BLOOD MANAGEMENT ACT

[Enforcement Date 04. Aug, 2016.] [Act No.14012, 03. Feb, 2016., Partial Amendment]

보건복지부 (생명윤리정책과)044 - 202 - 2943

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Article 1 (Purpose)

The purpose of this Act is to provide for matters necessary for blood management work for the protection of blood donors and recipients as well as appropriate blood management, thereby contributing to the improvement of national health.

[This Article Wholly Amended by Act No. 11525, Oct. 22, 2012]

Article 2 (Definitions)

The definitions of terms used in this Act shall be as follows:

1. The term "blood" means blood cells and plasma collected from the human body;
2. The term "blood management work" means work including the collection, testing, manufacturing, preservation, supply, and quality control of blood necessary for blood transfusions or for manufacturing blood products;
3. The term "blood center" means a person who obtains permission pursuant to Article 6 (3) in order to perform blood management work;
4. The term "blood donor" means a person who provides a blood center with his/her blood free of charge;
5. The term "blood unfit for use" means blood or blood products prescribed by Ordinance of the Ministry of Health and Welfare in which abnormalities are found at the time of or after collecting blood;
6. The term "person ineligible to donate blood" means a person who falls short of health standards, such as a patient with an infectious disease or a patient who take medication, who is prescribed by Ordinance of the Ministry of Health and Welfare as unfit to donate blood;
7. The term "specific side effect from blood transfusion" means any side effect caused by transfused blood products, which is prescribed by Ordinance of the Ministry of Health and Welfare;
8. The term "blood product" means any of the following medications defined in Article 2 of the Pharmaceutical Affairs Act which is made of blood as its raw material:

(a) Whole blood;
(b) Concentrated red blood cells;
(c) Fresh frozen plasma;
(d) Concentrated platelets;
(e) Other blood-related medications prescribed by Ordinance of the Ministry of Health and Welfare;

9. The term "deposit on blood donation" means a deposit made by a blood center to the Minister of Health and Welfare to compensate for expenses incurred in blood transfusions or to use for blood donation projects pursuant to Article 14 (4);
10. The term "blood collection" means the collection of blood from a blood donor to manufacture blood products used for blood transfusions, etc.;
11. The term "side effect from blood collection" means any unexpected side effect, such as vasovagal response or subcutaneous hemorrhage, which may occur to a blood donor after collecting blood.

[This Article Wholly Amended by Act No. 11525, Oct. 22, 2012]

Article 3 (Prohibition against Blood Transactions, etc.) (1) No person shall provide or promise to provide his/her blood (including a blood donor card referred to in Article 14) upon obtaining or promising to obtain any monetary or property interests, or other compensatory benefits.

(2) No person shall be provided with or promise to be provided with blood (including a blood donor card referred to in Article 14) of any third person upon giving or promising to give any monetary or property interests, or other compensatory benefits.

(3) No person shall instigate, assist or mediate any act violating paragraph (1) or (2).

(4) When a person becomes aware that any act violating paragraph (1) or (2) has been done, he/she shall not collect or transfuse blood related to such act.

[This Article Wholly Amended by Act No. 11525, Oct. 22, 2012]

Article 4 (Encouragement, etc. of Blood Donation) (1) The Minister of Health and Welfare may encourage healthy people to donate their blood.

(2) The Minister of Health and Welfare may fully or partially subsidize blood centers for expenses incurred in conducting blood management work.

(3) Matters necessary for encouraging blood donations shall be prescribed by Presidential Decree.

[This Article Wholly Amended by Act No. 11525, Oct. 22, 2012]

Article 4-2 (Protection, Duties, etc. of Blood Donors) (1) A blood donor shall be held in esteem as a person practicing a noble humanitarian spirit at the site of blood donation.

(2) A blood donor shall honestly and conscientiously provide information on his/her medical history and physical conditions in order to ensure the collection and supply of safe blood.

(3) A blood center shall collect blood from blood donors in a pleasant and safe environment.

(4) A blood center shall explain to a blood donor about matters that require attention concerning blood donation so that he/she may donate blood of his/her own volition, and obtain his/her consent to blood donation.

(5) Questions and answers about health by interview to determine whether a person is eligible to donate blood shall be recorded in an environment in which his/her privacy can be protected.

(6) A blood center shall carefully observe whether a side effect from blood collection occurs, and take necessary measures to prevent any side effect from blood collection.

