

SIXTEENTH CONGRESS OF THE REPUBLIC
OF THE PHILIPPINES
First Regular Session

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Senate
Office of the Secretary

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SENATE
Senate Bill No. 1058

RECORDED BY: *ja*

INTRODUCED BY SEN. JINGGOY EJERCITO ESTRADA

EXPLANATORY NOTE

The lack of supply to satisfy the need for organs and tissues is a serious problem common to all programs in organ and tissue transplantation.

This bill seeks to establish a unified national system of organ sharing encompassing a patient registry to facilitate the success of organ transplantation and survival of patients by regulating the procurement of human organ and tissue transplantation. Some of the salient features of this bill are the following:

1. The establishment and maintenance of a Human Organ and Tissue Procurement and Transplantation Network. This shall be a national system which will facilitate the acquisition and transplantation of the same by individuals in need of receiving life-saving organ transplantation.
2. The creation of a Task Force which will conduct a study on all tissues and common problem area in the human organ and tissue procurement and transplantation.
3. The prohibition and punishment of individuals engaged in the marketing of human organs and tissues for profit.
4. The enhancement and promotion of programs for organ and tissue donations.

In the light of foregoing considerations, approval of this bill is earnestly sought.


JINGGOY EJERCITO ESTRADA
Senator

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AN ACT
TO REGULATE THE PROCUREMENT AND TRANSPLANT OF HUMAN
ORGANS AND TISSUES AND FOR OTHER PURPOSES

Be it enacted by the Senate and House of Representatives of the Philippines in Congress assembled:

SECTION 1. Title. This Act shall be known as the "**Human Organ and Tissue Procurement and Transplant Act of 2013**".

SEC. 2. Declaration of Policies. It is hereby declared national policy of the State to:

- (a) Promote public access to multiple human organs and tissues;
- (b) Address the technical and ethical issues involved in human organ and tissue procurement and transplantation;
- (c) Develop policies ensuring fair access to transplant surgery for individuals who without such surgery would be at risk of losing their lives;
- (d) Devise a system by which valuable human organs and tissues which are desperately needed by waiting victims of end-stage organ failure could be readily obtained and equally distributed;
- (e) Motivate the public to become human organ and tissue donors;
- (f) Encourage health professionals to identify in a timely manner prospective donors of human organs and tissues;
- (g) Encourage and extend support to the laudable initiative and efforts of the voluntary non-governmental health organizations to encourage our citizens to become voluntary organ and tissue donors and enable those in need to benefit from the dramatic achievements and developments in the field of human organ and tissue transplantation;
- (h) Support and direct the development of a rational and fair national health policy regarding the appropriate government and private sector roles human organ and tissue procurement and transplantation; and
- (i) Prohibit and penalize the for-profit marketing of human organs and tissues.

SEC. 3. Definition of Terms. As used in this Act, the term:

- (a) Human Organ and Tissue – refers to the kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, skin, nerve, muscle tissues and any other human organ or tissue that may be specified by the Secretary of Health by regulation.
- (b) For-profit Marketing – refers to a transaction whereby a person agrees for valuable consideration, whether given or to be given to himself or to another person to the sale or supply of any human organ or tissue from his body or from the body of another person, whether before or after his death or the death of the other person, as the case maybe.
- (c) Valuable Consideration – does not include the reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control and storage of a human organ or tissue or other hospitalization expenses or the expense of travel housing and last wage or funeral expenses incurred by the donor of a human organ or tissue in connection with the donation of the organ or tissue. It will not also include any reasonable incentives to be given by the donee or other government or non-governmental organizations;
- (d) Transplant Center – refers to health care facility in which transplants of organs and tissues are performed.

SEC. 4. *For-Profit Marketing.* The for-profit marketing of human organs and tissues is hereby declared unlawful.

SEC. 5. *Human Organ and Tissue Procurement and Transplantation Network (Network).* The Secretary of Health shall encourage the establishment and maintenance of the Human Organ and Tissue Procurement and Transplantation Network in various strategic geographical areas of the country to be determined by the Task Force as hereinafter created.

SEC. 6. *Composition.* The Human Organ and Tissue Procurement and Transplantation Network shall be a non-profit entity which is not engaged in any activity not related to organ and tissue procurement, and shall have a board of directors which include representatives of organ and tissue procurement organizations.

SEC. 7. *Function of the Network.* The Network shall establish a list of individuals in one location who needs organs or tissues, and a national system in accordance with established medical criteria, to match organs or tissues and individuals included in the list especially individuals whose immune system makes it difficult for them to readily or successfully receive organs or tissues.

In addition, the Network shall:

- (a) Maintain a twenty-four hour telephone service to facilitate matching organs or tissues which individuals included in the list;
- (b) Assist local organ and tissue procurement organizations in the distribution of organs and tissues which cannot be placed within the service areas of the organizations;
- (c) Adopt and use standards of quality for the acquisition and transportation of donated organs and tissues;

- (d) Prepare and distribute, on a regionalized basis, samples of blood sera from individuals who are included on a list and whose immune system makes it difficult for them to receive organs or tissues, in order to facilitate matching the compatibility of such individuals with organ and tissue donors;
- (e) Coordinate the transportation of organs and tissues from procurement organizations to transplant including those from other countries. In case, the latter shall be facilitated in accordance with Section 14 of Republic Act No. 7170, otherwise known as the Organ Donation Act of 1991 under the provision on International Sharing of Human Organs or Tissues;
- (f) Provide information to physicians and other health professionals regarding organ and tissue donations; and
- (g) Collect, analyze and publish data concerning organ and tissue donations and transplants.

