

難病の患者に対する医療等に関する法律

Act on Medical Care for Patients with Intractable Diseases

(平成二十六年五月三十日法律第五十号)
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第一章 総則

Chapter I General Provisions

（目的）

(Purpose)

第一条 この法律は、難病（発病の機構が明らかでなく、かつ、治療方法が確立していない希少な疾病であつて、当該疾病にかかることにより長期にわたり療養を必要とす

ることとなるものをいう。以下同じ。)の患者に対する医療その他難病に関する施策(以下「難病の患者に対する医療等」という。)に関し必要な事項を定めることにより、難病の患者に対する良質かつ適切な医療の確保及び難病の患者の療養生活の質の維持向上を図り、もって国民保健の向上を図ることを目的とする。

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.

(基本理念)

(Basic Principles)

第二条 難病の患者に対する医療等は、難病の克服を目指し、難病の患者がその社会参加の機会が確保されること及び地域社会において尊厳を保持しつつ他の人々と共生することを妨げられないことを旨として、難病の特性に応じて、社会福祉その他の関連施策との有機的な連携に配慮しつつ、総合的に行われなければならない。

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.

(国及び地方公共団体の責務)

(Responsibilities of National and Local Governments)

第三条 国及び地方公共団体は、難病に関する情報の収集、整理及び提供並びに教育活動、広報活動等を通じた難病に関する正しい知識の普及を図るよう、相互に連携を図りつつ、必要な施策を講ずるよう努めなければならない。

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 国及び都道府県は、難病の患者に対する医療に係る人材の養成及び資質の向上を図

るとともに、難病の患者が良質かつ適切な医療を受けられるよう、相互に連携を図りつつ、必要な施策を講ずるよう努めなければならない。

(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 国は、難病に関する調査及び研究並びに難病の患者に対する医療のための医薬品及び医療機器の研究開発の推進を図るための体制を整備し、国際的な連携を確保するよう努めるとともに、地方公共団体に対し前二項の責務が十分に果たされるように必要な技術的及び財政的援助を与えることに努めなければならない。

(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.

第二章 基本方針

Chapter II Basic Policy

第四条 厚生労働大臣は、難病の患者に対する医療等の総合的な推進を図るための基本的な方針（以下「基本方針」という。）を定めなければならない。

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 基本方針は、次に掲げる事項について定めるものとする。

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

一 難病の患者に対する医療等の推進の基本的な方向

(i) basic direction to promote medical care, etc. for patients with intractable diseases;

二 難病の患者に対する医療を提供する体制の確保に関する事項

(ii) particulars concerning the securing of systems to provide medical care for patients with intractable diseases;

三 難病の患者に対する医療に関する人材の養成に関する事項

(iii) particulars concerning the fostering of human resources for medical care for patients with intractable diseases;

四 難病に関する調査及び研究に関する事項

(iv) particulars concerning surveys and research on intractable diseases;

五 難病の患者に対する医療のための医薬品及び医療機器に関する研究開発の推進に

関する事項

(v) particulars concerning the promotion of research and development of medicines and medical equipment for the medical care for patients with intractable diseases;

六 難病の患者の療養生活の環境整備に関する事項

(vi) particulars concerning the improvement of the environment in which patients with intractable diseases undergoing treatment live;

七 難病の患者に対する医療等と難病の患者に対する福祉サービスに関する施策、就労の支援に関する施策その他の関連する施策との連携に関する事項

(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;

八 その他難病の患者に対する医療等の推進に関する重要事項

(viii) other important particulars concerning the promotion of medical care, etc. for patients with intractable diseases.

3 厚生労働大臣は、少なくとも五年ごとに基本方針に再検討を加え、必要があると認めるときは、これを変更するものとする。

(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 厚生労働大臣は、基本方針を定め、又はこれを変更しようとするときは、あらかじめ、関係行政機関の長に協議するとともに、厚生科学審議会の意見を聴かなければならない。

(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 厚生労働大臣は、基本方針を定め、又はこれを変更したときは、遅滞なく、これを公表しなければならない。

(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 厚生労働大臣は、基本方針の策定のため必要があると認めるときは、医療機関その他の関係者に対し、資料の提出その他必要な協力を求めることができる。

(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.

第三章 医療

Chapter III Medical Care

第一節 特定医療費の支給

Section 1 Payment of Specific Medical Expenses

(特定医療費の支給)

(Payments of Specific Medical Expenses)

第五条 都道府県は、支給認定（第七条第一項に規定する支給認定をいう。以下この条及び次条において同じ。）を受けた指定難病（難病のうち、当該難病の患者数が本邦において厚生労働省令で定める人数に達せず、かつ、当該難病の診断に関し客観的な指標による一定の基準が定まっていることその他の厚生労働省令で定める要件を満たすものであって、当該難病の患者の置かれている状況からみて当該難病の患者に対する良質かつ適切な医療の確保を図る必要性が高いものとして、厚生労働大臣が厚生科学審議会の意見を聴いて指定するものをいう。以下同じ。）の患者が、支給認定の有効期間（第九条に規定する支給認定の有効期間をいう。第七条第四項において同じ。）内において、特定医療（支給認定を受けた指定難病の患者に対し、都道府県知事が指定する医療機関（以下「指定医療機関」という。）が行う医療であって、厚生労働省令で定めるものをいう。以下同じ。）のうち、同条第三項の規定により定められた指定医療機関から受けるものであって当該支給認定に係る指定難病に係るもの（以下「指定特定医療」という。）を受けたときは、厚生労働省令で定めるところにより、当該支給認定を受けた指定難病の患者又はその保護者（児童福祉法（昭和二十二年法律第百六十四号）第六条に規定する保護者をいう。以下同じ。）に対し、当該指定特定医療に要した費用について、特定医療費を支給する。