(7) Where any side effect from blood collection occurs to a blood donor, a blood center shall, without delay, take appropriate measures for such blood donor.

(8) Except as otherwise expressly provided in paragraphs (1) through (7), matters necessary for protecting blood donors shall be prescribed by Presidential Decree.

[This Article Wholly Amended by Act No. 11525, Oct. 22, 2012]

Article 5 (Establishment and Operation of Blood Management Committee) (1) A Blood Management Committee (hereinafter referred to as the "Committee") shall be established under the jurisdiction of the Minister of Health and Welfare to deliberate on the following regarding blood management:

1. A plan to improve the blood management system and promote blood donations;
2. A plan to utilize a reserve for refund on blood donation under Article 15 (2);

3. Adjustment of the prices of blood;
4. Matters concerning the supply of and demand for blood products and the safety thereof;
5. Mattes concerning the opening of blood centers and the review and assessment of blood management work;
6. Matters concerning specific side effects from blood transfusions;
7. Other matters concerning blood management referred by the Minister of Health and Welfare to the Committee.

(2) The Committee shall be comprised of no more than 15 members, including one chairperson and one vice chairperson, and the term of office of members shall be two years: Provided, That the term of office of a public official member shall be the period during which he/she holds office.

(3) The chairperson of the Committee shall be appointed by the Minister of Health and Welfare from among those who have knowledge of and administrative experience in blood management, and have firm cognizance of bioethics.

(4) Except as otherwise expressly provided for in paragraph (1) through (3), matters necessary for the composition and operation of the Committee shall be prescribed by Presidential Decree.

[This Article Wholly Amended by Act No. 11525, Oct. 22, 2012]

Article 6 (Blood Management Work) (1) Only the following persons may engage in blood management work: Provided, That a person who falls under subparagraph 3 shall not conduct the collection of blood among blood management work:

1. A medical institution established under the Medical Service Act (hereinafter referred to as "medical institution");
2. The Korean National Red Cross established under the Organization of the Korean National Red Cross Act (hereinafter referred to as the "Korean Red Cross");
3. A manufacturer of blood products prescribed by Ordinance of the Ministry of Health and Welfare.

(2) A person who engages in blood management work pursuant to paragraph (1) 1 or 2 shall have the facilities and equipment satisfying the standards prescribed by Ordinance of the Ministry of Health and Welfare.

(3) A person who falls under paragraph (1) 1 or 2 and intends to open a blood center shall obtain permission from the Minister of Health and Welfare, as prescribed by Ordinance of the Ministry of Health and Welfare. The same shall also apply where he/she intends to revise any important matters prescribed by Ordinance of the Ministry of Health and Welfare among matters permitted.

(4) A person who intends to engage in blood management work shall obtain permission to conduct business of manufacturing medicines pursuant to Article 31 of the Pharmaceutical Affairs Act, and shall either obtain permission for individual items or file reports on individual items.

[This Article Wholly Amended by Act No. 11525, Oct. 22, 2012]

Article 6-2 (Prohibition, etc. from Blood Management Work) (1) A person who fails to obtain permission from the Minister of Health and Welfare pursuant to Article 6 (3) shall be prohibited from performing blood management work: Provided, That this shall not apply to a person who falls under Article 6 (1) 3.

(2) No entity that fails to obtain permission as a blood center pursuant to this Act shall use the name of a blood center or other name similar thereto.

[This Article Wholly Amended by Act No. 11525, Oct. 22, 2012]

Article 6-3 (Manufacturing Managers, etc. of Blood Products) (1) A blood center shall have at least one medical doctor to manage the manufacture of blood products, such as testing of blood, manufacture and preservation of blood products.

(2) A person who manages the manufacture of blood products (hereinafter referred to as "manufacturing manager") pursuant to paragraph (1) shall observe matters concerning the direction and supervision of persons engaged in the manufacture of blood products, and matters concerning the quality control of blood products, management of manufacturing facilities and other matters prescribed by Ordinance of the Ministry of Health and Welfare concerning the manufacturing management of blood products.

(3) The head of a blood center, etc. shall not interfere with the management work of a manufacturing manager, and if a manufacturing manager requests matters necessary for performing his/her duties, the head of the blood center shall not refuse such request without any justifiable grounds.

