of incorporation or articles of endowment.
- (2) When amendment to the articles of incorporation or articles of endowment pertains to a case where the medical corporation intends to newly establish a hospital, or clinic, long-term care health facility or long-term care home prescribed in Article 39, paragraph (1) of the Act, beyond the documents referred to in the items of the preceding paragraph, the medical corporation must attach to the application form referred to in the preceding paragraph the documents set forth in Article 31, items (v) and (xi) as well as a business plan for two years after amendment to the articles of incorporation or articles of endowment and a budget document incidental thereto.
- (3) When amendment to the articles of incorporation or articles of endowment pertains to a case where the medical corporation carries out the operations set forth in the items of Article 42 of the Act, beyond the documents referred to in the items of paragraph (1), the medical corporation must attach to the application form referred to in paragraph (1) the documents set forth in Article 31, item (vi) as well as a business plan for two years after amendment to the articles of incorporation or articles of endowment and a budget document incidental thereto.
- (4) When amendment to the articles of incorporation or articles of endowment pertains to a case where a medical corporation which is a social medical corporation carries out the profit-making operations referred to in Article 42-2, paragraph (1) of the Act, beyond the documents referred to in the items of paragraph (1), the medical corporation must attach to the application form referred to in paragraph (1) a document stating an outline of the profit-making operations and the operating method as well as a business plan for two years after amendment to the articles of incorporation or articles of endowment and a budget document incidental thereto.

(Particulars Specified by Order of the Ministry of Health, Labour and Welfare as Referred to in Article 54-9, Paragraph (3) of the Act)

Article 33-26 Particulars specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 54-9, paragraph (3) of the Act are the particulars set forth in Article 44, paragraph (2), items (iv) and (xii) of the Act.

Section 7 Dissolution and Liquidation

(Application for Authorization for Dissolution)

Article 34 When a medical corporation intends to obtain authorization for dissolution pursuant to the provisions of Article 55, paragraph (6) of the Act, the medical corporation must submit to a prefectural governor an application form with the following documents:

- (i) a statement of reasons;
- (ii) a document certifying that the medical corporation has gone through the procedure for dissolution as specified in the Act, the articles of incorporation or articles of endowment;
- (iii) the inventory of assets and balance sheet; and
- (iv) a document stating particulars concerning the disposition of residual assets.

Section 8 Mergers and Splits

Subsection 1 Mergers

Division 1 Absorption-type Mergers

(Particulars Specified by Order of the Ministry of Health, Labour and Welfare as Referred to in Article 58 of the Act)

Article 35 Particulars specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 58 of the Act is the following:

- (i) a business plan for two years after the absorption-type merger (which means the absorption-type merger prescribed in Article 58 of the Act; hereinafter the same applies in this Subsection) of a medical corporation surviving an absorption-type merger (which means the medical corporation surviving an absorption-type merger prescribed in Article 58 of the Act; hereinafter the same applies in this Division) or an outline thereof; and
- (ii) the day on which the absorption-type merger becomes effective.

(Application for Authorization for Absorption-Type Mergers)

Article 35-2 (1) When a medical corporation intends to obtain authorization for an absorption-type merger pursuant to the provisions of Article 58-2,

paragraph (4) of the Act, the medical corporation must submit to a prefectural governor an application form with the following documents:

- (i) a statement of reasons;
 - (ii) a document certifying that the medical corporation has gone through the procedure referred to in Article 58-2, paragraphs (1) or (3) of the Act;
 - (iii) a copy of the absorption-type merger agreement;
 - (iv) the articles of incorporation or articles of endowment of the medical corporation surviving an absorption-type merger after the absorption-type merger;
 - (v) the articles of incorporation or articles of endowment of the medical corporation surviving an absorption-type merger and the medical corporation disappearing in an absorption-type merger (which means the medical corporation disappearing in an absorption-type merger prescribed in Article 58 of the Act; the same applies in the following item) before the absorption-type merger;
 - (vi) the inventories of assets and balance sheets of the medical corporation surviving an absorption-type merger and the medical corporation disappearing in an absorption-type merger before the absorption-type merger; and
 - (vii) the documents set forth in Article 31, items (vii), (x) and (xi) which pertain to the medical corporation surviving an absorption-type merger (in this case, the term "after establishment" in item (vii) of the relevant Article is deemed to be replaced with "after the absorption-type merger," and the term "officers" in item (x) with "officers who newly assume office."
- (2) When both medical corporations before an absorption-type merger are a medical corporation with provisions for equity interests, if a provision for a person to whom residual assets are to belong is made in the articles of incorporation of the medical corporation surviving an absorption-type merger as referred to in item (iv) of the preceding paragraph, notwithstanding the provisions of Article 44, paragraph (5) of the Act, other person than those prescribed in the relevant paragraph may be prescribed.

(Method of Inspecting Inventories of Assets and Balance Sheets)

Article 35-3 Documents under the provisions of Article 58-3, paragraphs (2) of the Act is inspected in writing or by means of displaying particulars recorded in the file of electronic or magnetic record or a magnetic disk or the like on the surface of paper or on the screen of an input-output unit installed at the office.