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 特定医療費の額は、一月につき、第一号に掲げる額（当該指定特定医療に食事療養（健康保険法（大正十一年法律第七十号）第六十三条第二項第一号に規定する食事療養をいう。以下この項において同じ。）が含まれるときは、当該額及び第二号に掲げる額の合算額、当該指定特定医療に生活療養（同条第二項第二号に規定する生活療養をいう。以下この項において同じ。）が含まれるときは、当該額及び第三号に掲げる額の合算額）とする。

(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)):

一 同一の月に受けた指定特定医療（食事療養及び生活療養を除く。）につき健康保険の療養に要する費用の額の算定方法の例により算定した額から、当該支給認定を受けた指定難病の患者又はその保護者の家計の負担能力、当該支給認定を受けた指定難病の患者の治療状況、当該支給認定を受けた指定難病の患者又はその保護者と同一の世帯に属する他の支給認定を受けた指定難病の患者及び児童福祉法第十九条の三第三項に規定する医療費支給認定に係る同法第六条の二第一項に規定する小児慢性特定疾病児童等の数その他の事情をしん酌して政令で定める額（当該政令で定める額が当該算定した額の百分の二十（当該支給認定を受けた指定難病の患者が高齢者の医療の確保に関する法律（昭和五十七年法律第八十号）第五十条及び第五十一条の規定による後期高齢者医療の被保険者であって、同法第六十七条第一項第一号に掲げる場合に該当する場合その他政令で定める場合にあつては、百分の十）に相当する額を超えるときは、当該相当する額）を控除して得た額

(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));

二 当該指定特定医療（食事療養に限る。）につき健康保険の療養に要する費用の額の算定方法の例により算定した額から、健康保険法第八十五条第二項に規定する食事療養標準負担額、支給認定を受けた指定難病の患者又はその保護者の所得の状況その他の事情を勘案して厚生労働大臣が定める額を控除した額

(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);

三 当該指定特定医療（生活療養に限る。）につき健康保険の療養に要する費用の額の算定方法の例により算定した額から、健康保険法第八十五条の二第二項に規定する生活療養標準負担額、支給認定を受けた指定難病の患者又はその保護者の所得の状況その他の事情を勘案して厚生労働大臣が定める額を控除した額

(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 前項に規定する療養に要する費用の額の算定方法の例によることができないとき、及びこれによることを適当としないときの特定医療に要する費用の額の算定方法は、厚生労働大臣の定めるところによる。

(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.

(申請)

(Application)

第六条 支給認定を受けようとする指定難病の患者又はその保護者は、厚生労働省令で定めるところにより、都道府県知事の定める医師（以下「指定医」という。）の診断書（指定難病の患者が指定難病にかかっていること及びその病状の程度を証する書面として厚生労働省令で定めるものをいう。）を添えて、その居住地の都道府県に申請をしなければならない。

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 指定医の指定の手續その他指定医に関し必要な事項は、厚生労働省令で定める。

(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.

(支給認定等)

(Grant Recipient Approval)

第七条 都道府県は、前条第一項の申請に係る指定難病の患者が、次の各号のいずれかに該当する場合であつて特定医療を受ける必要があるときは、支給認定を行うものとする。

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:

一 その病状の程度が厚生労働大臣が厚生科学審議会の意見を聴いて定める程度であるとき。

(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;

二 その治療状況その他の事情を勘案して政令で定める基準に該当するとき。

(ii) if the patient falls under standards provided by Cabinet Order in consideration of the status of the treatment and other circumstances.

2 都道府県は、前条第一項の申請があった場合において、支給認定をしないこととするとき（申請の形式上の要件に適合しない場合として厚生労働省令で定める場合を除く。）は、あらかじめ、次条第一項に規定する指定難病審査会に当該申請に係る指定難病の患者について支給認定をしないことに関し審査を求めなければならない。

(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 都道府県は、支給認定をしたときは、厚生労働省令で定めるところにより、指定医療機関の中から、当該支給認定を受けた指定難病の患者が特定医療を受けるものを定めるものとする。

(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 都道府県は、支給認定をしたときは、支給認定を受けた指定難病の患者又はその保護者（以下「支給認定患者等」という。）に対し、厚生労働省令で定めるところにより、支給認定の有効期間、前項の規定により定められた指定医療機関の名称その他の厚生労働省令で定める事項を記載した医療受給者証（以下「医療受給者証」という。）を交付しなければならない。

(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 支給認定は、その申請のあった日に遡ってその効力を生ずる。

(5) The approval for a grant recipient approval becomes effective retroactively as of the date of the application.

