

# Act on Medical Care for Patients with Intractable Diseases

(Act No. 50 of May 30, 2014)

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## Chapter I General Provisions

(Purpose)

Article 1 The purpose of this Act is to provide for necessary matters concerning medical care for patients with intractable diseases (meaning rare diseases of which the pathogenic mechanism is not clear and the treatment methods are not established and which require long-term medical treatment having contracted the disease; the same applies hereinafter) and other measures for intractable diseases (hereinafter referred to as "medical care, etc. for patients with intractable diseases") in order to promote securing high-quality and appropriate medical care for patients with intractable diseases and maintaining and improving the quality of life of patients with intractable diseases undergoing treatment, and thereby improving public health.

(Basic Principles)

Article 2 Medical care, etc. for patients with intractable diseases must be conducted comprehensively with due regard to maintaining seamless coordination in connection with social welfare and other related measures according to the nature of intractable diseases with making it a principle goal that patients with intractable diseases are secured opportunities for their participation in society and are not prevented from co-existing with other

people while maintaining personal dignity with the aim of overcoming intractable diseases.

(Responsibilities of National and Local Governments)

Article 3 (1) The national and local governments must endeavor to implement necessary measures in their mutual coordination in order to collect, organize and provide information on intractable diseases, and disseminate correct knowledge on intractable diseases through educational, publicity-related and other similar activities.

(2) The national government and prefectures must endeavor to educate personnel engaged in medical care for patients with intractable diseases and improve their professional qualifications, while endeavoring to implement necessary measures in their mutual coordination to enable patients with intractable diseases to receive high-quality and appropriate medical care.

(3) The national government must endeavor to establish systems to promote surveys and research on intractable diseases and research and development of medicine and medical equipment for medical care for patients with intractable diseases, and to ensure international coordination, while endeavoring to offer necessary technical and financial assistance to local governments to encourage them to adequately fulfill the responsibilities referred to in the preceding two paragraphs.

## **Chapter II Basic Policy**

Article 4 (1) The Minister of Health, Labour and Welfare must formulate the basic policy for comprehensively promoting medical care for patients with intractable diseases (hereinafter referred to as "basic policy").

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

- (i) basic direction to promote medical care, etc. for patients with intractable diseases;
- (ii) particulars concerning the securing of systems to provide medical care for patients with intractable diseases;
- (iii) particulars concerning the fostering of human resources for medical care for patients with intractable diseases;
- (iv) particulars concerning surveys and research on intractable diseases;
- (v) particulars concerning the promotion of research and development of medicines and medical equipment for the medical care for patients with intractable diseases;
- (vi) particulars concerning the improvement of the environment in which patients with intractable diseases undergoing treatment live;
- (vii) particulars concerning the coordination among medical care, etc. for

- patients with intractable diseases and measures concerning welfare services, measures concerning support for employment and other relevant measures for patients with intractable diseases;
- (viii) other important particulars concerning the promotion of medical care, etc. for patients with intractable diseases.
- (3) The Minister of Health, Labour and Welfare is to review the basic policy at least once every five years and revise the basic policy if it is deemed necessary.
- (4) When the Minister of Health, Labour and Welfare intends to formulate or revise the basic policy, the Minister of Health, Labour and Welfare must consult with the head of the relevant administrative organ and hear opinions of the Health Sciences Council in advance.
- (5) When the Minister of Health, Labour and Welfare has formulated or revised the basic policy, the Minister of Health, Labour and Welfare must make it public without delay.
- (6) If it is deemed necessary for the formulation of the basic policy, the Minister of Health, Labour and Welfare may request to provide materials and other necessary cooperation from medical institutions and other persons concerned.

### **Chapter III Medical Care**

#### **Section 1 Payment of Specific Medical Expenses**

(Payments of Specific Medical Expenses)

Article 5 (1) If a patient with a designated intractable disease (meaning an intractable disease with which the number of the patients have not reached the number of people provided by Order of the Ministry of Health, Labour and Welfare in Japan, of which the certain standards are established by objective indicators with regard to diagnosis of the intractable disease which fulfill other requirements provided by Order of the Ministry of Health, Labour and Welfare, and which is designated by the Minister of Health, Labour and Welfare after hearing opinions of the Health Sciences Council as an intractable disease which has high necessity to ensure high-quality and appropriate medical care for patients with the intractable disease judging from the situation in which the patients is put; the same applies hereinafter) who has been given a grant recipient approval (meaning an approval as a grant recipient provided in Article 7, paragraph (1), the same applies in this and the following Articles), within the effective period of the grant recipient approval (meaning an effective period provided in Article 9, the same applies to Article 7, paragraph (4)), has received specific medical care (meaning medical care which is provided to a patient with a designated intractable disease given a grant recipient approval by a medical institution designated by a prefectural governor (hereinafter referred to as "designated medical institution") and which is

provided by Order of the Ministry of Health, Labour and Welfare; the same applies hereinafter) which is provided by a designated medical institution provided in the provisions of paragraph (3) of the same Article and which pertains to the designated intractable disease pertaining to a grant recipient approval (hereinafter referred to as "designated specific medical care"); a prefecture is to pay specific medical expenses to the patient with a designated intractable disease or the custodian (meaning custodian provided in Article 6 of the Child Welfare Act (Act No. 164 of 1947); the same applies hereinafter) given a grant recipient approval pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare with regard to expenses required for the designated specific medical care.