Division 2 Consolidation-Type Mergers

(Particulars Specified by Order of the Ministry of Health, Labour and Welfare)

as Referred to in Article 59, Item (iv) of the Act)

Article 35-4 Particulars specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 59, item (iv) of the Act are as follows:

- (i) a business plan for two years after a consolidation-type merger (which means the consolidation-type merger prescribed in Article 59 of the Act; the same applies in the following Article) of a medical corporation incorporated in a consolidation-type merger (which means the medical corporation incorporated in a consolidation-type merger prescribed in item (ii) of the relevant Article) or an outline thereof; and
- (ii) the day on which the consolidation-type merger becomes effective.

(Application, Mutatis Mutandis, of Provisions for Absorption-Type Mergers)

Article 35-5 The provisions of Articles 35-2 and 35-3 apply mutatis mutandis to the case where a medical corporation carries out a consolidation-type merger. In this case, the term "Article 58-2, paragraph (4)" in Article 35-2, paragraph (1) is replaced with "Article 58-2, paragraph (4) of the Act, as applied mutatis mutandis pursuant to Article 59-2 following the deemed replacement of terms," and the term "Article 58-2, paragraph (1)" in item (ii) of the relevant paragraph with "Article 58-2, paragraph (1) of the Act, as applied mutatis mutandis pursuant to Article 59-2 following the deemed replacement of terms," and the term "absorption-type merger agreement" in item (iii) of the relevant paragraph with "consolidation-type merger agreement," and the term "medical corporation surviving an absorption-type merger" in item (iv) of the relevant paragraph with "medical corporation incorporated in a consolidation-type merger (which means the medical corporation incorporated in a consolidation-type merger prescribed in Article 59, item (ii) of the Act; the same applies in item (vii) and the following paragraph)," and the term "medical corporation surviving an absorption-type merger and medical corporation disappearing in an absorption-type merger (the medical corporation disappearing in an absorption-type merger as prescribed in Article 58 of the Act" in item (v) of the relevant paragraph with "medical corporation disappearing in a consolidation-type merger (the medical corporation disappearing in a consolidation-type merger prescribed in Article 59, item (i) of the Act," and the term "medical corporation surviving an absorption-type merger and medical corporation disappearing in an absorption-type merger" in item (vi) of the relevant paragraph with "medical corporation disappearing in a consolidation-type merger," and the term "medical corporation surviving an absorption-type merger" in item (vii) of the relevant paragraph and paragraph (2) of the relevant Article with "medical corporation incorporated in a consolidation-type merger," and the term "Article 58-3, paragraph (2)" in Article 35-3 with "Article 58-3, paragraph (2) of the Act, as applied mutatis mutandis pursuant to Article

59-2 following the deemed replacement of terms."

Subsection 2 Splits

Division 1 Absorption-Type Company Splits

(Persons Specified by Order of the Ministry of Health, Labour and Welfare as Referred to in Article 60 of the Act)

Article 35-6 Persons specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 60 of the Act are the following persons:

- (i) a social medical corporation;
- (ii) a specific medical corporation prescribed in Article 67-2, paragraph (1) of the Act on Special Measures concerning Taxation;
- (iii) a medical corporation with provisions for equity interests; and
- (iv) a medical corporation which has obtained authorization for an implementation plan under the provisions of Article 42-3, paragraph (1) of the Act.

(Particulars Specified by Order of the Ministry of Health, Labour and Welfare as Referred to in Article 60-2, Item (iii) of the Act)

Article 35-7 Particulars specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 60-2, item (iii) of the Act are as follows:

- (i) a business plan for two years after the absorption-type company split (which means the absorption-type company split prescribed in Article 60 of the Act; hereinafter the same applies in this Subsection) of a medical corporation splitting in an absorption-type split (which means the medical corporation splitting in an absorption-type split prescribed in Article 60-2, item (i) of the Act; hereinafter the same applies in this Division) and a medical corporation succeeding in an absorption-type split (which means the medical corporation succeeding in an absorption-type split prescribed in Article 60 of the Act; hereinafter the same applies in this Division) or an outline thereof; and
- (ii) the day on which the absorption-type company split becomes effective.

(Application for Authorization for Absorption-Type Company Splits)

Article 35-8 When a medical corporation intends to obtain authorization for an absorption-type company split pursuant to the provisions of Article 60-3, paragraph (4) of the Act, the medical corporation must submit to a prefectural governor an application form with the following documents:

- (i) a statement of reasons;
- (ii) a document certifying that the medical corporation has gone through the procedure referred to in Article 60-3, paragraph (1) or (3) of the Act;
- (iii) a copy of the absorption-type company split agreement;

- (iv) the articles of incorporation or articles of endowment of the medical corporation splitting in an absorption-type split and the medical corporation succeeding in an absorption-type split after the absorption-type company split;
- (v) the articles of incorporation or articles of endowment of the medical corporation splitting in an absorption-type split and the medical corporation succeeding in an absorption-type split before the absorption-type company split;
- (vi) the inventories of assets and balance sheets of the medical corporation splitting in an absorption-type split and the medical corporation succeeding in an absorption-type split before the absorption-type company split; and
- (vii) the documents set forth in Article 31, items (vii), (x) and (xi) regarding the medical corporation splitting in an absorption-type split and the medical corporation succeeding in an absorption-type split (in this case, the term "after establishment" in item (vii) of the relevant Article is deemed to be replaced with "after an absorption-type company split," and the term "officers" in item (x) with "officers who newly assume office").

