

Act for Appropriate Provision of Hematopoietic Stem Cells to be Used in Transplantations

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Chapter 1 General Provisions

(Purpose)

Article 1 The purpose of this Act is to establish basic principles and clarify the responsibilities of the national government in promoting the appropriate provision of hematopoietic stem cells (bone marrow, peripheral blood stem cells, umbilical cord blood) for use in transplantation, and to promote the appropriate provision of hematopoietic stem cells for use in transplantations and contribute to the smooth and appropriate implementation of hematopoietic stem cell transplantation, by defining the matters that will form the basis for measures to promote the appropriate provision of hematopoietic stem cells for use in transplantation and implementing the necessary

regulations and subsidies for entities that serve as intermediary agencies in the provision of bone marrow and peripheral blood stem cells and services that provide cord blood.

(Definitions)

Article 2 The term “hematopoietic stem cells for use in transplantations” as used in this Act means bone marrow used in transplantations, peripheral blood stem cells used in transplantations, and umbilical cord blood used in transplantations.

2 The term “bone marrow for use in transplantations” as used in this Act means human bone marrow collected for use in hematopoietic stem cells transplantations (the transplantation of hematopoietic stem cells to humans for the purpose of treating disease with associated hematopoietic disorders and other diseases, as stipulated in Ministry of Health, Labour and Welfare ordinances. The same shall apply hereinafter).

3 The term “peripheral blood stem cells for use in transplantations” as used in this Act means human hematopoietic stem cells collected from peripheral blood by methods stipulated in Ministry of Health, Labour and Welfare ordinances for use in hematopoietic stem cells transplantations.

4 The term “umbilical cord blood for use in transplantations” as used in this Act means human umbilical cord blood (fetal blood in the umbilical cord and placenta that is expelled during childbirth) collected for use in hematopoietic stem cells transplantations, and included materials prepared after said collection to be made suitable for hematopoietic stem cells transplantations.

5 The term “Bone Marrow and Peripheral Blood Stem Cell Agency” as used in this Act means agencies that act as intermediaries in the provision of peripheral bone marrow for use in transplantation or peripheral blood stem cells blood stem cells for use in transplantation (hereinafter called “bone marrow and peripheral blood stem cell services”)

6 The term “Cord Blood Suppliers” as used in this Act means enterprises (including

information management and other services stipulated in Ministry of Health, Labour and Welfare ordinances as services incidental to or associated with these services. Hereinafter called “cord blood supply services”) that perform collection, preparation, storage, testing, and delivery services (excluding cord blood supply services for cord blood used in said transplantations to be used by the person in question or his or her family, performed at the request of the person from whom the cord blood used in transplantation is collected) for the supply of umbilical cord blood used in transplantations.

(Basic Principles)

Article 3 With regard to hematopoietic stem cells used in transplantation, efforts shall be made to promote the provision of these cells with the aim of ensuring sufficient opportunities of people who need hematopoietic stem cell transplantation to receive hematopoietic stem cells transplantation.

2 Hematopoietic stem cells used in transplantations shall be provided voluntarily

3 With regard to the provision of hematopoietic stem cells used in transplantations, consideration shall be given so that opportunities to receive hematopoietic stem cell transplantation are granted fairly to people who need hematopoietic stem cells transplantation.

4 In view of the fact that hematopoietic stem cells used in transplantations are derived from humans, the safety of these cells shall be ensured during the provision of hematopoietic stem cells for use in transplantations.

5 In view of the physical burden associated with the collection of bone marrow and peripheral blood stem cells for use in transplantations, utmost efforts shall be made to protect the health of donors during the provision of bone marrow and peripheral blood stem cells for use in transplantations.

6 In view of the characteristics of umbilical cord blood used in transplantations and associated processes such as preparation and preservation, efforts shall be made to

ensure the safety of that blood and other aspects of quality during the provision of umbilical cord blood for use in transplantations.

(Responsibilities of National Government)

Article 4 In accordance with the basic principles of the preceding Article (in the following Articles referred to as “Basic Principles”), the national government shall have the responsibility to formulate and implement measures related to the promotion of appropriate provision of stem cells for use in transplantations.