(2) The amount of specific medical expenses per month, is the amount set forth in item (i) (or the aggregate amount and the amount set forth in item (ii) if the designated specific medical care includes dietary treatment (meaning dietary treatment provided in Article 63, paragraph (2), item (i) of the Health Insurance Act (Act No. 70 of 1922), hereinafter the same applies in this paragraph), or the aggregate of the amount and the amount set forth in item (iii) if the designated specific medical care includes living support (meaning living support provided in paragraph (2) item (ii) of the same Article, hereinafter the same applies in this paragraph)):

(i) the amount obtained by deducting, from the amount calculated in accordance with the method for calculating the amount of expenses incurred for medical treatment of health insurance on designated specific medical care (excluding dietary treatment and living treatment) in the same month, the amount provided in Cabinet Order as considering the financial capacity of the household budget of the patient with a designated intractable disease or the custodian given a grant recipient approval, the status of treatment of the patient with a designated intractable disease given a grant recipient approval, the number of other patients with designated intractable diseases given a grant recipient approval and of children, etc. with specific chronic pediatric diseases provided in Article 6-2, paragraph (2) of the Child Welfare Act pertaining to the a grant recipient approval of medical expenses provided in Article 19-3, paragraph (3) who belong to the same household of the patient with a designated intractable disease or the custodian given a grant recipient approval and other circumstances (or the equivalent amount if the amount provided by Cabinet Order exceeds the amount equivalent to twenty percent of the calculated amount (or ten percent of the calculated amount if the patient with a designated intractable disease given a grant recipient approval is an insured person of the medical care for older senior citizens under Articles 50 and 51 of the Act on Assurance of Medical Care for Elderly People (Act No. 80 of 1982) and falls under the cases set forth in Article 67,

- paragraph (1), item (i) of the same Act and other cases provided by Cabinet Order));
- (ii) the amount obtained by deducting the amount provided by the Minister of Health, Labour and Welfare in consideration of the amount of the standard co-payment for dietary treatment stipulated in Article 85, paragraph (2) of the Health Insurance Act, the income status of a patient with a designated intractable disease or the custodian given a grant recipient approval and other circumstances from the amount calculated in accordance with the method for calculating the amount of expenses incurred for medical treatment of health insurance on the designated specific medical care (limited to dietary treatment);
  - (iii) the amount obtained by deducting the amount provided by the Minister of Health, Labour and Welfare in consideration of the amount of the standard co-payment for living treatment provided in Article 85-2, paragraph (2) of the Health Insurance Act, the income status of a patient with a designated intractable disease or the custodian given a grant recipient approval and other circumstances from the amount calculated in accordance with the method of calculating the amount of expenses incurred for medical treatment of health insurance on the designated specific medical care (limited to living support).
- (3) If it is not possible to calculate an amount in accordance with the method of calculating the amount of expenses incurred for medical treatment provided in the preceding paragraph, or that method is not suitable, the method of calculating the amount of expenses for a specific medical treatment is to be prescribed by the Minister of Health, Labour and Welfare.

(Application)

- Article 6 (1) A patient with a designated intractable disease or the custodian who intends to receive a grant recipient approval, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, must apply to the prefecture where the patient with a designated intractable disease or the custodian resides by attaching a medical certificate (meaning a document provided by Order of the Ministry of Health, Labour and Welfare as a document certifying that a patient with a designated intractable disease has contracted the designated intractable disease and the degree of severity of the medical condition of the disease) issued by a physician designated by a prefectural governor (hereinafter referred to as "designated physician").
- (2) Procedures to designate a designated physician and other necessary matters concerning a designated physician are provided by Order of the Ministry of Health, Labour and Welfare.

(Grant Recipient Approval)

Article 7 (1) If the patient with a designated intractable disease pertaining to the application referred to in paragraph (1) of the preceding Article falls under any of the following items and needs to receive specific medical care, a prefecture is to give a grant recipient approval:

- (i) if the degree of severity of the medical condition of the disease, is of one which the Minister of Health, Labour and Welfare determines after hearing opinions of the Health Sciences Council;
  - (ii) if the patient falls under standards provided by Cabinet Order in consideration of the status of the treatment and other circumstances.
- (2) If the application referred to in paragraph (1) of the preceding Article has been filed and a prefecture has no intention to give a grant recipient approval (excluding the cases provided by Order of the Ministry of Health, Labour and Welfare as cases not to meet formal requirements for application), the prefecture in advance, must request the Designated Intractable Disease Examination Board provided in paragraph (1) of the following Article to examine in not giving the approval for the grant to the patient with a designated intractable disease pertaining to the application.
- (3) If a prefecture has given a grant recipient approval, the prefecture is to determine a designated medical institution among designated medical institutions where the patient with a designated intractable disease given a grant recipient approval, receives specific medical care pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (4) If a prefecture has given a grant recipient approval, the prefecture, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, must issue a medical care recipient certificate which describes the effective period of the grant recipient approval, the names of the designated medical institutions determined pursuant to the provisions of the preceding paragraph and other matters provided by Order of the Ministry of Health, Labour and Welfare (hereinafter referred to as "medical care recipient certificate") to the patient with a designated intractable disease or the custodian given a grant recipient approval (hereinafter referred to as "patient, etc. given a grant recipient approval").
- (5) The approval for a grant recipient approval becomes effective retroactively as of the date of the application.
- (6) A patient, etc. given a grant recipient approval who intends to receive designated specific medical care, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, is to receive designated specific medical care by presenting the medical care recipient certificate to a designated medical institution determined pursuant to the provisions of paragraph (3); provided, however, that in the case of an emergency or any

other unavoidable circumstances, presenting the medical care recipient certificate is not required.