(Method of Inspecting Inventories of Assets and Balance Sheets)

Article 35-9 Documents under the provisions of Article 60-4, paragraphs (2) of the Act is inspected in writing or by means of displaying the particulars recorded in the file of an electronic or magnetic record or a magnetic disk or the like on the surface of paper or on the screen of an input-output unit installed at the office.

Division 2 Incorporation-type Company Splits

(Particulars Specified by Order of the Ministry of Health, Labour and Welfare as Referred to in Article 61-2, Item (iv) of the Act)

Article 35-10 Particulars specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 61-2, item (iv) of the Act are as follows:

- (i) business plans for two years after an incorporation-type company split (which means the incorporation-type company split prescribed in Article 61, paragraph (1) of the Act; the same applies in the following Article) of a medical corporation splitting in an incorporation-type split (which means the medical corporation splitting in an incorporation-type split prescribed in Article 61-2, item (iii) of the Act) and a medical corporation incorporated in an incorporation-type split (which means the medical corporation incorporated in an incorporation-type split prescribed in item (i) of the relevant Article) or outlines thereof; and
- (ii) the day on which the incorporation-type company split becomes effective.

(Application, Mutatis Mutandis, of Provisions for Absorption-Type Company Splits)

Article 35-11 The provisions of Articles 35-8 and 35-9 apply mutatis mutandis to the case where a medical corporation carries out an incorporation-type company split. In this case, the term "Article 60-3, paragraph (4)" in Article 35-8 is replaced with "Article 60-3, paragraph (4) of the Act, as applied mutatis mutandis pursuant to Article 61-3 following the replacement of terms," and the term "Article 60-3, paragraph (1)" in item (ii) of the relevant Article with "Article 60-3, paragraph (1) of the Act, as applied mutatis mutandis pursuant to Article 61-3 following the deemed replacement of terms," and the term "absorption-type company split agreement" in item (iii) of the relevant Article with "incorporation-type company split plan," and in item (iv) of the relevant Article, the term "medical corporation splitting in an absorption-type split" with "medical corporation splitting in an incorporation-type split (which means the medical corporation splitting in an incorporation-type split prescribed in Article 61-2, item (iii) of the Act; the same applies in the following item through item (vii))," and the term "medical corporation succeeding in an absorption-type split" with "medical corporation incorporated in an incorporation-type split (which means the medical corporation incorporated in an incorporation-type split prescribed in item (i) of the relevant Article; the same applies in item (vii))," and the term "medical corporation splitting in an absorption-type split and medical corporation succeeding in an absorption-type split" in items (v) and (vi) of the relevant Article with "medical corporation splitting in an incorporation-type split," and in item (vii) of the relevant Article, the term "medical corporation splitting in an absorption-type split" with "medical corporation splitting in an incorporation-type split," and the term "medical corporation succeeding in an absorption-type split" with "medical corporation incorporated in an incorporation-type split," and the term "Article 60-4, paragraph (2)" in Article 35-9 with "Article 60-4, paragraph (2) of the Act, as applied mutatis mutandis pursuant to Article 61-3 following the deemed replacement of terms."

Section 9 Miscellaneous Provisions

(Attachment of Duplicate Copies)

Article 36 To application forms prescribed in Article 5-15 of the Order and Article 31, Article 33-25, paragraph (1), Article 34, Article 35-2, paragraph (1) (including as applied mutatis mutandis pursuant to Article 35-5 following the deemed replacement of terms), Article 35-8 (including as applied mutatis mutandis pursuant to the preceding Article), Article 39-23, Article 39-24,

paragraph (1) and Article 39-27 and documents attached thereto as well as application forms prescribed in Articles 31-5 through 31-5-3, a duplicate copy thereof must be attached.

Article 37 Deleted.

(Particulars to Be Stated in Medical Corporation Registers)

Article 38 (1) Information that must be stated in the medical corporation register referred to in Article 5-11, paragraph (1) of the Order is as follows:

- (i) the name;
 - (ii) the location of the office;
 - (iii) the name of the president;
 - (iv) the names and locations of hospitals, clinics, long-term care health facilities or long-term care homes to establish;
 - (v) when the medical corporation carries out the operations set forth in the items of Article 42 of the Act, those operations;
 - (vi) the date of authorization for establishment and the date of registration of establishment;
 - (vii) assets at the time of authorization for establishment;
 - (viii) particulars concerning officers;
 - (ix) when the medical corporation carries out the profit-making operations referred to in Article 42-2, paragraph (1) of the Act, those operations; and
 - (x) other necessary particulars.
- (2) When any of the particulars stated in the items of the preceding paragraph has been changed, the prefectural governor must correct it without delay.