(Responsibilities of Local Public Authorities)

Article 5 In accordance with the Basic Principles, local public authorities shall have the responsibility to formulate and implement measures related to the promotion of proper provision of stem cells used in transplantations, based on an appropriate division of roles with the national government.

(Responsibilities of Businesses Related to the Provision of Hematopoietic Stem Cells)

Article 6 Bone marrow and peripheral blood stem cell agencies defined in Article 19 and cord blood suppliers defined in Article 32 (hereinafter, “hematopoietic stem cell related businesses”), and the support organization defined in Article 44, paragraph 1 fulfill central roles in the provision of hematopoietic stem cells for transplantations, and shall therefore endeavor to actively contribute to promoting the appropriate provision of hematopoietic stem cells for use in transplantations.

(Responsibilities of Healthcare Professionals)

Article 7 Physicians and other healthcare professionals shall endeavor to cooperate in the measures adopted by national and local government authorities in relation to promoting the appropriate provision of hematopoietic stem cells for use in transplantations.

- 2 Proprietors and managers of medical facilities shall endeavor to provide information necessary for efforts to monitor and analyze health status, etc. described Article 12.

(Coordination among Related Parties)

Article 8 The national government, local public authorities, hematopoietic stem cell related businesses, the support organization defined in Article 44, paragraph 1, and healthcare professionals shall endeavor to cooperate while coordinating among themselves to promote the appropriate provision of hematopoietic stem cells used in transplantations.

Chapter 2 Basic Policy

Article 9 The Minister of Health, Labour and Welfare shall establish a basic policy (in the following Articles, “Basic Policy”), for the promotion of appropriate provision of hematopoietic stem cells for use in transplantations.

- 2 The Basic Policy shall establish the following matters.
 - (i) The basic direction for promotion of appropriate provision of hematopoietic stem cells for use in transplantations.
 - (ii) Matters relevant to the goal of providing hematopoietic stem cells for use in transplantations and other matters that facilitate the provision of hematopoietic stem cells for use in transplantations.
 - (iii) Matters relevant to ensuring the safety of hematopoietic stem cells for use in transplantations.
 - (iv) Other necessary matters relevant to promoting the appropriate provision of hematopoietic stem cells for use in transplantations.
- 3 The Minister of Health, Labour and Welfare shall establish the Basic Policy, and when changes are made to the Basic Policy shall publicly announce them without delay.

Chapter 3 Measures to Promote the Appropriate Provision of Hematopoietic Stem Cells for Use in Transplantations

(Enhancing Public Understanding)

Article 10 The national government shall take necessary measures to deepen the public understanding to promote the appropriate provision of hematopoietic stem cells for use in transplantations.

(Unified Provision of Information)

Article 11 The national government shall take necessary measures for the uniform supply of information on the provision of hematopoietic stem cells for use in transplantations to physicians who will perform stem cell transplantation and other people who need hematopoietic stem cells used in transplantations.

(Support for Efforts to Monitor and Analyze the Health Status of Donors and Others)

Article 12 The national government shall take necessary measures to support efforts to monitor and analyze the health status of people who provide bone marrow and peripheral blood stem cells for use in transplantations and people who will receive these hematopoietic stem cells provided for use in transplantations, in a way that contributes to promoting the appropriate provision of hematopoietic stem cells used in transplantations.

(Ensuring the Stable Operation of Hematopoietic Stem Cell Related Businesses)

Article 13 The national government shall take necessary financial and other measures to ensure the stable business operation of hematopoietic stem cell related businesses, in a way that contributes to promoting the appropriate provision of hematopoietic stem cells for use in transplantations.

(Encouraging Research and Development)

Article 14 The national government shall take necessary measures to encourage research and development that will contribute to promoting the appropriate provision of hematopoietic stem cells for use in transplantations, and dissemination of the results of that research and development.

(Promoting international cooperation)

Article 15 The national government shall take necessary measures to promote international technical cooperation related to ensuring the quality of umbilical cord blood used in transplantations, and other international cooperation for the provision of hematopoietic stem cells for use in transplantations.

(Development of Healthcare Delivery Systems Related to the Collection of Bone Marrow and Peripheral Blood Stem Cells for Use in Transplantations)

Article 16 The national government shall adopt necessary measures for the development of healthcare delivery systems related to the collection of bone marrow and peripheral stem cells used in transplantations, so that bone marrow and peripheral stem cells used in transplantations can be provided smoothly.