[This Article Wholly Amended by Act No. 11525, Oct. 22, 2012]

Article 6-4 (Reporting on Suspension, etc. of Business of Blood Centers) (1) When a person who has opened a blood center intends to suspend, discontinue, or resume his/her business, he/she shall report thereon, as prescribed by Ordinance of the Ministry of Health and Welfare.

(2) When a person who has opened a blood center intends to report on the discontinuation or suspension of his/her business pursuant to paragraph (1), he/she shall transfer blood management work records, etc. prepared and kept pursuant to Article 12 or 12-2 to the President of the Korean Red Cross: Provided, That where a person who has opened a blood center submits a plan to keep blood management work records, etc. and obtains permission from the Minister of Health and Welfare, as prescribed by Ordinance of the Ministry of Health and Welfare, he/she may keep such records.

[This Article Wholly Amended by Act No. 11525, Oct. 22, 2012]

Article 7 (Identity Verification, Health Examinations, etc. of Blood Donors) (1) A blood center shall verify the identity and conduct a health examination of a blood donor prior to collecting blood, as prescribed by Ordinance of the Ministry of Health and Welfare.

(2) No blood center shall collect blood from any patient with an infectious disease or any other person who falls short of health standards prescribed by Ordinance of the Ministry of Health and Welfare.

(3) No blood center shall collect blood from any person whose identity is unverified or who fails to comply with a request necessary for identity verification.

(4) When the Minister of Health and Welfare deems it necessary to guarantee the safety of blood products, he/she may request the head of the relevant central administrative agency or the head of the relevant public institution to provide blood centers, etc. with the relevant information on patients with an infectious disease, patients who take medicine, etc. In such cases, the head of the relevant central administrative agency or the head of the relevant public institution shall comply with such request unless any justifiable grounds exist.

(5) Before collecting blood from a blood donor, a blood center shall make inquiries as to whether he/she is ineligible to donate blood, his/her blood donation history and the

results of his/her blood tests, as prescribed by Ordinance of the Ministry of Health and Welfare: Provided, That this shall not apply to cases prescribed by Ordinance of the Ministry of Health and Welfare, such as a natural disaster or emergency blood transfusion.

(6) Specific matters regarding the limits of providing information, inquiries, etc. under paragraphs (4) and (5) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Wholly Amended by Act No. 11525, Oct. 22, 2012]

Article 7-2 (Management of Persons Ineligible to Donate Blood) (1) The Minister of Health and Welfare may create and manage a list of persons ineligible to donate blood, as prescribed by Ordinance of the Ministry of Health and Welfare.

(2) No blood center shall collect blood from any person ineligible to donate blood.

(3) Notwithstanding paragraph (2), a blood center may collect blood from a person ineligible to donate blood who has passed a safety test prescribed by Ordinance of the Ministry of Health and Welfare. In such cases, the blood center shall report the results thereof to the Minister of Health and Welfare, as prescribed by Ordinance of the Ministry of Health and Welfare.

(4) The Minister of Health and Welfare may individually notify a person on the list of persons ineligible to donate blood of details, etc. on the list, as prescribed by Presidential Decree.

(5) No one who is or was engaged in affairs creating and managing a list of persons ineligible to donate blood under paragraph (1) shall divulge any confidential information he/she has learned in the course of conducting such affairs, without any justifiable grounds.

[This Article Wholly Amended by Act No. 11525, Oct. 22, 2012]

Article 8 (Securing Safety of Blood, etc.) (1) A blood center shall test whether blood and blood products are fit for use and confirm the results thereof in the following manners: <Amended by Act No. 14012, Feb. 3, 2016>

1. Blood collection from a blood donor;
2. Testing whether prohibited medication for blood donation prescribed by Ordinance of the Ministry of Health and Welfare was taken.

(2) When a person who engages in blood management work, such as a blood center, (hereinafter referred to as "blood center, etc.") finds blood unfit for use as a result of tests conducted under paragraph (1), he/she shall discard such blood, as prescribed by Ordinance of the Ministry of Health and Welfare, and report the results thereof to the Minister of Health and Welfare: Provided, That this shall not apply to cases prescribed by Presidential Decree, such as the use of blood unfit for use as a raw material of vaccines.