6 指定特定医療を受けようとする支給認定患者等は、厚生労働省令で定めるところにより、第三項の規定により定められた指定医療機関に医療受給者証を提示して指定特定医療を受けるものとする。ただし、緊急の場合その他やむを得ない事由のある場合については、医療受給者証を提示することを要しない。

(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 支給認定を受けた指定難病の患者が第三項の規定により定められた指定医療機関から指定特定医療を受けたとき（当該支給認定患者等が当該指定医療機関に医療受給者証を提示したときに限る。）は、都道府県は、当該支給認定患者等が当該指定医療機関に支払うべき当該指定特定医療に要した費用について、特定医療費として当該支給認定患者等に支給すべき額の限度において、当該支給認定患者等に代わり、当該指定医療機関に支払うことができる。

(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 前項の規定による支払があったときは、当該支給認定患者等に対し、特定医療費の支給があったものとみなす。

(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.

(指定難病審査会)

(Designated Intractable Disease Examination Board)

第八条 前条第二項の規定による審査を行わせるため、都道府県に、指定難病審査会を置く。

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 指定難病審査会の委員は、指定難病に関し学識経験を有する者（指定医である者に限る。）のうちから、都道府県知事が任命する。

(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 委員の任期は、二年とする。

(3) The term of office of a member is two years.

4 この法律に定めるもののほか、指定難病審査会に関し必要な事項は、厚生労働省令で定める。

(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.

(支給認定の有効期間)

(Effective Period of a Grant Recipient Approval)

第九条 支給認定は、厚生労働省令で定める期間（以下この節において「支給認定の有効期間」という。）内に限り、その効力を有する。

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).

(支給認定の変更)

(Change of a Grant Recipient Approval)

第十条 支給認定患者等は、現に受けている支給認定に係る第七条第三項の規定により定められた指定医療機関その他の厚生労働省令で定める事項を変更する必要があるときは、厚生労働省令で定めるところにより、都道府県に対し、当該支給認定の変更の申請をすることができる。

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 都道府県は、前項の申請又は職権により、支給認定患者等につき、同項の厚生労働省令で定める事項を変更する必要があると認めるときは、厚生労働省令で定めるところにより、支給認定の変更の認定を行うことができる。この場合において、都道府県は、当該支給認定患者等に対し、医療受給者証の提出を求めるものとする。

(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 都道府県は、前項の支給認定の変更の認定を行ったときは、医療受給者証に当該変更の認定に係る事項を記載し、これを返還するものとする。

(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.

(支給認定の取消し)

(Rescission of an Approval for a Grant Recipient Approval)

第十一条 支給認定を行った都道府県は、次に掲げる場合には、当該支給認定を取り消すことができる。

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

一 支給認定を受けた患者が、第七条第一項各号のいずれにも該当しなくなったと認めるとき。

(i) if a patient given a grant recipient approval fails to qualify under either of the items of Article 7, paragraph (1);

二 支給認定患者等が、支給認定の有効期間内に、当該都道府県以外の都道府県の区域内に居住地を有するに至ったと認めるとき。

(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;

三 支給認定患者等が、正当な理由がなく、第三十五条第一項又は第三十六条第一項の規定による命令に応じないとき。

(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;

四 その他政令で定めるとき。

(iv) in other cases provided by Cabinet Order.

2 前項の規定により支給認定の取消しを行った都道府県は、厚生労働省令で定めるところにより、当該取消しに係る支給認定患者等に対し、医療受給者証の返還を求めるものとする。

(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.

(他の法令による給付との調整)

(Adjustment of Benefits Provided by Other Laws and Regulations)

第十二条 特定医療費の支給は、当該指定難病の患者に対する医療につき、健康保険法の規定による療養の給付その他の法令に基づく給付であって政令で定めるもののうち特定医療費の支給に相当するものを受けるときは政令で定める限度において、当該政令で定める給付以外の給付であって国又は地方公共団体の負担において特定医療費の支給に相当するものが行われたときはその限度において、行わない。

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.

(厚生労働省令への委任)

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

第十三条 この節に定めるもののほか、特定医療費の支給に関し必要な事項は、厚生労働省令で定める。

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.

第二節 指定医療機関

Section 2 Designated Medical Institutions

(指定医療機関の指定)

(Designation of a Designated Medical Institution)

第十四条 第五条第一項の規定による指定医療機関の指定（以下この節において「指定医療機関の指定」という。）は、厚生労働省令で定めるところにより、病院若しくは診療所（これらに準ずるものとして政令で定めるものを含む。以下同じ。）又は薬局の開設者の申請により行う。

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 都道府県知事は、前項の申請があった場合において、次の各号のいずれかに該当するときは、指定医療機関の指定をしてはならない。

(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:

一 申請者が、禁錮以上の刑に処せられ、その執行を終わり、又は執行を受けることがなくなるまでの者であるとき。

(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;

二 申請者が、この法律その他国民の保健医療に関する法律で政令で定めるものの規定により罰金の刑に処せられ、その執行を終わり、又は執行を受けることがなくなるまでの者であるとき。

(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;