(Documents to be Preserved by Prefectural Governors)

Article 39 Documents specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 5-14 of the Order are documents submitted pursuant to the provisions of the Act and this Chapter (except for those reported pursuant to the provisions of Article 52, paragraph (1) of the Act).

Chapter VI Regional Medical Coordination Promoting Corporations

(Members of Regional Medical Coordination Promoting Corporations)

Article 39-2 Persons specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 70, paragraph (1) and Article 70-3, paragraph (1), item (vii) of the Act are the following persons whose purpose is not to make profit:

- (i) an individual who establishes a hospital, clinic, long-term care health facility, or long-term care home (hereinafter referred to as "hospital, etc." in

- this Chapter) in a medical coordination promotion zone;
- (ii) an individual who establishes or manages a facility or place of business pertaining to the nursing care business, etc. prescribed in Article 70, paragraph (1), item (ii) of the Act (hereinafter simply referred to as "nursing care business, etc." in this Chapter) in a medical coordination promotion zone;
 - (iii) a corporation prescribed in any of the items of Article 70, paragraph (1) of the Act which does not wish to become a participating corporation;
 - (iv) a person who establishes an organization relating to the training of medical workers, such as a university, in a medical coordination promotion zone; and
 - (v) a person who carries out operations relating to the medical coordination promotion operations prescribed in Article 70, paragraph (1) of the Act (hereinafter simply referred to as "medical coordination promotion operations") which are carried out by a local public entity or other general incorporated association which carries out operations relating to medical care, in a medical coordination promotion zone.

(Support to Raise Funds)

Article 39-3 (1) Support specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 70, paragraph (2), item (iii) of the Act is the following:

- (i) a loan of a fund;
 - (ii) a guarantee for a debt; and
 - (iii) solicitation of persons to accept a fund under the provisions of Article 131 of the Act on General Incorporated Associations and General Incorporated Foundations (Act No. 48 of 2006).
- (2) When a regional medical coordination promoting corporation gives the support prescribed in items (i) or (ii) of the preceding paragraph, the corporation is to go through a resolution of the council of that regional medical coordination promoting corporation and must hear opinions in advance from the councillor board on regional medical coordination promotion which is established in the regional medical coordination promoting corporation.

(Form Pertaining to Application for Authorization for Medical Coordination Promotion)

Article 39-4 An application for authorization for medical coordination promotion as prescribed in Article 70-2, paragraph (1) of the Act is made in the appended form 1-4.

(Attached Documents Pertaining to Application for Authorization for Medical

Coordination Promotion)

Article 39-5 Documents specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 5-15 of the Order are the following documents:

- (i) a certificate of the registered information of the general incorporated association;
- (ii) a document stating the names, dates of birth, and addresses of the directors and auditors of the general incorporated association;
- (iii) a document certifying that the general incorporated association conforms to the standards set forth in the items of Article 70-3, paragraph (1) of the Act;
- (iv) a document certifying that the directors and auditors of the general incorporated association do not fall under any of Article 70-4, item (i), (a) through (d) of the Act;
- (v) a document certifying that the general incorporated association does not fall under either of Article 70-4, items (ii) and (iii) of the Act; and
- (vi) beyond what is set forth in the preceding items, documents which the prefectural governor finds necessary for authorization for medical coordination promotion.

(Corporations Whose Business Activities are Controlled by a Corporation)

Article 39-6 (1) A corporation specified by Order of the Ministry of Health, Labour and Welfare as a corporation whose business activities are controlled by a corporation as prescribed in Article 5-15-2, item (vi) of the Order is, a case where a person set forth in item (ii) of the relevant Article who is a corporation controls decisions on the finance and operation or business policy of other corporation, that other corporation (referred to as "subsidiary corporation" in paragraph (3)).

- (2) A person specified by Order of the Ministry of Health, Labour and Welfare as a person who controls the business activities of a corporation as prescribed in Article 5-15-2, item (vi) of the Order is, a case where a single person controls decisions on the finance and the operation or business policy of that corporation, that single person.
- (3) The case of controlling decisions on the finance and the operation or business policy as prescribed in the preceding two paragraphs means a case where a single person or one or two or more of its subsidiary corporations have the majority of voting rights in a body which decides the finance and the operation or business policy of an organization, such as the general meeting of members.

(Composition of Participating Corporations)

Article 39-7 A necessary condition specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 70-3, paragraph (1), item (viii) of

the Act is that it falls under all the following items:

- (i) the number of participating corporations which establish a hospital, etc. is two or more; and
- (ii) the total of voting rights which the participating corporations establishing a hospital, etc. is to exceed the total of voting rights which the participating corporations establishing or managing a facility or place of business pertaining to nursing care business, etc.