(3) Criteria for determining whether blood and blood products are fit for use under paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

(4) Where a blood center finds blood unfit for use as a result of tests conducted under paragraph (1) 2, but such blood was already delivered to a medical institution, it shall notify, without delay, the relevant medical institution of the matters regarding the blood unfit for use and take measures to discard such blood unit unfit for use. <Newly Inserted by Act No. 14012, Feb. 3, 2016>

(5) When an accident is likely to occur or occurs due to a transfusion, etc. of blood unfit for use, a blood center shall notify a person who received a blood transfusion thereof. <Newly Inserted by Act No. 14012, Feb. 3, 2016>

(6) A blood center shall report information on blood donors and their blood tests to the Minister of Health and Welfare, as prescribed by Ordinance of the Ministry of Health and Welfare.

(7) The Minister of Health and Welfare shall appropriately keep and manage information on blood donors and their blood tests reported pursuant to paragraph (6). <Amended by Act No. 14012, Feb. 3, 2016>

(8) Matters necessary for conducting tests for determining whether blood and blood products are fit for use pursuant to paragraph (1) and taking measures at the time of occurrence of blood unfit for use pursuant to paragraphs (4) and (5), shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Newly Inserted by Act No. 14012, Feb. 3, 2016>

[This Article Wholly Amended by Act No. 11525, Oct. 22, 2012]

Article 8-2 (Measures, etc. at Time of Occurrence of Blood Accidents) (1) When an accident is likely to occur or occurs due to a transfusion, etc. of blood unfit for use,

the Minister of Health and Welfare may take necessary measures, such as disposal of related blood and blood products, or order a blood center, etc. to take such measures, as prescribed by Ordinance of the Ministry of Health and Welfare.

(2) If the Minister of Health and Welfare deems necessary when he/she takes measures under paragraph (1) or issues an order to take such measures, he/she may request cooperation from related administrative agencies, such as the Minister of Food and Drug Safety. <Amended by Act No. 11690, Mar. 23, 2013>

(3) The Minister of Health and Welfare may formulate and implement guidelines for performing the duties of related agencies required for measures and cooperation provided for in paragraphs (1) and (2), and the relevant agencies shall faithfully implement such guidelines, unless justifiable grounds exist.

[This Article Wholly Amended by Act No. 11525, Oct. 22, 2012]

Article 9 (Management, etc. of Blood) (1) A blood center, etc. shall conduct blood management work in compliance with the standards prescribed by Ordinance of the Ministry of Health and Welfare, such as the volume of blood drawn at the time of collection, and the optimal temperature for blood management.

(2) A blood center may operate blood supply vehicles in order to ensure the safe and prompt supply of the collected blood.

(3) Specific matters concerning the types, marks and internal equipment of blood supply vehicles referred to in paragraph (2) and other matters shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Wholly Amended by Act No. 11525, Oct. 22, 2012]

Article 10 (Measures against Specific Side Effects from Blood Transfusion) (1) Where any specific side effect from blood transfusion occurs, the head of the relevant medical institution shall file a report on such fact with the Minister of Health and Welfare, as prescribed by Ordinance of the Ministry of Health and Welfare.

(2) Upon receipt of a report on the occurrence of any specific side effect from blood transfusion filed under paragraph (1), the Minister of Health and Welfare shall conduct a fact-finding survey to comprehend the cause thereof. In such cases, the head of a medical institution and the head of a blood center, etc. involved in such specific side effect from blood transfusion shall cooperate in the fact-finding survey.

[This Article Wholly Amended by Act No. 11525, Oct. 22, 2012]

Article 10-2 (Indemnity for Specific Side Effects from Blood Transfusion and Side Effects from Blood Collection) (1) A blood center may pay an indemnity for a specific side effect from blood transfusion and a side effect from blood collection (hereinafter referred to as "indemnity") to any of the following:

1. A person having a side effect from blood collection who contracts a disease or died of a blood donation which is the direct cause of such disease or death;
2. A person having a specific side effect from blood transfusion who contracts a disease or died of blood supplied by a blood center, which is the direct cause of such disease or death.

(2) Indemnities referred to in paragraph (1) shall be determined by the deliberation of the Committee, and where the indemnities are determined, the chairperson shall notify a blood center of the deliberation result without delay.<Newly Inserted by Act No. 14012, Feb. 3, 2016>

(3) Notwithstanding paragraph (1), indemnities may not be paid in any of the following cases:<Newly Inserted by Act No. 14012, Feb. 3, 2016>

1. Where a side effect from blood collection occurs due to the intent or gross negligence of the blood donor himself/herself;
2. Where a person who was determined as having a side effect from blood collection or his/her family member files a damage suit, etc. or expresses his/her intention to file such suit.