三 申請者が、第二十三条の規定により指定医療機関の指定を取り消され、その取消の日から起算して五年を経過しない者（当該指定医療機関の指定を取り消された者が法人である場合においては、当該取消しの処分に係る行政手続法（平成五年法律第八十八号）第十五条の規定による通知があった日前六十日以内に当該法人の役員又はその医療機関の管理者（以下「役員等」という。）であった者で当該取消しの日から起算して五年を経過しないものを含み、当該指定医療機関の指定を取り消された者が法人でない場合においては、当該通知があった日前六十日以内に当該者の管理者であった者で当該取消しの日から起算して五年を経過しないものを含む。）であるとき。ただし、当該取消しが、指定医療機関の指定の取消しのうち当該取消しの処分の理由となった事実その他の当該事実に関して当該指定医療機関の開設者が有していた責任の程度を考慮して、この号本文の規定による指定医療機関

の指定の取消しに該当しないこととすることが相当であると認められるものとして厚生労働省令で定めるものに該当する場合を除く。

(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;

四 申請者が、第二十三条の規定による指定医療機関の指定の取消しの処分に係る行政手続法第十五条の規定による通知があった日（第六号において「通知日」という。）から当該処分をする日又は処分をしないことを決定する日までの間に第二十条の規定による指定医療機関の指定の辞退の申出をした者（当該辞退について相当の理由がある者を除く。）で、当該申出の日から起算して五年を経過しないものであるとき。

(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;

五 申請者が、第二十一条第一項の規定による検査が行われた日から聴聞決定予定日（当該検査の結果に基づき第二十三条の規定による指定医療機関の指定の取消しの処分に係る聴聞を行うか否かの決定をすることが見込まれる日として厚生労働省令で定めるところにより都道府県知事が当該申請者に当該検査が行われた日から十日

以内に特定の日を通知した場合における当該特定の日をいう。)までの間に第二十条の規定による指定医療機関の指定の辞退の申出をした者(当該辞退について相当の理由がある者を除く。)で、当該申出の日から起算して五年を経過しないものであるとき。

(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;

六 第四号に規定する期間内に第二十条の規定による指定医療機関の指定の辞退の申出があった場合において、申請者が、通知日前六十日以内に当該申出に係る法人(当該辞退について相当の理由がある者を除く。)の役員等又は当該申出に係る法人でない者(当該辞退について相当の理由がある者を除く。)の管理者であった者で、当該申出の日から起算して五年を経過しないものであるとき。

(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;

七 申請者が、前項の申請前五年以内に特定医療に関し不正又は著しく不当な行為をした者であるとき。

(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;

八 申請者が、法人で、その役員等のうちに前各号のいずれかに該当する者のあるものであるとき。

(viii) if the applicant is a corporation and has a person among its officers, etc. who falls under any of the preceding items;

九 申請者が、法人でない者で、その管理者が第一号から第七号までのいずれかに該当する者であるとき。

(ix) if the applicant is not a corporation and its manager falls under any of item (i) to (vii).

3 都道府県知事は、第一項の申請があった場合において、次の各号のいずれかに該当するときは、指定医療機関の指定をしないことができる。

(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:

一 当該申請に係る病院若しくは診療所又は薬局が、健康保険法第六十三条第三項第一号に規定する保険医療機関若しくは保険薬局又は厚生労働省令で定める事業所若しくは施設でないとき。

(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;

二 当該申請に係る病院若しくは診療所若しくは薬局又は申請者が、特定医療費の支給に関し診療又は調剤の内容の適切さを欠くおそれがあるとして重ねて第十八条の規定による指導又は第二十二條第一項の規定による勧告を受けたものであるとき。

(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;

三 申請者が、第二十二條第三項の規定による命令に従わないものであるとき。

(iii) if an applicant does not comply with an order under Article 22, paragraph (3);

四 前三号に掲げる場合のほか、当該申請に係る病院若しくは診療所又は薬局が、指定医療機関として著しく不相当と認めるものであるとき。

(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.

(指定の更新)

(Renewal of Designation)

第十五条 指定医療機関の指定は、六年ごとにその更新を受けなければ、その期間の経過によって、その効力を失う。

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 健康保険法第六十八条第二項の規定は、前項の指定医療機関の指定の更新について準用する。この場合において、同条第二項中「保険医療機関（第六十五条第二項の病院及び診療所を除く。）又は保険薬局」とあるのは「難病の患者に対する医療等に関する法律第五条第一項に規定する指定医療機関」と、「前項」とあるのは「同法第十

五条第一項」と、「同条第一項」とあるのは「同法第十四条第一項」と読み替えるものとする。

(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".

(指定医療機関の責務)

(Responsibilities of a Designated Medical Institution)

第十六条 指定医療機関は、厚生労働省令で定めるところにより、良質かつ適切な特定医療を行わなければならない。

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.

(診療方針)

(Medical Service Policy)

第十七条 指定医療機関の診療方針は、健康保険の診療方針の例による。

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

2 前項に規定する診療方針によることができないとき、及びこれによることを相当としないときの診療方針は、厚生労働大臣が定めるところによる。

(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.

(都道府県知事の指導)

(Guidance from the Prefectural Governor)

第十八条 指定医療機関は、特定医療の実施に関し、都道府県知事の指導を受けなければならない。

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

(変更の届出)

(Notification of Change)

第十九条 指定医療機関は、当該指定医療機関の名称及び所在地その他厚生労働省令で定める事項に変更があったときは、厚生労働省令で定めるところにより、その旨を都道府県知事に届け出なければならない。

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.