(Persons Who Are Liable to Have an Unjust Influence on Resolutions of General Meeting of Members)

Article 39-8 Persons specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 70-3, paragraph (1), item (xii) of the Act are the following persons:

- (i) an officer or employee of an organization whose purpose is to make profit and which has an interest in the general incorporated association, or a spouse or a relative within the third degree of kinship of that officer;
- (ii) an individual who conducts business for profit and has an interest in the general incorporated association, or the spouse or a relative within the third degree of kinship of that individual;
- (iii) an officer or employee of an organization whose purpose is to make profit and which has an intent in the participating corporation of the general incorporated association;
- (iv) an individual who conducts business for profit and has an intent in the participating corporation of the general incorporated association; and
- (v) a person similar to those set forth in the preceding items.

(Persons Who Have a Special Relationship with an Officer of a Regional Medical Coordination Promoting Corporation)

Article 39-9 Persons who have a special relationship specified by Order of the Ministry of Health, Labour and Welfare with an officer as prescribed in Article 70-3, paragraph (1), item (xiii), (b) of the Act are the following persons:

- (i) a person in a relationship with an officer where a marital relationship is de facto, though a marriage has not been registered;
- (ii) a person who is an employee of an officer and other person than that employee and earns a living by property, such as money, which is received from that officer; and
- (iii) a relative of any of the persons set forth in the preceding two items who depends on that person for their living.

(Director Necessary for the Effective Carrying Out of Medical Coordination Promotion Operations)

Article 39-10 A person specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 70-3, paragraph (1), item (xiii), (c) of the Act is a representative of a related body, such as a body of persons with relevant expertise in medical care, or a person with relevant expertise in medical care.

(Particulars About Which Opinions Have to Be Asked from Regional Medical Coordination Promoting Corporations)

Article 39-11 Grounds specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 70-3, paragraph (1), item (xvii), (g) of the Act is the inability to succeed in the intended business.

(Persons Who May Be a Person to Whom Residual Assets Are to Belong)

Article 39-12 Persons specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 70-3, paragraph (1), item (xviii) of the Act are the persons set forth in the items of Article 31-2.

(Method of Public Notice)

Article 39-13 A public notice under the provisions of Article 70-6 and Article 70-21, paragraph (4) of the Act is given by an appropriate method such as the use of the Internet.

(Necessary Condition in Case Where a Contribution May Be Given)

Article 39-14 A necessary condition specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 70-8, paragraph (2), item (iii) of the Act is that a regional medical coordination promoting corporation have all the voting rights of an enterprise which receives a contribution from that regional medical coordination promoting corporation.

(Facility or Place of Business Which Has to Be Verified by an Authorized Prefectural Governor at Establishment)

Article 39-15 A facility or place of business specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 70-8, paragraph (3) and Article 70-17, item (vi) of the Act is a facility or place of business pertaining to the type 1 social welfare service prescribed in Article 2, paragraph (2) of the Social Welfare Act (hereinafter simply referred to as "type 1 social welfare service").

(Application Made by a Regional Medical Coordination Promoting Corporation Which Has Not Been Verified by an Authorized Prefectural Governor)

Article 39-16 (1) Facilities specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 70-8, paragraph (4) of the Act are,

facilities pertaining to nursing care business, etc., those which conduct the type 1 social welfare service.

- (2) An application specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 70-8, paragraph (4) of the Act is an application for permission to establish a hospital, etc. or application for the permission under the provisions of Article 62, paragraph (2) of the Social Welfare Act (limited to that pertaining to the establishment of the facility prescribed in the preceding paragraph).

(Legitimate Grounds for Use or Disposition of Assets Acquired for Purpose of Medical Coordination Promotion)

Article 39-17 Cases where there are legitimate grounds as specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 18 of the Act on Authorization of Public Interest Incorporated Associations and Public Interest Incorporated Foundations (Act No. 49 of 2006; hereinafter referred to as "Public Interest Authorization Act"), as applied mutatis mutandis pursuant to Article 70-9 of the Act following the deemed replacement of terms, are the following cases:

- (i) a case where assets are lost or damaged despite the due care of a prudent manager;
- (ii) a case where assets have fallen in value for such reasons as obsolescence or non-adaptation, and it is appropriate to destroy those assets; and
- (iii) a case where the regional medical coordination promoting corporation is a corporation which has obtained the authorization under the provisions of Article 4 of the Public Interest Authorization Act.

(Rate by Which Profit from Operations Other than Medical Coordination Promotion Operations Is Multiplied)

Article 39-18 A rate specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 18, item (iv) of the Public Interest Authorization Act, as applied mutatis mutandis pursuant to Article 70-9 of the Act following the deemed replacement of terms, is fifty-hundredths.

(Method of Showing That It Is Provided for Use in Medical Coordination Promotion Operations)

Article 39-19 (1) A method specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 18, item (vii) of the Public Interest Authorization Act, as applied mutatis mutandis pursuant to Article 70-9 of the Act following the deemed replacement of terms, is a method of showing the accounting title of assets separately from that of other assets in an inventory of assets and a balance sheet or an annexed detailed statement thereof.