- (7) If a patient with a designated intractable disease given a grant recipient approval has received designated specific medical care from a designated medical institution determined pursuant to the provisions of paragraph (3) (limited to a case where the patient, etc. given grant recipient approval presents the medical care recipient certificate to the designated medical institution), the prefecture, on behalf of the patient, etc. given grant approval, may pay the designated medical institution, expenses incurred for the designated specific medical care payable by the patient, etc. given grant recipient approval to the designated medical institution within the extent of the amount payable to the patient, etc. given grant recipient approval as specific medical expenses.
- (8) If a payment has been made pursuant to the provisions of the preceding paragraph, the patient, etc. given grant recipient approval is deemed to have received specific medical expenses.

(Designated Intractable Disease Examination Board)

- Article 8 (1) A prefecture is to establish a Designated Intractable Disease Examination Board in order to have the Board conduct the examination under paragraph (2) of the preceding Article.
- (2) Members of the Designated Intractable Disease Examination Board are appointed by the prefectural governor from among persons with relevant knowledge and experience in designated intractable diseases (limited to designated physicians).
- (3) The term of office of a member is two years.
- (4) Beyond what is provided for in this Act, necessary matters concerning the Designated Intractable Disease Examination Board are provided by Order of the Ministry of Health, Labour and Welfare.

(Effective Period of a Grant Recipient Approval)

- Article 9 A grant recipient approval is effective only within the period provided by Order of the Ministry of Health, Labour and Welfare (hereinafter referred to as "effective period of a grant recipient approval" in this section).

(Change of a Grant Recipient Approval)

- Article 10 (1) If a patient, etc. given an grant recipient approval needs to change the designated medical institution determined pursuant to Article 7, paragraph (3) pertaining to the grant recipient approval which the patient, etc. given a grant recipient approval has already been given or other matters provided by Order of the Ministry of Health, Labour and Welfare, the patient, etc. given

grant recipient approval may apply to the prefecture for change on the a grant recipient approval pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

- (2) If a prefecture finds it necessary to change matters provided by Order of the Ministry of Health, Labour and Welfare referred to in the same paragraph with regard to a patient, etc. given a grant recipient approval, the prefecture may, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, approve the change of a grant recipient approval upon receiving an application referred to in the preceding paragraph or authority. In this case, the prefecture is to request that the patient, etc. given a grant recipient approval submit the medical care recipient certificate.
- (3) If a prefecture has approved the change of a grant recipient approval referred to in the preceding paragraph, the prefecture is to describe the matters pertaining to the approval of the change on the medical care recipient certificate and return it to the patient.

(Rescission of an Approval for a Grant Recipient Approval)

Article 11 (1) A prefecture that has given a grant recipient approval may rescind a grant recipient approval in the following cases:

- (i) if a patient given a grant recipient approval fails to qualify under either of the items of Article 7, paragraph (1);
  - (ii) if a patient, etc. given a grant recipient approval is deemed to have their place of residence in a prefecture other than the prefecture during the effective period of the grant recipient approval;
  - (iii) if a patient, etc. given a grant recipient approval does not comply with an order under Article 35, paragraph (1) or Article 36, paragraph (1) without reasonable grounds;
  - (iv) in other cases provided by Cabinet Order.
- (2) The prefecture that has rescinded a grant recipient approval pursuant to the provisions of the preceding paragraph is to ask the patient, etc. given a grant recipient approval pertaining to the rescission to return the medical care recipient certificate pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Adjustment of Benefits Provided by Other Laws and Regulations)

Article 12 Payment of specific medical expenses is not to be made for medical care of a patient with a designated intractable disease to the extent provided by Cabinet Order if the patient is eligible for benefits equivalent to payment of specific medical expenses among benefits provided by Cabinet Order which are benefits for medical treatment under the Health Insurance Act or any other benefits based on Laws and Regulations or to the extent covered by the



benefits granted if benefits have been provided which are other than the benefits provided by Cabinet Order and which are equivalent to payment of specific medical expenses at the expense of the national or local governments.

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

Article 13 Beyond what is provided for in this section, necessary matters concerning payment of specific medical expenses are provided by Order of the Ministry of Health, Labour and Welfare.

## **Section 2 Designated Medical Institutions**

(Designation of a Designated Medical Institution)

Article 14 (1) A designation of a designated medical institution under Article 5, paragraph (1) (hereinafter referred to as "designation of a designated medical institution" in this Section) is made by an application from the establisher, who opened a hospital, clinic (including other institutions provided by Cabinet Order as being equivalent; the same applies hereinafter) or by an establisher of a pharmacy, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(2) A prefectural governor must not make a designation of a designated medical institution if an application referred to in the preceding paragraph is filed and the filed application falls under any of the following items:

- (i) if the applicant has been sentenced to imprisonment without work or a heavier punishment and the execution of the sentence for the applicant has not yet been completed or the sentence has not yet been ceased to be applicable;
- (ii) if the applicant has been punished by a fine pursuant to the provisions of this Act, or other Acts concerning national healthcare provided by Cabinet Order and the execution of the penalty for the applicant has not yet been completed or has not yet expired;
- (iii) if the applicant is a person whose designation of a designated medical institution has been rescinded pursuant to the provisions of Article 23 and for whom five years have not yet elapsed since the date of the rescission (if a person whose designation of a designated medical institution which has been rescinded is a corporation, including a person who used to be an officer of the corporation or a manager of a medical institution (hereinafter referred to as "officer, etc.") within 60 days prior to the date of notification under Article 15 of the Administrative Procedure Act (Act No. 88 of 1993) pertaining to the rescission, and five years have not yet elapsed since the date of the rescission; and if a person whose designation of a designated medical institution has been rescinded is not a corporation, including a person who

used to be a manager of a person within 60 days prior to the date of the notification and for whom five years have not yet elapsed since the date of the rescission); provided, however, that this does not apply if the rescission falls under a rescission of designation of a designated medical institution provided by Order of the Ministry of Health, Labour and Welfare as a rescission which is found appropriate for not falling under a rescission of a designated medical institution under the main clause of this item in consideration of facts as reasons for the disposition of the rescission and the degree of responsibility held by the establisher of the designated medical institution with regard to the facts;

- (iv) if the applicant is a person who has offered to decline the designation of a designated medical institution under Article 20 during the period from the date of the notification under Article 15 of the Administrative Procedure Act pertaining to the rescission of designation of a designated medical institution under Article 23 (referred to as "the date of notification" in item (vi)) to the date of the disposition or the date of determination not to dispose (excluding a person who has an appropriate reason for the declination); and for whom five years have not elapsed since the date of the relevant offer;
- (v) if the applicant is a person who, during the period from the date of examination under Article 21, paragraph (1) to the scheduled date of determination of hearing (meaning the specified date which a prefectural governor has notified to the applicant within ten days since the examination pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare as the date expected to determine whether the hearing pertaining to the rescission of designation of a designated medical institution under Article 23 or not based on the conclusion of the examination), has offered to decline the designation of a designated medical institution under Article 20 (excluding a person who has an appropriate reason for the declination) and for whom five years have not yet elapsed since the date of the offer;
- (vi) if the declination of designation of a designated medical institution under Article 20 has been offered within the period provided in item (iv) and the applicant is a person who used to be an officer, etc. of the corporation pertaining to the offer (excluding a person who has an appropriate reason for the declination) or a manager of a person who is not a corporation pertaining to the offer (excluding a person who has an appropriate reason for the declination) within 60 days prior to the date of notification, and for whom five years have not yet elapsed since the date of the offer;
- (vii) if the applicant is a person who has committed a wrongful or extremely unjust act concerning specific medical care within five years prior to the application referred to in the preceding paragraph;
- (viii) if the applicant is a corporation and has a person among its officers, etc.

- who falls under any of the preceding items;
- (ix) if the applicant is not a corporation and its manager falls under any of item (i) to (vii).
- (3) A prefectural governor may determine not to make a designation of a designated medical institution, if an application referred to in paragraph (1) is filed and the application falls under any of the following items:
- (i) if a hospital, clinic or pharmacy pertaining to the application is not a health insurance-covered medical institution or a health insurance-covered pharmacy provided in Article 63, paragraph (3), item (i) of the Health Insurance Act or a place of business or a facility provided by Order of the Ministry of Health, Labour and Welfare;
  - (ii) if a hospital, clinic or pharmacy pertaining to the application or an applicant has been repeatedly directed under Article 18 or recommended under Article 22, paragraph (1) in fear of lack of appropriateness for contents of medical care or prescription with regard to payment of specific medical expenses;
  - (iii) if an applicant does not comply with an order under Article 22, paragraph (3);
  - (iv) beyond what is set forth in the preceding three items, if a hospital, clinic or pharmacy pertaining to the application is found extremely inappropriate as a designated medical institution.

#### (Renewal of Designation)

- Article 15 (1) Unless the designation of a designated medical institution is renewed every six years, the designation ceases to be effective upon the expiration of such period.
- (2) The provisions of Article 68, paragraph (2) of the Health Insurance Act apply mutatis mutandis to the renewal of designation of a designated medical institution referred to in the preceding paragraph. In this case, in paragraph (2) of the same Article, the term "health insurance-covered medical institutions (excluding hospitals and clinics referred to in Article 65, paragraph (2)) or health insurance-covered pharmacies" is deemed to be replaced with "designated medical institution provided in Article 5, paragraph (1) of the Act on Medical Care for Patients with Intractable Diseases", the term "the preceding paragraph" is deemed to be replaced with "Article 15, paragraph (1) of the same Act", and the term "paragraph (1) of the same Article" is deemed to be replaced with "Article 14, paragraph (1) of the same Act".

#### (Responsibilities of a Designated Medical Institution)

- Article 16 A designated medical institution must provide high-quality and appropriate specific medical care pursuant to the provisions of Order of the

Ministry of Health, Labour and Welfare.

(Medical Service Policy)

Article 17 (1) The medical service policy for a designated medical institution is governed by the medical service policy of the health insurance.

(2) If the medical service policy provided in the preceding paragraph cannot be followed or if it is inappropriate to be followed, the medical service policy is to be as provided by the Minister of Health, Labour and Welfare.

(Guidance from the Prefectural Governor)

Article 18 A designated medical institution must receive guidance from the prefectural governor with regard to implementation of specific medical care.