(指定の辞退)

(Declination of Designation)

第二十条 指定医療機関は、一月以上の予告期間を設けて、指定医療機関の指定を辞退することができる。

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

(報告等)

(Reports)

第二十一条 都道府県知事は、特定医療の実施に関して必要があると認めるときは、指定医療機関若しくは指定医療機関の開設者若しくは管理者、医師、薬剤師その他の従業者であった者（以下この項において「開設者であった者等」という。）に対し報告若しくは診療録、帳簿書類その他の物件の提出若しくは提示を命じ、指定医療機関の開設者若しくは管理者、医師、薬剤師その他の従業者（開設者であった者等を含む。）に対し出頭を求め、又は当該職員に、関係者に対し質問させ、若しくは指定医療機関について設備若しくは診療録、帳簿書類その他の物件を検査させることができる。

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 前項の規定による質問又は検査を行う場合においては、当該職員は、その身分を示す証明書を携帯し、かつ、関係人の請求があるときは、これを提示しなければならない

い。

(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 第一項の規定による権限は、犯罪捜査のために認められたものと解釈してはならない。

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

4 指定医療機関が、正当な理由がなく、第一項の規定による報告若しくは提出若しくは提示を命ぜられてこれに従わず、若しくは虚偽の報告をし、又は同項の規定による検査を拒み、妨げ、若しくは忌避したときは、都道府県知事は、当該指定医療機関に対する特定医療費の支払を一時差し止めることができる。

(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.

(勧告、命令等)

(Recommendation or Order)

第二十二條 都道府県知事は、指定医療機関が、第十六条又は第十七条の規定に従って特定医療を行っていないと認めるときは、当該指定医療機関の開設者に対し、期限を定めて、第十六条又は第十七条の規定を遵守すべきことを勧告することができる。

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 都道府県知事は、前項の規定による勧告をした場合において、その勧告を受けた指定医療機関の開設者が、同項の期限内にこれに従わなかったときは、その旨を公表することができる。

(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 都道府県知事は、第一項の規定による勧告を受けた指定医療機関の開設者が、正当な理由がなくその勧告に係る措置をとらなかったときは、当該指定医療機関の開設者に対し、期限を定めて、その勧告に係る措置をとるべきことを命ずることができる。

(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 都道府県知事は、前項の規定による命令をしたときは、その旨を公示しなければならない。

(4) If a prefectural governor has ordered under the preceding paragraph, the prefectural governor must make a public announcement.

(指定の取消し等)

(Rescission of the Designation)

第二十三条 都道府県知事は、次の各号のいずれかに該当する場合には、当該指定医療機関に係る指定医療機関の指定を取り消し、又は期間を定めてその指定医療機関の指定の全部若しくは一部の効力を停止することができる。

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:

一 指定医療機関が、第十四条第二項第一号、第二号、第八号又は第九号のいずれかに該当するに至ったとき。

(i) if a designated medical institution has come to fall under any of Article 14, paragraph (2), item (i), (ii), (viii) or (ix);

二 指定医療機関が、第十四条第三項各号のいずれかに該当するに至ったとき。

(ii) if a designated medical institution has come to fall under any of the items of Article 14, paragraph (3);

三 指定医療機関が、第十六条又は第十七条の規定に違反したとき。

(iii) if a designated medical institution has violated Article 16 or 17;

四 特定医療費の請求に関し不正があったとき。

(iv) if specific medical expenses were claimed for by wrongful means;

五 指定医療機関が、第二十一条第一項の規定により報告若しくは診療録、帳簿書類その他の物件の提出若しくは提示を命ぜられてこれに従わず、又は虚偽の報告をしたとき。

(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;

六 指定医療機関の開設者又は従業者が、第二十一条第一項の規定により出頭を求められてこれに応ぜず、同項の規定による質問に対して答弁せず、若しくは虚偽の答弁をし、又は同項の規定による検査を拒み、妨げ、若しくは忌避したとき。ただし、当該指定医療機関の従業者がその行為をした場合において、その行為を防止するため、当該指定医療機関の開設者が相当の注意及び監督を尽くしたときを除く。

(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;

七 指定医療機関が、不正の手段により指定医療機関の指定を受けたとき。

(vii) if a designated medical institution has received a designation of a designated medical institution by wrongful means;

八 前各号に掲げる場合のほか、指定医療機関が、この法律その他国民の保健医療に関する法律で政令で定めるもの又はこれらの法律に基づく命令若しくは処分に違反したとき。

(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;

九 前各号に掲げる場合のほか、指定医療機関が、特定医療に関し不正又は著しく不当な行為をしたとき。

(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;

十 指定医療機関が法人である場合において、その役員等のうちに指定医療機関の指定の取消し又は指定医療機関の指定の全部若しくは一部の効力の停止をしようとするとき前五年以内に特定医療に関し不正又は著しく不当な行為をした者があるに至ったとき。

(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;

十一 指定医療機関が法人でない場合において、その管理者が指定医療機関の指定の取消し又は指定医療機関の指定の全部若しくは一部の効力の停止をしようとするとき前五年以内に特定医療に関し不正又は著しく不当な行為をした者があるに至ったとき。

(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.