Chapter 4 Bone marrow and peripheral blood stem cell agencies

(Licensing of Bone Marrow and Peripheral Blood Stem Cell Agencies)

Article 17 Bone Marrow and Peripheral Blood Stem Cell Agencies must be licensed by the Minister of Health, Labour and Welfare, pursuant to Ministry of Health, Labour and Welfare ordinances.

(Licensing Criteria)

Article 18 The Minister of Health, Labour and Welfare shall not grant the license set forth in the preceding Article unless he/she has found that the application for the

license set forth in that Article conforms to all of the following items.

- (i) The service is not being offered for the purpose of profit.
- (ii) Necessary measures are taken to ensure the safety of bone marrow and peripheral blood stem cells used in transplantation.
- (iii) Necessary measures are taken to protect the health of donors of the bone marrow or peripheral blood stem cells to be used in transplantation.
- (iv) There is no reason to doubt that the service will be provided fairly and properly.
- (v) None of the following apply to the applicant.
 - (a) The person is an adult ward or a person under curatorship, or person who is the subject of a ruling for commencement of bankruptcy proceedings and has not had his/her rights restored.
 - (b) The person has been sentenced under the provisions of this Act, and three years have not passed from the date on which the enforcement of such punishment was completed or ceased to be applicable.
 - (c) The person has had a license rescinded under the provisions of Article 27, and three years have not passed since that rescindment (in the case that the person whose said license was rescinded was a corporation (including unincorporated entities for which a representative or administrator is appointed. The same shall apply hereinafter except in Article 61, paragraph 2) the person was an executive officer (including the person stipulated as the representative person or administrator of an organization that is not a legal person. The same shall apply hereinafter) of the said corporation within 60 days before the notification under the provisions of Article 15 of the Administrative Procedure Act (Act No. 88 of 1993) regarding the disposition of the said rescindment, including cases in which three years have not passed from the date of the said rescindment).
 - (d) A corporation to which any of (a) to (c) apply to any of its executive officers.

(Ensuring Safety)

Article 19 Persons who are licensed according to Article 17 (hereinafter, “Bone Marrow And Peripheral Blood Stem Cell Agencies”) shall survey infectious and other diseases in bone marrow and peripheral stem cell donors and take other necessary measures to ensure the safety of bone marrow and peripheral blood stem cells to be used in transplantations.

(Measures to Protect the Health of Donors)

Article 20 Bone Marrow and Peripheral Blood Stem Cell Agencies shall conduct medical examinations of people who will donate bone marrow or peripheral blood stem cells to be used in transplantations, take other measures to protect the health of people who will donate bone marrow or peripheral blood stem cells for use in transplantations, and take measures to compensate for health risks associated with the collection of bone marrow or peripheral blood stem cells to be used in transplantations.

(Explanation and Consent at the Time of Collection)

Article 21 When collecting bone marrow or peripheral blood stem cells for use in transplantations, Bone Marrow And Peripheral Blood Stem Cell Agencies shall provide the donors of these bone marrow or peripheral blood stem cells with appropriate explanations of the physical burden associated with such collection, matters related to ensuring the safety of these materials that require cooperation, and other matters necessary for such collection, and obtain their consent.

(Confidentiality obligations)

Article 22 Bone Marrow and Peripheral Blood Stem Cell Agencies (in the case of a legal person, an officer of said person), their employees, and former employees shall not, without justifiable grounds, divulge any confidential information on people obtained in performing the work of the Bone Marrow And Peripheral Blood Stem

Cell Agency.

(Keeping of records)

Article 23 Bone Marrow and Peripheral Blood Stem Cell Agencies shall keep and preserve, pursuant to the provisions of Ministry of Health, Labour and Welfare ordinances, books recording the matters with respect to bone marrow and peripheral blood stem cell services which are specified by Ministry of Health, Labour and Welfare ordinances.

(Collection of reports)

Article 24 The Minister of Health, Labour and Welfare may, as far as it is necessary for the enforcement of the provisions of this Chapter, request necessary reports from bone marrow and peripheral blood stem cell agencies on their bone marrow and peripheral blood stem cell services, or have an official of the Ministry enter the offices or other facilities of a bone marrow and peripheral blood stem cell agency and inspect the situation of the bone marrow and peripheral blood stem cell services or books, documents, or other materials or to question relevant persons.