(Notification of Change)

Article 19 If the name, address and any other particulars provided by Order of the Ministry of Health, Labour and Welfare of the designated medical institution has been changed, the designated medical institution must notify a prefectural governor of the change pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Declination of Designation)

Article 20 A designated medical institution may decline the designation of a designated medical institution by offering one month or more of prior notice.

(Reports)

Article 21 (1) If a prefectural governor finds it necessary in relation for implementing specific medical care, the prefectural governor may order a designated medical institution or any of the persons who were establishers, managers, physicians, pharmacists or other employees of the designated medical institution (hereinafter referred to as "the former establishers, etc." in this paragraph) to make a report or submit or present medical records, books and documents or other items, may request any of the establishers, managers, physicians, pharmacies or other employees of the designated medical institution (including the former establishers, etc.) to appear, or may have personnel question persons concerned or inspect any equipment or medical records, the books and other documents or other items of the designated medical institution.

(2) If questions or inspections are conducted under the preceding paragraph, the personnel must carry an identification card and present it at the request of any person concerned.

(3) The authority under paragraph (1) must not be construed as being granted for

criminal investigation.

- (4) If a designated medical institution has failed to comply with an order to report, submit or present records pursuant to paragraph (1) or has made a false report, or refused, or has prevented or avoided inspection under the same paragraph without reasonable grounds, a prefectural governor may temporarily suspend payment of specific medical expenses to the designated medical institution.

(Recommendation or Order)

Article 22 (1) If a prefectural governor finds a designated medical institution fails to provide specific medical care in accordance with Article 16 or 17, the prefectural governor may recommend that an establisher of the designated medical institution comply with Article 16 or 17 by a set deadline.

- (2) If a prefectural governor has made a recommendation under the preceding paragraph and an establisher of the designated medical institution who has received the recommendation have failed to comply, within the deadline referred to in the same paragraph, the prefectural governor may make that failure public.
- (3) If an establisher of the designated medical institution who has received a recommendation under paragraph (1) has failed to take any measures pertaining to the recommendation without reasonable grounds, the prefectural governor may order the establishers of the designated medical institution to take measures pertaining to the recommendation, by a set deadline.
- (4) If a prefectural governor has ordered under the preceding paragraph, the prefectural governor must make a public announcement.

(Rescission of the Designation)

Article 23 A prefectural governor may rescind the designation of a designated medical institution pertaining to the designated medical institution or suspend the whole or part of the validity of the designation of a designated medical institution with setting a term in the cases set forth in the following items:

- (i) if a designated medical institution has come to fall under any of Article 14, paragraph (2), item (i), (ii), (viii) or (ix);
- (ii) if a designated medical institution has come to fall under any of the items of Article 14, paragraph (3);
- (iii) if a designated medical institution has violated Article 16 or 17;
- (iv) if specific medical expenses were claimed for by wrongful means;
- (v) if a designated medical institution ordered to make a report, submit or present medical records, books and other documents or other items pursuant to the provisions of Article 21, paragraph (1) failed to comply with the order or has made a false report;

- (vi) if an establisher or an employee of a designated medical institution have been requested to appear pursuant to the provisions of Article 21, paragraph (1) and does not comply with the requirement, have failed to answer or made a false answer to questions under the same paragraph, or have refused, interfered with or evaded an inspection under the same paragraph; provided, however, that this does not apply if, the employee of the designated medical institution has conducted the actions and the establisher of the designated medical institution has fulfilled the duty of reasonable care and supervision so as to prevent the actions;
- (vii) if a designated medical institution has received a designation of a designated medical institution by wrongful means;
- (viii) beyond what is set forth in the preceding items, if a designated medical institution has violated this Act and other Acts on national healthcare provided by Cabinet Order, or an order or disposition based on these Acts;
- (ix) beyond what is set forth in the preceding items, if a designated medical institution has committed a wrongful or extremely unjust act concerning specific medical care;
- (x) if a designated medical institution is a corporation, and an officer, etc. thereof who has committed a wrongful or extremely unjust act concerning specific medical care within five years from the time when a prefectural governor intends to rescind the validity of the designation of a designated medical institution or suspend the whole or part of a validity of the designation of a designated medical institution that has come to belong thereto;
- (xi) if a designated medical institution is not a corporation and a manager thereof who has committed a wrongful or extremely unjust act concerning specific medical care within five years from the time when the manager intends to rescind the validity of the designation of designated medical institution or suspend in whole or part of the validity of the designation of a designated medical institution that has come to belong thereto.

(Public Notice)

Article 24 A prefectural governor must make a public announcement in the following cases:

- (i) if a prefectural governor has made a designation of a designated medical institution;
- (ii) if a notification under Article 19 (excluding notification pertaining to change of matters provided by Order of the Ministry of Health, Labour and Welfare referred to in the same Article) has been made;
- (iii) if a designated medical institution has declined a designation of a designated medical institution under Article 20;

(iv) if a designation of a designated medical institution has been rescinded pursuant to the preceding Article.

(Review and Payment of Specific Medical Expenses)

Article 25 (1) A prefectural governor may from time to time examine the content of medical treatment provided and specific medical expenses claimed by a designated medical institution and decide the amount of specific medical expenses which the designated medical institution is entitled to claim pursuant to the provisions of Article 7, paragraph (7).

(2) A designated medical institution must follow the decisions made by a prefectural governor referred to in the preceding paragraph.