(公示)

(Public Notice)

第二十四条 都道府県知事は、次に掲げる場合には、その旨を公示しなければならない。

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

一 指定医療機関の指定をしたとき。

(i) if a prefectural governor has made a designation of a designated medical institution;

二 第十九条の規定による届出（同条の厚生労働省令で定める事項の変更に係るものを除く。）があったとき。

(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;

三 第二十条の規定による指定医療機関の指定の辞退があったとき。

(iii) if a designated medical institution has declined a designation of a designated medical institution under Article 20;

四 前条の規定により指定医療機関の指定を取り消したとき。

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

(特定医療費の審査及び支払)

(Review and Payment of Specific Medical Expenses)

第二十五条 都道府県知事は、指定医療機関の診療内容及び特定医療費の請求を随時審査し、かつ、指定医療機関が第七条第七項の規定によって請求することができる特定医療費の額を決定することができる。

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 指定医療機関は、都道府県知事が行う前項の決定に従わなければならない。

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

3 都道府県知事は、第一項の規定により指定医療機関が請求することができる特定医療費の額を決定するに当たっては、社会保険診療報酬支払基金法（昭和二十三年法律第二百二十九号）に定める審査委員会、国民健康保険法（昭和三十二年法律第九十二号）に定める国民健康保険診療報酬審査委員会その他政令で定める医療に関する審査機関の意見を聴かなければならない。

(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 都道府県は、指定医療機関に対する特定医療費の支払に関する事務を社会保険診療報酬支払基金、国民健康保険法第四十五条第五項に規定する国民健康保険団体連合会その他厚生労働省令で定める者に委託することができる。

(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 前各項に定めるもののほか、特定医療費の請求に関し必要な事項は、厚生労働省令で定める。

(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 第一項の規定による特定医療費の額の決定については、審査請求をすることができない。

(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).

(厚生労働省令への委任)

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

第二十六条 この節に定めるもののほか、指定医療機関に関し必要な事項は、厚生労働省令で定める。

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.

第四章 調査及び研究

Chapter IV Survey and Research

第二十七条 国は、難病の患者に対する良質かつ適切な医療の確保を図るための基盤となる難病の発病の機構、診断及び治療方法に関する調査及び研究を推進するものとする。

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 国は、前項に規定する調査及び研究の推進に当たっては、小児慢性特定疾病（児童福祉法第六条の二に規定する小児慢性特定疾病をいう。）の治療方法その他同法第二十一条の四第一項に規定する疾病児童等の健全な育成に資する調査及び研究との適切な連携を図るよう留意するものとする。

(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 厚生労働大臣は、第一項に規定する調査及び研究の成果を適切な方法により難病の発病の機構、診断及び治療方法に関する調査及び研究を行う者、医師、難病の患者及びその家族その他の関係者に対して積極的に提供するものとする。

(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 厚生労働大臣は、前項の規定により第一項に規定する調査及び研究の成果を提供するに当たっては、個人情報保護に留意しなければならない。

(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.

第五章 療養生活環境整備事業

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

(療養生活環境整備事業)

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

第二十八条 都道府県は、厚生労働省令で定めるところにより、療養生活環境整備事業として、次に掲げる事業を行うことができる。

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:

一 難病の患者の療養生活に関する各般の問題につき、難病の患者及びその家族その他の関係者からの相談に応じ、必要な情報の提供及び助言その他の厚生労働省令で定める便宜を供与する事業

(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;

二 難病の患者に対する保健医療サービス若しくは福祉サービスを提供する者又はこれらの者に対し必要な指導を行う者を育成する事業

(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;

三 適切な医療の確保の観点から厚生労働省令で定める基準に照らして訪問看護（難病の患者に対し、その者の居宅において看護師その他厚生労働省令で定める者により行われる療養上の世話又は必要な診療の補助をいう。以下この号において同じ。）を受けることが必要と認められる難病の患者につき、厚生労働省令で定めるところにより、訪問看護を行う事業

(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 都道府県は、医療機関その他の厚生労働省令で定める者に対し、前項第一号に掲げる事業の全部又は一部を委託することができる。

(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 第一項の規定により同項第一号に掲げる事業を行う都道府県及び前項の規定による委託を受けて当該委託に係る事業を実施する者は、同号に掲げる事業及び当該委託に係る事業の効果的な実施のために、指定医療機関その他の関係者との連携に努めなければならない。

(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 第二項の規定による委託を受けて当該委託に係る事業を実施する者（その者が法人である場合にあっては、その役員）若しくはその職員又はこれらの者であった者は、正当な理由がなく、当該委託に係る事業に関して知り得た秘密を漏らしてはならない。

(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.

(難病相談支援センター)

(Intractable Disease Consultation Support Center)

第二十九条 難病相談支援センターは、前条第一項第一号に掲げる事業を実施し、難病の患者の療養生活の質の維持向上を支援することを目的とする施設とする。

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 前条第一項第一号に掲げる事業を行う都道府県は、難病相談支援センターを設置することができる。

(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 前条第二項の規定による委託を受けた者は、当該委託に係る事業を実施するため、厚生労働省令で定めるところにより、あらかじめ、厚生労働省令で定める事項を都道府県知事に届け出て、難病相談支援センターを設置することができる。

(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.

第六章 費用

Chapter VI Expenses

(都道府県の支弁)

(Payment by Prefectures)

第三十条 次に掲げる費用は、都道府県の支弁とする。

Article 30 The following expenses are paid by the prefecture:

一 特定医療費の支給に要する費用

(i) expenses required for payment of specific medical expenses;

二 療養生活環境整備事業に要する費用

(ii) expenses required for projects improving the living conditions of patients undergoing treatment.