2 Each employee who inspects a site or asks questions pursuant to the provisions of the preceding paragraph shall carry an identification card and present it to relevant persons.

3 The authority to conduct on-site inspections and questioning under paragraph (1) shall not be construed as having been granted for the purpose of investigating crime.

(Order for Improvement)

Article 25 The Minister of Health, Labour and Welfare may, when and to the extent that he/she finds that improvements are necessary in the operations of a bone marrow and peripheral blood stem cell service, order the Bone Marrow and Peripheral Blood Stem Cell Agency to take necessary measures for such improvements.

(Suspension or Discontinuation of Operations)

Article 26 When a Bone Marrow and Peripheral Blood Stem Cell Agency intends to suspend or discontinue some or all bone marrow and peripheral blood stem cell services, it must notify the Minister of Health, Labour and Welfare to that effect in advance, pursuant to Ministry of Health, Labour and Welfare ordinances.

(Rescindment of License)

Article 27 When any of the following items apply to a Bone Marrow and Peripheral Blood Stem Cell Agency, the Minister of Health, Labour and Welfare may rescind the agency's license or order the it to cease all or part of its operations for a fixed period not exceeding six months.

- (i) Any of (a), (b), or (d) of Article 18, Item 5 applies to the agency.
- (ii) The agency violates the provisions of this chapter.
- (iii) The agency violates an order issued under Article 25.

(Subsidy)

Article 28 The national government may, within budgetary limits, provide subsidies for part of the expenses necessary for bone marrow and peripheral blood stem cell services to bone marrow and peripheral blood stem cell agencies.

(Assistance from the Minister of Health, Labour and Welfare)

Article 29 The Minister of Health, Labour and Welfare shall endeavor to provide appropriate advice, guidance, and other assistance to Bone Marrow and Peripheral Blood Stem Cell Agencies to promote the proper provision of bone marrow and peripheral blood stem cells to be used in transplantations.

Chapter 5 Cord Blood Suppliers

(Licensing of Cord Blood Suppliers)

Article 30 Cord Blood Suppliers must be licensed by the Minister of Health, Labour and Welfare, pursuant to Ministry of Health, Labour and Welfare ordinances.

(Licensing Criteria)

Article 31 The Minister of Health, Labour and Welfare shall not grant the license set forth in the preceding Article unless he/she has found that the application for the license set forth in that Article conforms to all of the following items.

- (i) The service is not being offered for the purpose of profit.
- (ii) The activities are conducted in a way that conforms to the criteria in the following Articles.
- (iii) There is no concern that the service will not be provided fairly and properly.
- (iv) None of the following apply to the applicant.
 - (a) The person is an adult ward or a person under curatorship, or person who is the subject of a ruling for commencement of bankruptcy proceedings and has not had his/her rights restored.
 - (b) The person has been sentenced under the provisions of this Act, and three years have not passed from the date on which the enforcement of such punishment was completed or ceased to be applicable.
 - (c) The person has had a license rescinded under the provisions of Article 41, and three years have not passed since that rescindment (in the case that the person whose said license was rescinded was a corporation, the person was an executive officer of the said corporation within 60 days before the notification under the provisions of Article 15 of the Administrative Procedure Act regarding the disposition of the said rescindment, including cases in which three years have not passed from the date of the said rescindment).
 - (d) It is a corporation to which any of (a) to (c) apply to any of its executive officers.

(Compliance with Standards to Ensure Quality)

Article 32 Persons who are licensed according to Article 30 (hereinafter, “Cord Blood Suppliers”) shall, in providing cord blood supply services, comply with standards specified by Ministry of Health, Labour and Welfare ordinance with regard to how cord blood supply services are performed, which are necessary to ensure the safety and other aspects of quality for cord blood used in transplantations.

(Explanation and Consent at the Time of Collection)

Article 33 When collecting cord blood for use in transplantations, Cord Blood Suppliers shall provide the pregnant women who will donate this cord blood for use in transplantations with appropriate explanations of the usage of the collected cord blood for transplantations, matters related to ensuring the safety of this cord blood that require cooperation, and other necessary matters in the collection of cord blood for use in transplantations, and obtain their consent.