(3) When a prefectural governor decides the amounts of specific medical expenses which a designated medical institution is entitled to claim pursuant to the provisions of paragraph (1), the prefectural governor must hear the opinions of the review committee provided in the Act on Health Insurance Claims Review and Reimbursement Services Act (Act No. 129 of 1948), the National Health Insurance Medical Fees Review Committee provided in the National Health Insurance Act (Act No. 192 of 1958), and other reviewing bodies concerning medical care provided by Cabinet Order.

(4) A prefecture may entrust affairs concerning payment of specific medical expenses to a designated medical institution to the Health Insurance Claims Review and Reimbursement Services, the Federation of National Health Insurance Association provided in Article 45, paragraph (5) of the National Health Insurance Act, or other person provided by Order of the Ministry of Health, Labour and Welfare.

(5) Beyond what is provided for in the preceding paragraphs, necessary matters concerning claims for specific medical expenses are provided by Order of the Ministry of Health, Labour and Welfare.

(6) A request for administrative review may not be filed with regard to any decision on the amount of specific medical expenses under paragraph (1).

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

Article 26 Beyond what is provided for in this Section, necessary matters concerning designated medical institutions are provided by Order of the Ministry of Health, Labour and Welfare.

#### **Chapter IV Survey and Research**

Article 27 (1) The national government is to promote surveys and research on the mechanism of the occurrence, diagnosis and the treatment method of intractable diseases which serve as foundation for securing high-quality and

appropriate medical care for patients with intractable diseases.

- (2) When the national government promotes surveys and research provided in the preceding paragraph, the national government is to pay attention to appropriate coordination on surveys and research contributing to the treatment method of specific chronic pediatric diseases (meaning specific chronic pediatric diseases provided in Article 6-2 of the Child Welfare Act) and other sound upbringing of children, etc. with diseases provided in Article 21-4, paragraph (1) of the same Act.
- (3) The Minister of Health, Labour and Welfare is to actively provide results of the surveys and research provided in paragraph (1) to persons who conduct surveys and research on the mechanism of occurrence, the diagnosis and the treatment method of intractable diseases, physicians, patients with intractable diseases, their families, and other relevant persons by appropriate means.
- (4) When the Minister of Health, Labour and Welfare offers the results of the surveys and research provided in paragraph (1) pursuant to the provisions of the preceding paragraph, the Minister of Health, Labour and Welfare must pay attention to protecting personal information.

#### **Chapter V Projects for Improving the Living Environment of Patients Undergoing Treatment**

(Projects for Improving the Living Environment of Patients Undergoing Treatment)

Article 28 (1) A prefecture may implement the following projects as a project for improving the living environment of patients undergoing treatment pursuant to the provisions provided by Order of the Ministry of Health, Labour and Welfare:

- (i) a project to respond to a request for consultation from patients with intractable diseases and their families, offering necessary information and advice and other services provided in Order of the Ministry of Health, Labour and Welfare with regard to various issues on life of patients with intractable diseases undergoing treatment;
- (ii) a project to foster persons who provide services of healthcare or welfare to patients with intractable diseases or persons who give necessary guidance to these persons;
- (iii) a project to provide patients with intractable diseases found necessary for whom receive home-nursing (meaning caretaking or assistance for necessary medical care provided to patients with intractable diseases at their homes by a nurse or other persons provided by Order of the Ministry of Health, Labour and Welfare, hereinafter the same applies in this item) in light of the standards provided by Order of the Ministry of Health, Labour and Welfare



from the perspective of securing appropriate medical care, with home-nursing pursuant to the provisions provided by Order of the Ministry of Health, Labour and Welfare.

- (2) A prefecture may entrust all or a part of the project set forth in item (i) of the preceding paragraph to medical institutions or other persons provided by Order of the Ministry of Health, Labour and Welfare.
- (3) A prefecture which, pursuant to the provisions of the paragraph (1), implements the project set forth in item (i) of the same paragraph and a person who is entrusted pursuant to the provisions of the preceding paragraph and implements the project pertaining to the entrustment must endeavor to coordinate with designated medical institutions or other relevant persons for effective implement of the project set forth in the same item and the project pertaining to the entrustment.
- (4) A person who is entrusted pursuant to the provisions of paragraph (2) and implements a project pertaining to the entrustment (an officer, if the person is a corporation), an employee of the person, or a person who used to be any of those persons must not, without justifiable grounds, disclose any confidential information obtained in relation to the entrusted projects.

(Intractable Disease Consultation Support Center)

Article 29 (1) An Intractable Disease Consultation Support Center is a facility aiming to implement the project set forth in paragraph 1, item (i) of the preceding Article and support in maintaining and improving the quality of life of patients with intractable diseases undergoing treatment.

- (2) A prefecture which implements the project set forth in paragraph (1), item (i) of the preceding Article may establish an Intractable Disease Consultation Support Center.
- (3) A person who is entrusted pursuant to the provisions of paragraph 2 of the preceding Article, pursuant to the provisions provided by Order of the Ministry of Health, Labour and Welfare, may establish an Intractable Disease Consultation Support Center by notifying, in advance, the matters provided by Order of the Ministry of Health, Labour and Welfare to the prefectural governor in order to implement the project pertaining to the entrustment.

## **Chapter VI Expenses**

(Payment by Prefectures)

Article 30 The following expenses are paid by the prefecture:

- (i) expenses required for payment of specific medical expenses;
- (ii) expenses required for projects improving the living conditions of patients undergoing treatment.