(国の負担及び補助)

(Expenses Borne or Subsidized by the National Government)

第三十一条 国は、政令で定めるところにより、前条の規定により都道府県が支弁する費用のうち、同条第一号に掲げる費用の百分の五十を負担する。

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 国は、予算の範囲内において、政令で定めるところにより、前条の規定により都道府県が支弁する費用のうち、同条第二号に掲げる費用の百分の五十以内を補助することができる。

(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.

第七章 雑則

Chapter VII Miscellaneous Provisions

(難病対策地域協議会)

(Local Council on Measures for Intractable Diseases)

第三十二条 都道府県、保健所を設置する市及び特別区は、単独で又は共同して、難病の患者への支援の体制の整備を図るため、関係機関、関係団体並びに難病の患者及びその家族並びに難病の患者に対する医療又は難病の患者の福祉、教育若しくは雇用に関連する職務に従事する者その他の関係者（次項において「関係機関等」という。）により構成される難病対策地域協議会（以下「協議会」という。）を置くように努めるものとする。

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 協議会は、関係機関等が相互の連絡を図ることにより、地域における難病の患者への支援体制に関する課題について情報を共有し、関係機関等の連携の緊密化を図るとともに、地域の実情に応じた体制の整備について協議を行うものとする。

(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 協議会の事務に従事する者又は当該者であった者は、正当な理由がなく、協議会の事務に関して知り得た秘密を漏らしてはならない。

(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.

(協議会の定める事項)

(Matters Provided by a Council)

第三十三条 前条に定めるもののほか、協議会の組織及び運営に関し必要な事項は、協議会が定める。

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.

(不正利得の徴収)

(Collection of Wrongful Gains)

第三十四条 都道府県は、偽りその他不正の手段により特定医療費の支給を受けた者があるときは、その者から、その特定医療費の額に相当する金額の全部又は一部を徴収することができる。

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 都道府県は、指定医療機関が、偽りその他不正の行為により特定医療費の支給を受けたときは、当該指定医療機関に対し、その支払った額につき返還させるほか、その返還させる額に百分の四十を乗じて得た額を支払わせることができる。

(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 前二項の規定による徴収金は、地方自治法（昭和二十二年法律第六十七号）第二百三十一条の三第三項に規定する法律で定める歳入とする。

(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).

(報告等)

(Reports)

第三十五条 都道府県は、特定医療費の支給に関して必要があると認めるときは、指定難病の患者、その保護者若しくは配偶者若しくはその患者の属する世帯の世帯主その他その世帯に属する者又はこれらの者であった者に対し、報告若しくは文書その他の物件の提出若しくは提示を命じ、又は当該職員に質問させることができる。

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 第二十一条第二項の規定は前項の規定による質問について、同条第三項の規定は前項の規定による権限について準用する。

(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.

(厚生労働大臣の特定医療費の支給に関する調査等)

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

第三十六条 厚生労働大臣は、特定医療費の支給に関して緊急の必要があると認めるときは、当該都道府県の知事との密接な連携の下に、当該特定医療費の支給に係る指定難病の患者若しくはその保護者又はこれらの者であった者に対し、当該特定医療費の支給に係る特定医療の内容に関し、報告若しくは文書その他の物件の提出若しくは提示を命じ、又は当該職員に質問させることができる。

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 厚生労働大臣は、特定医療費の支給に関して緊急の必要があると認めるときは、当該都道府県の知事との密接な連携の下に、特定医療を行った者若しくはこれを使用した者に対し、その行った特定医療に関し、報告若しくは当該特定医療の提供の記録、帳簿書類その他の物件の提出若しくは提示を命じ、又は当該職員に関係者に対し質問させることができる。

(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 第二十一条第二項の規定は前二項の規定による質問について、同条第三項の規定は前二項の規定による権限について準用する。

(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.

(資料の提供等)

(Provision of Materials)

第三十七条 都道府県は、特定医療費の支給に関して必要があると認めるときは、指定難病の患者、その保護者若しくは配偶者又はその患者の属する世帯の世帯主その他その世帯に属する者の資産又は収入の状況につき、官公署に対し必要な文書の閲覧若しくは資料の提供を求め、又は銀行、信託会社その他の機関若しくは指定難病の患者の雇用主その他の関係人に報告を求めることができる。

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.

(受給権の保護)

(Protection of the Right to Receive Benefits)

第三十八条 特定医療費の支給を受ける権利は、譲り渡し、担保に供し、又は差し押さえることができない。

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

(租税その他の公課の禁止)

(Prohibition of Taxation and Other Public Charges)

第三十九条 租税その他の公課は、特定医療費として支給を受けた金銭を標準として、課することができない。

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

(大都市の特例)

(Special Provisions for Large Cities)

第四十条 この法律中都道府県が処理することとされている事務に関する規定で政令で定めるものは、地方自治法第二百五十二条の十九第一項の指定都市（以下この条において「指定都市」という。）においては、政令で定めるところにより、指定都市が処理するものとする。この場合においては、この法律中都道府県に関する規定は、指定都市に関する規定として指定都市に適用があるものとする。

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.