(4) The scope of indemnities that may be paid pursuant to paragraph (1) shall be as follows: Provided, That where there is no negligence of a blood center in the process of supplying blood, only consolation money referred to in subparagraph 6 may be paid:<Newly Inserted by Act No. 14012, Feb. 3, 2016>

1. Medical expenses;
2. Lump-sum compensation for a person who became disabled;
3. Lump-sum compensation for a person who died;
4. Funeral service expenses;
5. Future income losses;
6. Consolation money.

(5) Other matters necessary for the calculation, payment, etc. of indemnities, shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 14012, Feb. 3, 2016>

[This Article Wholly Amended by Act No. 11525, Oct. 22, 2012]

Article 11 (Prices of Blood Products)

The prices of blood products manufactured by a blood center with blood collected from blood donors and supplied to a medical institution, and the prices of blood products supplied to a blood recipient by the medical institution supplied with blood products by the blood center shall be determined and announced by the Minister of Health and Welfare.

[This Article Wholly Amended by Act No. 11525, Oct. 22, 2012]

Article 12 (Preparation, etc. of Records) (1) A blood center, etc. shall prepare and keep records on blood management work, as prescribed by Ordinance of the Ministry of Health and Welfare.

(2) Records (including electronic records on blood management referred to in Article 12-2 (1)) referred to in paragraph (1) shall be kept for a period prescribed by Ordinance of the Ministry of Health and Welfare from the date of preparation.

(3) No one who is engaged in blood management work shall divulge or announce confidential information about any third person, such as medical examinations, blood collection and tests, he/she has learned in the course of conducting such affairs, except as otherwise expressly provided for in this Act or other statutes.

[This Article Wholly Amended by Act No. 11525, Oct. 22, 2012]

Article 12-2 (Electronic Records, etc. on Blood Management) (1) A blood center, etc. may prepare and keep the registers of blood donors, etc. in the form of electronic documents, etc. bearing electronic signatures as provided for in the Digital Signature Act (hereinafter referred to as "electronic records on blood management").

(2) A blood center, etc. shall have facilities, equipment, etc. necessary for the safe management and preservation of electronic records on blood management work.

(3) No one shall detect, leak, alter or damage any personal information stored in the electronic records on blood management work without any justifiable grounds.

[This Article Wholly Amended by Act No. 11525, Oct. 22, 2012]

Article 13 (Inspection, etc.) (1) When the Minister of Health and Welfare deems it necessary for the quality control of blood, he/she may require a blood center, etc. to file necessary reports or require related public officials to enter its office, place of business or other necessary places to inspect books, documents and others, as prescribed by Presidential Decree.

(2) A public official who has access to or conducts an inspection pursuant to paragraph (1) shall produce a certificate of character indicating his/her authority to persons involved.

(3) The Minister of Health and Welfare may review and assess blood management work of a blood center, as prescribed by Presidential Decree, in order to ensure the safety and enhance effectiveness of blood products.

[This Article Wholly Amended by Act No. 11525, Oct. 22, 2012]

Article 14 (Issuance of Blood Donor Cards and Compensation, etc. for Expenses Incurred in Blood Transfusions) (1) When a blood center obtains blood from a blood donor, it shall issue a blood donor card to the blood donor, as prescribed by Ordinance of the Ministry of Health and Welfare.

(2) A blood donor referred to in paragraph (1) or a person to whom a blood donor card has been transferred by the blood donor may receive a transfusion of blood products free of charge if he/she submits such blood donor card to a medical institution.

(3) No medical institution in receipt of a request to provide a blood transfusion pursuant to paragraph (2) shall refuse the request without any justifiable reasons.

(4) Where a medical institution has provided a blood transfusion to a person who submitted a blood donor card pursuant to paragraph (2), the Minister of Health and Welfare shall compensate the relevant medical institution for expenses incurred in such blood transfusion from a reserve for refund on blood donation provided for in Article 15 (2), as prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Wholly Amended by Act No. 11525, Oct. 22, 2012]

Article 15 (Deposits on Blood Donation and Reserves for Refund on Blood Donation Return) (1) When a blood center obtains blood from a blood donor, it shall make a

deposit on blood donation to the Minister of Health and Welfare, as prescribed by Ordinance of the Ministry of Health and Welfare: Provided, That where the donated blood is found unfit for use as a result of tests conducted under Article 8 (1), he/she may fully or partially refund a deposit on blood donation or exempt it therefrom.