(Provision of information to support organizations)

Article 34 Cord Blood Suppliers, pursuant to the provisions of Ministry of Health, Labour and Welfare ordinances, shall provide information defined in Ministry of Health, Labour and Welfare ordinances on stored cord blood for use in transplantations to support organizations prescribed in Article 44, paragraph 1.

(Use and Provision for Research Purposes)

Article 35 In accordance with standards provided for by Ministry of Health, Labour and Welfare ordinance, Cord Blood Suppliers may use cord blood collected for use in transplantation themselves or provide it to others for research, insofar as this does not hinder the execution of cord blood supply services.

(Confidentiality Obligations)

Article 36 Cord blood suppliers (in the case of a legal person, an officer of said person), their employees, and former employees shall not, without justifiable grounds, divulge any confidential information on people obtained in performing the cord blood supply services.

(Keeping of Records)

Article 37 Cord Blood Suppliers shall keep and preserve, pursuant to the provisions of Ministry of Health, Labour and Welfare ordinances, books recording the matters with respect to cord blood supply services which are specified by Ministry of Health, Labour and Welfare ordinances.

(Collection of Reports)

Article 38 The Minister of Health, Labour and Welfare may, as far as it is necessary for the enforcement of the provisions of this Chapter, request necessary reports from Cord Blood Suppliers on their cord blood supply services, or have an official of the Ministry enter the offices or other facilities of a Cord Blood Supplier and inspect the situation of the cord blood supply services or books, documents, or other materials or to question relevant persons.

2 Each employee who inspects a site or asks questions pursuant to the provisions of the preceding paragraph shall carry an identification card and present it to relevant persons.

3 The authority to conduct on-site inspections and questioning under paragraph (1) shall not be construed as having been granted for the purpose of investigating crime.

(Order for Improvement)

Article 39 The Minister of Health, Labour and Welfare may, when and to the extent that he/she finds that improvements are necessary in the operations of a cord blood supply service, order the Cord Blood Supplier to take necessary measures for such

improvements.

(Suspension or Discontinuation of Operations)

Article 40 When a Cord Blood Supplier intends to suspend or discontinue some or all cord blood supply services, it must notify the Minister of Health, Labour and Welfare to that effect in advance, pursuant to Ministry of Health, Labour and Welfare ordinances.

(Rescindment of License)

Article 41 When any of the following items apply to a Cord Blood Supplier, the Minister of Health, Labour and Welfare may rescind the Supplier's license or order the Supplier to cease all or part of its operations for a fixed period not exceeding six months.

- (i) Any of (a), (b), or (d) of Article 31, Item 4 applies to the agency.
- (ii) The supplier violates the provisions of this chapter.
- (iii) The supplier violates an order issued under Article 39.

(Subsidy)

Article 42 The national government may, within budgetary limits, provide subsidies for part of the expenses necessary for cord blood supply services to Cord Blood Suppliers.

(Assistance from the Minister of Health, Labour and Welfare)

Article 43 The Minister of Health, Labour and Welfare shall endeavor to provide appropriate advice, guidance, and other assistance to Cord Blood Suppliers to ensure the quality of cord blood used in transplantations and promote the proper provision of cord blood for use in transplantations.

Chapter 6 Hematopoietic Stem Cell Provision Support Organizations

(Designation of Support Organization)

Article 44 The Minister of Health, Labour and Welfare may designate a legal person whose purpose is not profit and which is found to be able to conduct in a proper and reliable manner the services prescribed in the items of the next article (hereinafter, “support services”) as a hematopoietic stem provision support organization (hereinafter, “Support Organization”) in response to an application therefrom, limited to one throughout the country.

2 The Minister of Health, Labour and Welfare, when making the designation prescribed in the preceding paragraph, shall publicly notify the name, address, and office locations of the Support Organization.

3 When the Support Organization intends to change that name, address, or office locations, it shall notify the Minister of Health, Labour and Welfare to that effect in advance.

4 The Minister of Health, Labour and Welfare shall, when notified pursuant to the provision of the preceding paragraph, publicly notify matters related to said notification.

(Support Organization Services)

Article 45 The Support Organization shall perform the following services.