- (2) Other assets than those held to continue to be provided for use in medical coordination promotion operations may not be shown by the method referred to in the preceding paragraph.

(Assets Which are Found to Have Been Acquired by Carrying Out Medical Coordination Promotion Operations or to Be Held to Carry Out Medical Coordination Promotion Operations)

Article 39-20 Assets specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 18, item (viii) of the Public Interest Authorization Act, as applied mutatis mutandis pursuant to Article 70-9 of the Act following the deemed replacement of terms, are the following assets:

- (i) assets equivalent to, of expenses collected on and after the date on which authorization for medical coordination promotion has been obtained (which mean the expenses prescribed in Article 27 of the Act on General Incorporated Associations and General Incorporated Foundations and except for those which are substantially found to be the proceeds or the like from business, such as considerations), an amount obtained by multiplying the amount of those whose use has not been decided in collecting them by fifty-hundredths or the amount of the expenses whose use is decided for medical coordination promotion operations in collecting them;
- (ii) assets equivalent to the amount of profit accruing from assets held for the purpose of medical coordination promotion (which mean the assets set forth in Article 18, item (vii) of the Public Interest Authorization Act, as applied mutatis mutandis pursuant to items (v) and (vi) as well as Article 70-9 of the Act; the same applies hereinafter) on and after the date on which authorization for medical coordination promotion has been obtained;
- (iii) assets equivalent to a sum gained by disposing of assets held for the purpose of medical coordination promotion;
- (iv) assets equivalent to the amount of assets held for the purpose of medical coordination promotion which have been changed to other assets than assets held for purpose of medical coordination promotion;
- (v) assets acquired by spending the assets set forth in the preceding items;
- (vi) assets which are acquired by spending assets other than those set forth in items (i) through (iv) and Article 18, items (i) through (iv) of the Public Interest Authorization Act, as applied mutatis mutandis pursuant to Article 70-9 of the Act following the deemed replacement of terms, on and after the date on which authorization for medical coordination promotion has been obtained and shown pursuant to the provisions of paragraph (1) of the preceding Article on and after the relevant date; and
- (vii) beyond those set forth in Article 18, items (i) through (iv) of the Public Interest Authorization Act, as applied mutatis mutandis pursuant to Article

70-9 of the Act following the deemed replacement of terms, items (vii) and (viii) as well as Article 18, items (v) and (vi) of the Public Interest Authorization Act, as applied mutatis mutandis pursuant to Article 70-9 of the Act, and the preceding items, assets equivalent to the amount at which it is provided that the regional medical coordination promoting corporation is to use or dispose of assets for medical coordination promotion operations, in the articles of incorporation or the general meeting of members of the regional medical coordination promoting corporation.

(Assets of Regional Medical Coordination Promoting Corporations)

Article 39-21 A regional medical coordination promoting corporation must have facilities, equipment or funds needed to carry out medical coordination promotion operations.

(Application, Mutatis Mutandis, of Provisions for Account of Medical Corporations)

Article 39-22 The provisions of Section 4 of the preceding Chapter (except for Article 32-5, Article 32-6, item (ii), (b), Article 33, paragraph (1), items (i) and (ii) and paragraph (2), Article 33-2, Article 33-2-7, paragraph (2), and Article 33-2-8) apply mutatis mutandis to account of regional medical coordination promoting corporations. In this case, the terms set forth in the middle columns of the table below in the clauses set forth in the left columns of the relevant table are replaced with the terms set forth respectively in the right columns of the table.

(Application for Authorization for Dissolution)

Article 39-23 When a medical corporation intends to obtain authorization for dissolution pursuant to the provisions of Article 55, paragraph (6) of the Act, as applies mutatis mutandis pursuant to Article 70-15 of the Act following the deemed replacement of terms, the medical corporation must submit to an authorized prefectural governor an application form with the following documents:

- (i) a statement of reasons;
- (ii) a document certifying that the medical corporation has gone through the procedure for dissolution as specified in the Act or the articles of incorporation;
- (iii) the inventory of assets and balance sheet; and
- (iv) a document stating particulars concerning the disposition of residual assets.

(Authorization for Amendment to Articles of Incorporation)

Article 39-24 (1) When a medical corporation intends to obtain authorization for amendment to its articles of incorporation pursuant to the provisions of Article 54-9, paragraph (3) of the Act, as applies mutatis mutandis pursuant to Article 70-18, paragraph (1) of the Act following the deemed replacement of terms, the medical corporation must submit to an authorized prefectural governor an application form with the following documents:

- (i) a document stating the details of amendment to the articles of incorporation (a comparative table of old provisions and amended ones are attached to it) and the grounds therefor; and
 - (ii) a document certifying that it has gone through the procedure for amendment as specified in the articles of incorporation.
- (2) When amendment to the articles of incorporation pertains to the case where the regional medical coordination promoting corporation intends to newly establish a hospital, etc., beyond the documents referred to in the items of the preceding paragraph, the regional medical coordination promoting corporation must attach to the application form referred to in the preceding paragraph a document stating the clinical departments of that hospital, etc., the fixed number of its employees, and an outline of its premises and building structure and equipment and a document stating the name of a person to be the manager of the hospital, etc. as well as a business plan for two years after amendment to the articles of incorporation and a budget document incidental thereto.
- (3) When amendment to the articles of incorporation pertains to the case where the regional medical coordination promoting corporation intends to newly establish a facility pertaining to the type 1 social welfare service, beyond the documents referred to in the items of paragraph (1), the regional medical coordination promoting corporation must attach to the application form referred to in paragraph (1) a document stating the fixed number of its employees and an outline of its premises and building structure and equipment and a document stating the name of a person to be the manager of the facility as well as a business plan for two years after amendment to the articles of incorporation and a budget document incidental thereto.

Article 39-25 Particulars specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 54-9, paragraph (3) of the Act, as applied mutatis mutandis pursuant to Article 70-18, paragraph (1) of the Act following the deemed replacement of terms, are particulars concerning the location of the principal office and particulars concerning a method of public notice.

(Important Particulars)

Article 39-26 Important particulars specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 70-18, paragraph (2) of the Act are

those pertaining to the particulars set forth in Article 70-17, item (vi) of the Act.

(Application for Authorization for Appointment of a Representative Director)

Article 39-27 (1) When a medical corporation intends to obtain authorization for the appointment of a representative director pursuant to the provisions of Article 70-19, paragraph (1) of the Act, the medical corporation must submit to an authorized prefectural governor an application form stating the following particulars, with a curriculum vitae of a person to be that representative director:

- (i) the address and name of a person to be the representative director; and
- (ii) the reason for appointment.

(2) When a medical corporation intends to obtain authorization for removal of the representative director pursuant to the provisions of Article 70-19, paragraph (1) of the Act, the medical corporation must submit to an authorized prefectural governor an application form stating the following particulars:

- (i) the address and name of that representative director; and
- (ii) the reasons for removal.

(Taxes and Other Public Charges Decided After Rescission of Authorization for Medical Coordination Promotion)

Article 39-28 Assets specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 30, paragraph (2), item (iii) of the Public Interest Authorization Act, as applied mutatis mutandis pursuant to Article 70-22 of the Act following the deemed replacement of terms, are taxes and other public charges which the regional medical coordination promoting corporation has to bear in connection with carrying out of medical coordination promotion operations on and after the day on which it has obtained authorization for medical coordination promotion and are decided on and after the date of the rescission of authorization for medical coordination promotion as referred to in Article 30, paragraph (1) of the Public Interest Authorization Act, as applied mutatis mutandis pursuant to Article 70-22 of the Act following the deemed replacement of terms.

(Balance of Assets Acquired for the Purpose of Medical Coordination Promotion in Case of Rescission of Authorization for Medical Coordination Promotion)

Article 39-29 The balance of assets acquired for the purpose of medical coordination promotion as referred to in Article 30, paragraph (2) of the Public Interest Authorization Act, as applied mutatis mutandis pursuant to Article 70-22 of the Act following the deemed replacement of terms, in the case where an authorized prefectural governor makes a rescission of authorization for

medical coordination promotion under the provisions of Article 70-21, paragraphs (1) or (2) of the Act is the amount entered in, of the inventories of assets as prescribed in Article 51, paragraph (1) of the Act, as applied mutatis mutandis pursuant to Article 70-14 of the Act following the deemed replacement of terms, which have been reported pursuant to the provisions of Article 52, paragraph (1) of the Act, as applied mutatis mutandis pursuant to Article 70-14 of the Act following the deemed replacement of terms (hereinafter simply referred to as "inventories of assets" in this Article), the inventory of assets of the business year prior to the business year including the day of that rescission of authorization for medical coordination promotion (if that amount is below zero, zero).

(Special Provisions for Case Where a Medical Coordination Promoting Corporation Has Obtained Public Interest Authorization)

Article 39-30 (1) When a regional medical coordination promoting corporation is a corporation which has obtained the authorization under the provisions of Article 4 of the Public Interest Authorization Act, the provisions of Article 70-3, paragraph (1), items (xviii) and (xix) of the Act do not apply to the regional medical coordination promoting corporation.

(2) When a regional medical coordination promoting corporation is a corporation which has obtained the authorization under the provisions of Article 4 of the Public Interest Authorization Act, if that regional medical coordination promoting corporation is punished by rescission of authorization for medical coordination promotion under the provisions of Article 70-21, paragraphs (1) or (2) of the Act, the provisions of paragraphs (5) through (7) of the relevant Article and Article 70-22 of the Act do not apply to the regional medical coordination promoting corporation.

Chapter VII Miscellaneous Provisions

Article 40 An identification card of the employee pursuant to the provisions of Article 6-8, paragraph (3) of the Act is in accordance with the appended form 2.

Article 40-2 An identification card of the employee pursuant to the provisions of Article 6-8, paragraph (3) of the Act, as applied mutatis mutandis pursuant to Article 25, paragraph (5) of the Act, is in accordance with the appended form 3.