(2) The Minister of Health and Welfare shall create and manage a reserve for refund on blood donation (hereinafter referred to as "reserve") with deposits on blood donation referred to in paragraph (1).

(3) The Minister of Health and Welfare shall use a reserve only for the following purposes:

1. Compensation for expenses incurred in blood transfusions under Article 14 (4);
2. Encouragement of blood donations;
3. Research related to blood management;
4. Other purposes prescribed by Presidential Decree.

(4) Matters necessary for the management and operation of a reserve and other matters shall be prescribed by Presidential Decree.

[This Article Wholly Amended by Act No. 11525, Oct. 22, 2012]

Article 16 (Special Cases concerning Military Medical Institutions)

Blood management work of a blood center established in a military medical institution shall be prescribed by Ordinance of the Ministry of National Defense after the Minister of National Defense consults with the Minister of Health and Welfare, notwithstanding Articles 4, 6, 8, 8-2, 9, 10, 12, 12-2 and 13 through 15.

[This Article Wholly Amended by Act No. 11525, Oct. 22, 2012]

Article 17 (Delegation, Entrustment, etc. of Authority) (1) The Minister of Health and Welfare may partially delegate his/her authority bestowed under this Act, to the Special Metropolitan City Mayor, a Metropolitan City Mayor, a Metropolitan Autonomous City Mayor, a Do Governor, or a Special Self-Governing Province Governor, as prescribed by Presidential Decree.

(2) The Minister of Health and Welfare may entrust the following affairs bestowed under this Act, to the President of the Korean Red Cross, as prescribed by Presidential Decree:<Amended by Act No. 14012, Feb. 3, 2016>

1. Affairs regarding the preparation, management, and notification of lists of persons ineligible to donate blood prescribed in Article 7-2 (1) and (4);

2. Affairs regarding the management of blood information on blood donors prescribed in Article 8 (6) and (7);
3. Affairs regarding compensation prescribed in Article 14 (4);
4. Affairs regarding the receipt of deposits on blood donation prescribed in Article 15 (1);
5. Affairs regarding the creation and management of a reserve prescribed in Article 15 (2).

(3) The Minister of Health and Welfare may subsidize expenses incurred in conducting affairs entrusted to the President of the Korean Red Cross pursuant to paragraph (2) and the following affairs conducted by the President of the Korean Red Cross within budgetary limits each year:

1. The preservation of records on blood management (including electronic records on blood management) transferred by a person who has opened a blood center pursuant to Article 6-4 (2);
2. Inquiries about the blood donation history of blood donors;
3. Affairs concerning the management of blood information on blood donors;
4. Affairs concerning the issuance of blood donor cards and compensation for expenses incurred in blood transfusions under Article 14.

[This Article Wholly Amended by Act No. 11525, Oct. 22, 2012]

Article 17-2 (Revocation, etc. of Permission for Opening) (1) Where a blood center falls under any of the following, the Minister of Health and Welfare may revoke permission for opening the blood center or order it to suspend its business or to correct any violation within the period of six months: <Amended by Act No. 12073, Aug. 13, 2013>

1. Where it fails to commence its business without any justifiable grounds though three months have passed from the date it obtains permission for opening;
2. Where facilities of a blood center which has obtained permission for opening fail to meet standards for facilities and equipment referred to in Article 6 (2);
3. Where it fails to employ a manufacturing manager;
4. Where an inspection conducted under Article 13 (1) or the review of assessment conducted under paragraph (3) of the same Article has found the blood management work by a blood center to be inappropriate;

5. Where it violates this Act or any order issued under this Act.

(2) Detailed standards for administrative disposition specified in paragraph (1) shall be determined by Ordinance of the Ministry of Health and Welfare.<Newly Inserted by Act No. 12073, Aug. 13, 2013>

[This Article Wholly Amended by Act No. 11525, Oct. 22, 2012]

Article 17 - 3 (Exclusion from Application)

Where a blood center opened by a person falling under Article 6 (1) 1 supplies blood products for its own consumption, Articles 6 (4) and 6 - 3 shall not apply thereto.