(i) Provide necessary cooperation for the registration of persons who intend to donate bone marrow or peripheral blood stem cells for use in transplantations, and other bone marrow and peripheral blood stem cell services and cord blood supply services performed by hematopoietic stem cell related businesses.

(ii) Perform the necessary liaison and coordination work for bone marrow and peripheral blood stem cell services and cord blood supply services performed by hematopoietic stem cell related businesses.

- (iii) Manage in an integrated fashion information on bone marrow for use in transplantations and peripheral blood stem cells for use in transplantations for persons registered in item (i), and information on cord blood for use in transplantations provided by a Cord Blood Supplier pursuant to the provisions of Article 34, and provide this information to physicians planning to perform hematopoietic stem cell transplantation and other people who need hematopoietic stem cells used in transplantations.
- (iv) Disseminate information and raise awareness of providing hematopoietic stem cells for use in transplantation

(Confidentiality Obligations)

Article 46 Support Organization officers, employees, and former employees shall not, without justifiable grounds, divulge any confidential information on people obtained in performing the support services.

(Keeping of Records)

Article 47 The Support Organization shall keep and preserve, pursuant to the provisions of Ministry of Health, Labour and Welfare ordinances, books recording the matters with respect to support services which are specified by Ministry of Health, Labour and Welfare ordinances.

(Collection of Reports)

Article 48 The Minister of Health, Labour and Welfare may, as far as it is necessary to ensure the proper implementation of support services, request necessary reports from the Support Organization on its support services, or have an official of the Ministry enter the offices or other facilities of the support organization and inspect the situation of the support services or books, documents, or other materials or to question relevant persons.

2 Each employee who inspects a site or asks questions pursuant to the provisions of the preceding paragraph shall carry an identification card and present it to relevant persons.

3 The authority to conduct on-site inspections and questioning under paragraph (1) shall not be construed as having been granted for the purpose of investigating crime.

(Supervision Order)

Article 49 The Minister of Health, Labour and Welfare may, as far as it is necessary to ensure the proper implementation of support services, issue to the Support Organization orders that are necessary for supervision of support services.

(Suspension or Discontinuation of Operations)

Article 50 The Support Organization may not, without approval from the Minister of Health, Labour and Welfare, suspend or discontinue some or all support services.

(Rescindment of Designation)

Article 51 When any of the following items apply to the support organization, the Minister of Health, Labour and Welfare may rescind its designation pursuant to the provisions of Article 44, Paragraph 1.

(i) The Support Organization is seen to be unable to implement support services in a proper and reliable manner.

(ii) The Support Organization violates an order issued under Article 49.

2 When the designation is rescinded pursuant to the provisions of the preceding paragraph, the Ministry of Health, Labour and Welfare shall publicly notify that fact.

(Subsidy)

Article 52 The national government may, within budgetary limits, provide subsidies for part of the expenses necessary for support services to the Support Organization.

Chapter 7 Miscellaneous Provisions

(Transitional Measures)

Article 53 In cases where an ordinance of the Ministry of Health, Labour and Welfare is established, revised or abolished on the basis of the provisions of this Act, necessary transitional measures (including transitional measures on penal provisions) may be provided by such ordinance of the Ministry of Health, Labour and Welfare within the scope reasonably considered necessary as a result of such establishment, revision or abolition.

(Delegation to Ministry of Health, Labour and Welfare Ordinance)

Article 54 In addition to what is provided for in this Act, procedures for the implementation of this Act and other matters necessary for the enforcement of this Act shall be specified by Ministry of Health, Labour and Welfare ordinance.

Chapter 8 Penal Provisions

Article 55 A person to whom any of the following items applies shall be punished by imprisonment with work for not more than three years or a fine of not more than three million yen, or both.

- (i) A person who performs bone marrow or peripheral blood stem cell services without receiving approval under Article 17.
- (ii) A person who performs cord blood supply services without receiving approval under Article 30.

Article 56 A person who violates the order to suspend the operations pursuant to the provisions in Article 56 or Article 27 shall be punished by imprisonment with work for not more than one year or a fine not more than one million yen, or both.

Article 57 A person who has divulged confidential information in violation of Article

22, Article 36, or Article 46 shall be punished by imprisonment with work for not more than one year or a fine of not more than one million yen.