(権限の委任)

(Delegation of Authorities)

第四十一条 この法律に規定する厚生労働大臣の権限は、厚生労働省令で定めるところにより、地方厚生局長に委任することができる。

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 前項の規定により地方厚生局長に委任された権限は、厚生労働省令で定めるところにより、地方厚生支局長に委任することができる。

(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.

(実施規定)

(Enforcement Provisions)

第四十二条 この法律に特別の規定があるものを除くほか、この法律の実施のための手続その他その執行について必要な細則は、厚生労働省令で定める。

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.

第八章 罰則

Chapter VIII Penal Provisions

第四十三条 指定難病審査会の委員又はその委員であった者が、正当な理由がなく、職務上知り得た秘密を漏らしたときは、一年以下の懲役又は百万円以下の罰金に処する。

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.

第四十四条 第二十八条第四項又は第三十二条第三項の規定に違反した者は、一年以下の懲役又は百万円以下の罰金に処する。

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.

第四十五条 第三十六条第一項の規定による報告若しくは物件の提出若しくは提示をせず、若しくは虚偽の報告若しくは虚偽の物件の提出若しくは提示をし、又は同項の規定による当該職員の質問に対して、答弁せず、若しくは虚偽の答弁をした者は、三十万円以下の罰金に処する。

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.

第四十六条 第三十六条第二項の規定による報告若しくは物件の提出若しくは提示をせず、若しくは虚偽の報告若しくは虚偽の物件の提出若しくは提示をし、又は同項の規定による当該職員の質問に対して、答弁せず、若しくは虚偽の答弁をした者は、十万円以下の過料に処する。

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.

第四十七条 都道府県は、条例で、次の各号のいずれかに該当する者に対し十万円以下の過料を科する規定を設けることができる。

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:

一 第十一条第二項の規定による医療受給者証の返還を求められてこれに応じない者
(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;

二 正当な理由がなく、第三十五条第一項の規定による報告若しくは物件の提出若しくは提示をせず、若しくは虚偽の報告若しくは虚偽の物件の提出若しくは提示をし、又は同項の規定による当該職員の質問に対して、答弁せず、若しくは虚偽の答弁をした者

(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.

附 則 [抄]

Supplementary Provisions [Extract]

(施行期日)

(Effective Date)

第一条 この法律は、平成二十七年一月一日から施行する。ただし、次の各号に掲げる規定は、当該各号に定める日から施行する。

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:

一 附則第三条、第七条（子ども・子育て支援法及び就学前の子どもに関する教育、保育等の総合的な提供の推進に関する法律の一部を改正する法律の施行に伴う関係法律の整備等に関する法律（平成二十四年法律第六十七号）第六十五条の改正規定に限る。） 、第八条、第十二条及び第十三条の規定 公布の日

(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;

二 第四十条及び附則第四条の規定 平成三十年四月一日

(ii) provisions of Article 40 and Article 4 in Supplementary Provisions: April 1, 2018.

(検討)

(Review)

第二条 政府は、この法律の施行後五年以内を目途として、この法律の規定について、その施行の状況等を勘案しつつ、特定医療費の支給に係る事務の実施主体の在り方その他の事項について検討を加え、必要があると認めるときは、その結果に基づいて必要な措置を講ずるものとする。

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.

(施行前の準備)

(Preparations Prior to Enforcement)

第三条 厚生労働大臣は、この法律の施行前においても、第四条の規定の例により、基本方針を定めることができる。この場合において、厚生労働大臣は、この法律の施行前においても、同条の規定の例により、これを公表することができる。

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 前項の規定により定められた基本方針は、この法律の施行の日（以下この条において「施行日」という。）において第四条の規定により定められたものとみなす。

(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 厚生労働大臣は、この法律の施行前においても、第五条第一項の規定の例により、指定難病を指定することができる。

(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 前項の規定により指定された指定難病は、施行日において第五条第一項の規定によ

り指定されたものとみなす。

(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 都道府県知事は、この法律の施行前においても、第六条第一項の規定の例により、指定医の指定をすることができる。

(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 前項の規定により指定された指定医は、施行日において第六条第一項の規定により指定されたものとみなす。

(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 厚生労働大臣は、この法律の施行前においても、第七条第一項第一号の規定の例により、指定難病の病状の程度を定めることができる。

(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 前項の規定により定められた病状の程度は、施行日において第七条第一項第一号の規定により定められたものとみなす。

(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 都道府県知事は、この法律の施行前においても、第八条（第三項を除く。）の規定の例により、指定難病審査会を置くことができる。

(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 前項の規定により置かれた指定難病審査会は、施行日において第八条の規定により置かれたものとみなす。

(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 第九項の規定により置かれた指定難病審査会の委員の任期は、第八条第三項の規定にかかわらず、平成二十八年十二月三十一日までとする。

(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 この法律を施行するために必要な条例の制定又は改正、第六条及び第七条の規定による支給認定の手續、第十四条第一項の規定による指定医療機関の指定の手續その他の行為は、この法律の施行前においても行うことができる。

(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.

附 則 〔平成二十六年六月十三日法律第六十九号〕 〔抄〕
Supplementary Provisions [Act No. 69 of June 13, 2014] [Extract]

(施行期日)

(Effective Date)

第一条 この法律は、行政不服審査法（平成二十六年法律第六十八号）の施行の日から施行する。

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