[This Article Wholly Amended by Act No. 11525, Oct. 22, 2012]

Article 18 (Penalty Provisions)

Any of the following persons shall be punished by imprisonment with labor for not more than five years or by a fine not exceeding 20 million won:

1. A person who is engaged in blood transactions, etc., in violation of Article 3;
2. A person who engages in blood management work though he/she is not eligible to conduct blood management work, in violation of Article 6 (1);
3. A person who opens a blood center without permission or revises an important matter without permission to make a revision, in violation of Article 6 (3);
4. A person who performs blood management work without permission to conduct business of manufacturing medicines or conducts blood management work without permission for individual items or without reporting individual items, in violation of Article 6 (4);
5. A person who conducts blood management work without permission, in violation of Article 6 - 2 (1).

[This Article Wholly Amended by Act No. 11525, Oct. 22, 2012]

Article 19 (Penalty Provisions)

Any of the following persons shall be punished by imprisonment with labor for not exceeding two years or by a fine not exceeding five million won:<Amended by Act No. 14012, Feb. 3, 2016>

1. A person who fails to have facilities and equipment meeting standards prescribed by Ordinance of the Ministry of Health and Welfare, in violation of Article 6 (2);

2. A person who fails to verify the identity or conduct a physical examination of a blood donor before collecting blood, in violation of Article 7 (1);
3. A person who collects blood from a patient with an infectious disease or any person who falls short of health standards prescribed by Ordinance of the Ministry of Health and Welfare, in violation of Article 7 (2);
4. A person who collects blood from any person whose identity is not verified or who fails to comply with a request necessary for identity verification, in violation of Article 7 (3);
5. A person who fails to make inquiries before collecting blood as to whether a blood donor is ineligible to donate blood, his/her blood donation history or the results of his/her blood tests, in violation of Article 7 (5);
6. A person who collects blood from any person ineligible to donate blood who has failed to pass a safety test prescribed by Ordinance of the Ministry of Health and Welfare, in violation of Article 7-2 (2), or who fails to report the results of blood collection to the Minister of Health and Welfare after collecting blood from any person ineligible to donate blood who has passed a safety test, in violation of Article 7-2 (3);
7. A person who divulges confidential information he/she has learned in the course of preparing and managing the lists of persons ineligible to donate blood without justifiable grounds, in violation of Article 7-2 (5);
8. A person who fails to test whether blood and blood products are fit for use, or to confirm the results of tests, as prescribed by Ordinance of the Ministry of Health and Welfare, in violation of Article 8 (1);
9. A person who fails to discard blood unfit for use or to report the results of discarding to the Minister of Health and Welfare, as prescribed by Ordinance of the Ministry of Health and Welfare, in violation of Article 8 (2);
9-2. A person who fails to notify the information on blood unfit for use to the relevant medical institution, or to discard blood unfit for use, in violation of Article 8 (4);
9-3. A person who fails to notify a person who received a blood transfusion of blood unfit for use of such fact, in violation of Article 8 (5);
10. A person who fails to conduct blood management work according to standards prescribed by Ordinance of the Ministry of Health and Welfare, such as the volume

of blood drawn at the time of collection and the optimal temperature for blood management, in violation of Article 9 (1);

11. A person who divulges or announces confidential information about any third person which he/she has learned in the course of performing physical examinations, blood collection, and tests, in violation of Article 12 (3);
12. A person who detects, divulges, alters, or damages personal information stored in the electronic records of blood management without justifiable grounds, in violation of Article 12-2 (3).

[This Article Wholly Amended by Act No. 11525, Oct. 22, 2012]

Article 20 (Penalty Provisions)

Any of the following persons shall be punished by imprisonment with labor for not more than one year or by a fine not exceeding three million won:

1. A person who fails to issue a blood donor card to a blood donor, in violation of Article 14 (1), or who refuses to provide a transfusion service to any person who requests a transfusion of blood products free of charge upon submitting a blood donor card to a medical institution, in violation of Article 14 (3);
2. A person who fails to make a deposit on blood donation by deceit or other illegal means, in violation of Article 15 (1).

[This Article Wholly Amended by Act No. 11525, Oct. 22, 2012]

Article 21 (Penalty Provisions)

Any of the following persons shall be punished by a fine not exceeding one million won:

1. A person who violates Article 6-3 (2);
2. A person who supplies blood products in violation of the price of blood products announced pursuant to Article 11.