Article 58 A person who has violated an order pursuant to the provisions of Article 25 or Article 39 shall be punished by a fine not exceeding one million yen.

Article 59 A person to whom any of the following items applies shall be punished by a fine of not more than five hundred thousand yen.

(i) A person who, in violation of the provisions of Article 23 or Article 37, fails to keep books or make entries in books, makes false entries, or fails to preserve books.

(ii) A person who fails to make a report pursuant to the provisions of Article 24, Paragraph (1) or Article 38, Paragraph (1), makes a false report, or refuses, interferes with, or avoids inspection pursuant to the provisions of Article 24, Paragraph (1) or Article 38, Paragraph (1), or fails to answer a question pursuant to the provisions of Article 24, Paragraph (1) or Article 38, Paragraph (1), or gives a false answer.

(iii) A person who fails to make a notification pursuant to the provisions of Article 26 or Article 40, or makes a false notification.

Article 60 The officers or employees of the Support Organization have committed violations in which any of the following items apply shall be punished by a fine of not more than five hundred thousand yen.

(i) A person who, in violation of the provisions of Article 47, fails to keep books or make entries in books, makes false entries, or fails to preserve books.

(ii) A person who fails to make a report pursuant to the provisions of Article 48, Paragraph (1), makes a false report, or refuses, interferes with, or avoids inspection pursuant to the provisions of the same paragraph, or fails to answer a question pursuant to the provisions of the same paragraph, or gives a false answer.

(iii) A person who discontinues all support services without receiving the approval of Article 50.

Article 61 When a representative or manager of a legal person, or an agent, an employee, or any other worker in the service of a legal person or of an individual has, with regard to the business of the said legal person or individual, committed a violation stipulated in Article 55, Article 56, Article 58 or Article 59, not only the offender shall be punished but also the said legal person or the said individual shall be punished by fines as prescribed in the respective articles.

2 In the case where an organization that is not a legal person is punished pursuant to the provisions of the preceding paragraph, the representative or an administrator thereof shall represent that organization with regard to the said legal action, and the provisions of laws concerning criminal procedures in cases where a legal person is the accused or a suspect shall apply *mutatis mutandis*.

Supplementary provisions

(Enforcement Date)

Article 1 This Act shall come into force as from the day specified in the applicable cabinet order within a period not exceeding one year and six months counting from the day of promulgation. However, the provisions listed in the following items shall come into force as from the day specified in those items.

(i) Supplementary provision, Article 4 Date of promulgation

(ii) Provisions of next Article A date prescribed by cabinet order within a period not exceeding one year from the day of promulgation

(Preparations)

Article 2 The designation set forth in the provisions of Article 44, Paragraph (1), procedures necessary for this, and other actions may be governed by the provisions of the same article even if prior to the enforcement of this Act.

(Transitional Measures for Bone Marrow and Peripheral Blood Stem Cell Agencies and Cord Blood Suppliers)

Article 3 At the time of enforcement of this Act, persons serving as Bone Marrow and Peripheral Blood Stem Cell Agencies or Cord Blood Suppliers may continue providing bone marrow and peripheral blood stem cell services or cord blood services notwithstanding the provisions of Article 17 and Article 30 for 30 days from the date of enactment of this Act (when a disposition is made not to approve an application under Article 17 or Article 30 within that period, the time until the date of said disposition). In the case that such persons apply for approval according to the provisions of Article 17 and Article 30 within this period, this continues to apply at the conclusion of that period for the period until a disposition is made to grant or not to grant approval of that application.

(Delegation of Other Transitional Measures to Cabinet Order)

Article 4 In addition to the provisions of the preceding two articles, necessary transitional measures related to the enforcement of this Act shall be specified by cabinet order.

(Review)

Article 5 With regard to the provisions of this Act, if it is deemed necessary to consider the status of the enforcement of this Act after this Act has been in effect for three years, a review shall be made and necessary measures shall be taken based on the results.

(Partial Revision of the Act for Establishment of the Ministry of Health, Labour and Welfare)

Article 6 The Act for Establishment of the Ministry of Health, Labour and Welfare (Act No. 97 of 1999) is partially revised as follows.

The following item is added following Article 4, Paragraph 1, Item 20.

22 Matters related to hematopoietic stem cell transplantation.