(Expenses Borne or Subsidized by the National Government)

Article 31 (1) The national government, pursuant to the provisions of Cabinet Order, bears fifty percent of the expenses set forth in item (i) of the same Article among the expenses paid by a prefecture pursuant to the provisions of the preceding Article

(2) The national government, pursuant to the provisions of Cabinet Order, may provide assistance up to a maximum of fifty percent of the expenses set forth in item (ii) of the same Article among the expenses paid by a prefecture pursuant to the provisions of the preceding Article within the limits of its budget.

## **Chapter VII Miscellaneous Provisions**

(Local Council on Measures for Intractable Diseases)

Article 32 (1) In order to singly or jointly improve support systems for patients with intractable diseases, a prefectural government, cities establishing a health center, and special wards are to endeavor to establish a local council on measures for intractable diseases (hereinafter referred to as "council") consisting of relevant organs, relevant bodies and patients with intractable diseases and their families, and persons engaged in duties relevant to medical care for patients with intractable diseases or welfare, education or employment of patients with intractable diseases, and other relevant persons (referred to as "relevant organs, etc." in the following paragraph).

(2) The council is to share information on issues about support systems for patients with intractable diseases for its region, promote closer coordination with relevant organs, etc. and is to deliberate on the improvement of systems appropriate to actual circumstances of the region by communicating among relevant organs, etc.

(3) A current or former person engaged in the affairs of a council must not disclose, without a justifiable reason, any confidential information obtained in the course of duties of the council.

(Matters Provided by a Council)

Article 33 Beyond what is provided for in the preceding Article, a council is to prescribe necessary matters concerning the organization and administration of the council.

(Collection of Wrongful Gains)

Article 34 (1) If a person receives any payment of specific medical expenses by deception or other wrongful means, a prefecture may collect all or a part of the amount equivalent to the amount of the specific medical expenses from the

person.

- (2) If a designated medical institution receives any payment of specific medical expenses by deception or other wrongful acts, a prefecture may cause the designated medical institution to refund the amount so paid and to pay, in addition, the amount obtained by multiplying the amount to be refunded by forty percent.
- (3) The collected money under the preceding two paragraphs is considered revenue specified by the Act provided in Article 231-3, paragraph (3) of the Local Autonomy Act (Act No. 67 of 1947).

(Reports)

- Article 35 (1) If a prefecture finds it necessary with regard to a payment of specific medical expenses, the prefecture may order a patient with a designated intractable disease, the custodian or the spouse, the head of the household which the patient belongs to or other persons who belong to the household, or a person who used to be such to make a report or submit or present documents or other items, or may have the personnel question.
- (2) The provisions of Article 21, paragraph (2) apply mutatis mutandis to the questions under the preceding paragraph, and the provisions of paragraph (3) of the same Article apply mutatis mutandis to the authority under the preceding paragraph.

(Investigation on Payments of Specific Medical Expenses by the Minister of Health, Labour and Welfare)

- Article 36 (1) If the Minister of Health, Labour and Welfare finds it urgently necessary with regard to a payment of specific medical expenses, the Minister of Health, Labour and Welfare may order a patient with the designated intractable disease or the custodian of the patient pertaining to the payment of specific medical expenses or a person who used to be such to make a report or submit or present documents or other items, or may have personnel question concerning contents of specific medical care pertaining to payment of the specific medical expenses, under close cooperation with the governor of the prefecture.
- (2) If the Minister of Health, Labour and Welfare finds it urgently necessary regarding a payment of specific medical expenses, the Minister of Health, Labour and Welfare may order a person who has provided specific medical care or an employer of the person to make a report or submit or present records, books and documents and other items on the specific medical care, or may have personnel question the relevant persons, concerning the specific medical care provided under close cooperation with the governor of the prefecture.
  - (3) The provisions of Article 21, paragraph (2) apply mutatis mutandis to the

questions under the preceding two paragraphs, and the provisions of paragraph (3) of the same Article apply mutatis mutandis to the authority under the preceding two paragraphs.

(Provision of Materials)

Article 37 If a prefecture finds it necessary with regard to a payment of specific medical expenses, the prefecture may request a public agency to provide access to necessary documents or to provide necessary materials or may request a report from a bank, a trust company or other institution or the employer of a patient with a designated intractable disease or other relevant person, concerning the status of assets or income of the patient, the custodian or the spouse, the head of the household which the patient belongs to or other persons who belong to the household.

(Protection of the Right to Receive Benefits)

Article 38 The right to receive payments of specific medical expenses may not be transferred, pledged as collateral, or seized.

(Prohibition of Taxation and Other Public Charges)

Article 39 Taxes and other public charges may not be imposed on the basis of money received as payment of specific medical expenses.

(Special Provisions for Large Cities)

Article 40 In the case of a designated city referred to in Article 252-19, paragraph (1) of the Local Autonomy Act (hereinafter referred to as "designated city" in this Article), the provisions concerning affairs which a prefecture is supposed to conduct in this Act and which are provided by Cabinet Order are to be conducted by the designated city pursuant to the provisions of Cabinet Order. In this case, the provisions concerning a prefecture in this Act apply to a designated city as the provisions concerning a designated city.

(Delegation of Authorities)

Article 41 (1) The authority of the Minister of Health, Labour and Welfare provided for in this Act may be delegated to the Director General of Regional Bureau of Health and Welfare pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

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

and Welfare.