[This Article Wholly Amended by Act No. 14012, Feb. 3, 2016]

Article 22 (Joint Penalty Provisions)

If the representative of a corporation, or an agent, employee, or any other servant of the corporation or an individual commits an offence referred to in Articles 18 through 21 in connection with the affairs of the corporation or the individual, not only shall such offender be punished, but also the corporation or the individual shall be

punished by a fine under the relevant Article: Provided, That this shall not apply where such corporation or individual has not been negligent in giving considerable attention and supervision concerning the relevant affairs to prevent such offence.
[This Article Wholly Amended by Act No. 10611, Apr. 28, 2011]

Article 23 (Administrative Fines) (1) Any of the following persons shall be punished by an administrative fine not exceeding two million won: <Amended by Act No. 14012, Feb. 3, 2016>

1. A person who uses the name of a blood center or any other name similar thereto, in violation of Article 6 - 2 (2);
2. A person who fails to file a report, in violation of Article 8 (6), or files a false report;
3. A person who fails to file a report, in violation of Article 10 (1);
4. A person who fails to provide cooperation in a fact - finding survey, in violation of the latter part of Article 10 (2);
5. A person who fails to file a report under Article 13 (1) or files a false report, or refuses, evades, or interferes with an inspection.

(2) The Minister of Health and Welfare shall impose and collect administrative fines referred to in paragraph (1), as prescribed by Presidential Decree.
[This Article Wholly Amended by Act No. 11525, Oct. 22, 2012]

ADDENDA <No. 6555, 29. Dec, 2001>

This Act shall enter into force on July 1, 2002.

ADDENDA <No. 7145, 29. Jan, 2004>

(1) (Enforcement Date) This Act shall enter into force one year after the date of its promulgation.

(2) (Transitional Measures concerning Blood Centers) A person who is engaged in blood management work as at the time this Act enters into force may conduct blood management work only for one year from the date this Act enters into force, notwithstanding the amended provisions of Article 6 (4) or 6 - 2 (1).

(3) (Transitional Measures concerning Penalty Provisions) The application of penalty provisions to a violation already committed as at the time this Act enters into force shall be governed by the former provisions.

ADDENDA <No. 8365, 11. Apr, 2007>

Article 1 (Enforcement Date)

This Act shall come into force on the date of its promulgation. (Proviso Omitted.)
Articles 2 through 22 Omitted.

ADDENDA <No. 8852, 29. Feb, 2008>

Article 1 (Enforcement Date)

This Act shall enter into force on the date of its promulgation. (Proviso Omitted.)
Articles 2 through 7 Omitted.

ADDENDA <No. 9023, 28. Mar, 2008>

This Act shall enter into force one year after the date of its promulgation: Provided, That the amended provisions of Articles 7, 7 - 2 and 19 shall enter into force on the enforcement date of the partially amended Blood Management Act (Act No. 9387). <Amended by Act No. 9387, Jan. 30, 2009>

ADDENDA <No. 9387, 30. Jan, 2009>

This Act shall enter into force on the date of its promulgation.

ADDENDA <No. 9847, 29. Dec, 2009>

Article 1 (Enforcement Date)

This Act shall enter into force one year after the date of its promulgation.
Articles 2 through 22 Omitted.

ADDENDA <No. 9932, 18. Jan, 2010>

Article 1 (Enforcement Date)

This Act shall enter into force two months after the date of its promulgation. (Proviso Omitted.)

Articles 2 through 5 Omitted.

ADDENDA <No. 10611, 28. Apr, 2011>

This Act shall enter into force on the date of its promulgation.

ADDENDA <No. 11525, 22. Oct, 2012>

This Act shall enter into force on the date of its promulgation.

ADDENDA <No. 11690, 23. Mar, 2013>

Article 1 (Enforcement Date)

(1) This Act shall enter into force on the date of its promulgation.

(2) Omitted.

Articles 2 through 7 Omitted.

ADDENDA <No. 12073, 13. Aug, 2013>

Article 1 (Enforcement Date)

This Act shall enter into force on the date of its promulgation.

Article 2 (Applicability to Suspension of Business)

The amended provisions of Article 17 - 2 shall also apply to cases of administrative disposition against any violation committed before this Act enters into force.

ADDENDA <No. 14012, 03. Feb, 2016>

This Act shall enter into force six months after the date of its promulgation: Provided, That the amended provisions of Article 10-2 and 21 shall enter into force on the date of its promulgation.