Article 41 A medical care inspector appointed by the Minister of Health, Labour and Welfare pursuant to the provisions of Article 26 of the Act must be a person who has good knowledge of laws and regulations on medical care as well as management of hospitals, clinics, and birthing centers.

Article 42 When a medical care inspector conducts an on-site inspection, the inspector is to provide guidance on necessary matters concerning the improvement, management and other particulars of the structure and equipment of the hospital, clinic, or birthing center.

Article 42-2 An identification card of the employee pursuant to the provisions of Article 6-8, paragraph (3) of the Act, as applied mutatis mutandis pursuant to Article 63, paragraph (2) of the Act, is in accordance with the appended form 4.

Article 42-3 An identification card of the employee pursuant to the provisions of Article 6-8, paragraph (3) of the Act, as applied mutatis mutandis pursuant to Article 70-20 of the Act following the deemed replacement of terms, is in accordance with the appended form 5.

Article 43 (1) A hospital, clinic or birthing center established by the State to which it is difficult to apply the provisions of Article 16 or 17 due to special circumstances is pursuant to the separate provisions.

(2) In applying this Ministerial Order to hospitals, clinics or birthing centers established by the State, the term "establisher" in Article 23 is replaced with "manager."

Article 43-2 Regarding hospitals attached to a university which offers a course on medicine (except for advanced treatment hospitals and hospitals which have only psychiatric hospital beds) or hospitals which have facilities to hospitalize 100 or more patients and whose clinical department names include internal medicine, surgery, obstetrics and gynecology, ophthalmology, and otolaryngology (except for the case where a clinical department name is a combined name of those clinical department names pursuant to the provisions of Article 3-2, paragraph (1), item (i), (c) or (d), (2) of the Order) (except for advanced treatment hospitals) and have psychiatric hospital beds, the term "2.7 meters" in Article 16, paragraph (1), item (xi), (a) is replaced with "2.1 meters," and the term "psychiatric hospital beds and long-term care beds" in Article 19, paragraph (1), item (i) and paragraph (2), item (i) with "long-term care beds," and in paragraph (2), item (ii) of the relevant Article, the term "psychiatric hospital beds and tuberculosis hospital beds" with "tuberculosis hospital beds," and the term "infectious disease hospital beds and general beds" with "tuberculosis hospital beds and other sickbeds than long-term care beds."

(Special Provisions for Large Cities)

Article 43-3 In the case where a designated city referred to in Article 252-19, paragraph (1) of the Local Autonomy Act (Act No. 67 of 1947) conducts affairs relating to medical care pursuant to the provisions of Article 5-23 of the Order, the term "prefectural governor" in Article 1-14, paragraph (1), paragraphs (3) through (6) and paragraphs (8) through (11), Article 3, paragraph (1), Articles 7 through 9, Article 9-15-2, Article 23, Article 48-2, Article 50, Article 51-2, Article 52-2, Article 53-2, Article 54-2, and Article 55-2 is deemed to be replaced with "mayor of the designated city," and the term "prefecture" in Article 19, paragraphs (2) and (3), Article 21, Article 21-2, paragraphs (2) and (3), Article 21-4, Article 52-2, paragraph (2), Article 53-2, paragraph (2), Article 54-2, paragraph (2), and Article 55-2, paragraph (2) with "designated city," and in Article 22-4-2, the term "of a prefecture" with "of a designated city," and the term "prefectural governor" with "mayor of a designated city," and the term "a prefecture" in Article 52, as applied pursuant to the provisions of Article 52-2, paragraph (1) following the deemed replacement of terms, Article 53, as applied pursuant to the provisions of Article 53-2, paragraph (1) following the deemed replacement of terms, Article 54, as applied pursuant to the provisions of Article 54-2, paragraph (1) following the deemed replacement of terms, and Article 55, as applied pursuant to the provisions of Article 55-2, paragraph (1) following the deemed replacement of terms, with "a designated city."

(Delegation of Authority)

Article 43-4 (1) The following authority of the Minister of Health, Labour and Welfare is delegated to the chief of the Regional Bureau of Health and Welfare pursuant to the provisions of Article 75, paragraph (1) of the Act and Article 5-24, paragraph (1) of the Order; provided, however, that this does not preclude the Minister of Health, Labour and Welfare from exercising the authority set forth in items (ii) through (iv) for themselves:

- (i) the authority prescribed in Article 12-3 of the Act;
- (ii) the authority prescribed in Article 25, paragraphs (3) and (4) of the Act;
- (iii) the authority prescribed in Article 26, paragraph (1) of the Act; and
- (iv) the authority prescribed in Article 74, paragraph (1) of the Act.

(2) Of the authority set forth in items (i) through (iii) of the preceding paragraph, that pertaining to the jurisdictional district of a branch of Regional Bureau of Health and Welfare is delegated to the chief of the branch of the Regional Bureau of Health and Welfare pursuant to the provisions of Article 75, paragraph (2) of the Act and Article 5-24, paragraph (2) of the Order.