(Enforcement Provisions)

Article 42 Unless otherwise specially provided in this Act, procedures for the enforcement of this Act and other detailed regulations necessary for the execution thereof are provided by Order of the Ministry of Health, Labour and Welfare.

### **Chapter VIII Penal Provisions**

Article 43 If a current or former member of the Designated Intractable Disease Examination Board has disclosed any confidential information obtained in the course of duties without reasonable grounds, the person is punished by imprisonment for not more than one year or a fine of not more than 1,000,000 yen.

Article 44 A person who has violated the provisions of Article 28, paragraph (4) or Article 32, paragraph (3) is punished by imprisonment for not more than one year or a fine of not more than 1,000,000 yen.

Article 45 A person who fails to submit or present reports or materials or who submit or presents false reports or materials pursuant to Article 36, paragraph (1), or has failed to reply, or made a false reply, to questions by personnel under the same paragraph is punished by a fine of not more than 300,000 yen.

Article 46 A person who fails to submit or present reports or materials or presents false reports or materials pursuant to Article 36, paragraph (2), or has failed to reply, or made a false reply, to questions by personnel under the same paragraph is punished by a non-criminal fine of not more than 100,000 yen.

Article 47 A prefecture, in its Prefectural Ordinance, may prescribe a provision to impose a civil fine not more than 100,000 yen on a person who falls under any of the following items:

- (i) a person who has been requested to return the medical care recipient certification under Article 21, paragraph (2) and fails to respond to the request;
- (ii) a person who fails to submit or present reports or materials or presents false reports or materials under Article 35, paragraph (1), or has failed to reply, or made a false reply, to questions by personnel under the same paragraph without reasonable grounds.

## Supplementary Provisions [Extract]

### (Effective Date)

Article 1 This Act comes into effect as of January 1, 2015; provided, however, that the provisions set forth in the following items come into effect as of the date provided in the each items:

- (i) provisions of Article 3, Article 7 (limited to the amendment provisions of Article 65 of the Act on the Arrangement of Related Acts that Accompany the enforcement of the Act partially amending the Children and Child-Rearing Support Act and the Act on Advancement of Comprehensive Service Related to Education, Child Care of Preschool Children (Act No. 67 of 2012)), Article 8, Article 12 and Article 13 in Supplementary Provisions: the date of promulgation;
- (ii) provisions of Article 40 and Article 4 in Supplementary Provisions: April 1, 2018.

### (Review)

Article 2 The government, within five years after this Act comes into effect, is to review responsible entities implementing the affairs pertaining to the payment of specific medical expenses and other matters with regard to the provisions of this Act in consideration of circumstances of the enforcement and take necessary measures based on the results if it is found necessary.

### (Preparations Prior to Enforcement)

- Article 3 (1) The Minister of Health, Labour and Welfare may formulate the basic policy in accordance with the provisions of Article 4 even prior to the enforcement of this Act. In this case, the Minister of Health, Labour and Welfare may make it public in accordance with the provisions of the same Article even prior to the enforcement of this Act.
- (2) The basic policy formulated pursuant to the provisions of the preceding paragraph is deemed to be formulated pursuant to the provisions of Article 4 on the date of enforcement of this Act (hereinafter referred to as "enforcement date" in this Article).
  - (3) The Minister of Health, Labour and Welfare may designate intractable diseases as designated intractable diseases in accordance with the provisions of Article 5, paragraph (1) even prior to the enforcement date of this Act.
  - (4) The designated intractable diseases designated pursuant to the provisions of the preceding paragraph are deemed to be designated pursuant to the provisions of Article 5, paragraph (1) on the enforcement date.
  - (5) A prefectural governor may designate physicians as designated physicians in

accordance with the provisions of Article 6, paragraph (1) even prior to the enforcement of this Act.

- (6) The designated physician designated pursuant to the provisions of the preceding paragraph is deemed to be designated pursuant to the provisions of Article 6, paragraph (1) on the enforcement date.
- (7) The Minister of Health, Labour and Welfare may determine the degree of severity of the medical condition of the designated intractable diseases in accordance with the provisions of Article 7, paragraph (1), item (i) even prior to the enforcement of this Act.
- (8) The degree of severity of the medical condition determined pursuant to the provisions of the preceding paragraph is deemed to be determined pursuant to the provisions of Article 7, paragraph (1), item (i) on the enforcement date.
- (9) A prefectural governor may establish a Designated Intractable Disease Examination Board in accordance with the provisions of Article 8 (excluding paragraph (3)) even prior to the enforcement of this Act.
- (10) The Designated Intractable Disease Examination Board established pursuant to the provisions of the preceding paragraph is deemed to be established pursuant to the provisions of Article 8 on the enforcement date.
- (11) The term of office of members for the Designated Intractable Disease Examination Board established pursuant to the provisions of paragraph (9) is until December 31 of 2016, notwithstanding the provisions of Article 8, paragraph (3).
- (12) The enactment or amendment of Prefectural Ordinances, procedures of a grant recipient approval under Articles 6 and 7, procedures of the designation of designated medical institutions under Article 14, paragraph (1) and other acts required to enforce this Act may be implemented even prior to the enforcement of this Act.

### **Supplementary Provisions [Act No. 69 of June 13, 2014] [Extract]**

(Effective Date)

Article 1 This Act comes into effect as of the date of enforcement of the Administrative Appeal Act (Act No. 68 of 2014).