SEC. 8. *Human Organ and Tissue Procurement (HOTPO).* A human organ and tissue procurement may be established in strategic geographical country, subject respectively, the approval and of the Secretary of Health. Such organization shall:

- (a) Be a non-profit entity;
- (b) Have an accounting and other fiscal procedures necessary to assure the fiscal stability of the organization;
- (c) Have a Board of Directors or Advisory Board, the composition of which shall be determined by the Task Force as may be hereinafter be created;
- (d) Have a director and such other staff, including the human organ donation and tissues coordinators and human organ and tissue procurement specialist necessary to effectively obtain human organs and tissues from donors in its service area.

SEC. 9. *Functions of the HOTPO.* A human organ and tissue procurement organization shall:

- (a) Conduct and participate in systematic efforts, including professional education, to acquire all useable organs and tissues from potential donors;
- (b) Arrange for the acquisition and preservation of donated human organs and tissues and provide quality standards for the acquisition of human organs and tissues which are consistent with the standards adopted by the Network;
- (c) Arrange for the appropriate tissue typing of donated human organs;
- (d) Have a system to allocate donated human organs and tissues among transplant centers and patients according to medical criteria;
- (e) Participate in the Network authorized to be established under this Act; and
- (f) Make arrangements to cooperate with human organ and tissue banks for the retrieval, processing, preservation, storage and distribution of human organs and tissues as may be appropriate to assure that all useable human organs and tissues are obtained from potential donors.

SEC. 10. *Registry of Recipients/Report.* The Secretary of Health shall require the network to develop and maintain a scientific registry of the recipients of human organ and tissue transplants. The registry shall include such information respecting patients and transplant procedures as he may deem necessary to an on-going evaluation of the scientific and clinical status of human organ and tissue transplantation.

The Secretary of Health shall regularly report to Congress on the analysis of information derived from registry.

SEC. 11. *Advisory Panel or Board.* The Secretary of Health shall form an advisory panel or board in the Department of Health which shall assist him in:

- (a) Supervising the private sector in the human organ and tissue procurement activities provided for in this Act;
- (b) Conducting a program of public information to inform the public of the need for human organ and tissue donations;
- (c) Providing technical assistance to human organ and tissue procurement organizations established in accordance with this Act;
- (d) The preparation of an annual report to be submitted to Congress on the status of human organ and tissue donation and coordination services, including an analysis of the efficiency and effectiveness of the procurement and allocation of human organs and tissues, a description of problems encountered in the procurement and allocation of human organs and tissues, and clinical and scientific status of human organ and tissue transplantation;

SEC. 12. *Task Force.* Within two (2) months from the effectivity of this Act, the Secretary of Health shall establish a Task Force on Human Organs and Tissue Procurement and Transplantation (hereinafter referred to as the Task Force).

SEC. 13. *Composition/Appointment and Business.*

- (a) The Task Force shall be composed of the following:
 - (1) Five (5) physicians or scientist who are eminent the various medical and scientific specialties related to human organ and tissue transplantation;
 - (2) One (1) person who is not a physician or a scientist and who represent the field of human organ and tissue procurement;
 - (3) Three (3) individuals who are not physicians and who as a group have expertise in the fields of law, theology, ethics, health care financing and social and behavioral sciences;
 - (4) Two (2) individuals who are not physicians or scientists and who are members of the general public.
- (b) The members of the Task Force shall be appointed by the President which need not be submitted for confirmation by the Commission on Appointments;
- (c) No individual who is a full-time officer or employee of the Philippine Government may be appointed by the Task Force. A vacancy in the Task Force shall be in the manner in which the original appointment;
- (d) The members shall be appointed for the life of the Task Force;

- (e) The Task Force shall elect its Chairman from among its members;
- (f) One-half plus one of the members of the Task Force shall constitute a *quorum* to do business, but may hold hearings;
- (g) The Task Force, shall hold its first meeting on the date specified by the Secretary of Health which shall not be later than thirty (30) days from the establishment of the Task Force. Thereafter, the Task Force shall meet at the call of the Chairman or a majority of its members but shall meet at least twelve (12) times during the lifetime of the Task Force.
- (h) The Secretary of Health shall provide the Task Force with administrative and support services as the Force may require to carry out effectively its duties.

SEC. 14. *Honorarium.* The members of the Task Force shall receive *honorarium* in such amount the President of the Philippines shall determine for each meeting of the Force actually attended by them, but in no case shall *honorarium* exceed the sum of Twenty Four Thousand Pesos (P24,000.00) for each member for the whole life of the Task Force.

SEC. 15. *Functions.* The Task Force shall perform the following functions:

- (a) Conduct comprehensive examinations of the medical, legal, ethical, economic and social issues presented by human organ and tissue procurement and transplantation;
- (b) Make an assessment of immunosuppressive medications used to prevent organ and tissue rejection in transplant patients, including –
 - (1) An analysis of the safety, effectiveness, and cost (including cost savings from improved success rates of transplantation) of different modalities of treatment.
 - (2) An identification of problems that patients encounter in obtaining immunosuppressive medications;
 - (3) An analysis of the extent of insurance reimbursement for long-therapy for organ and tissue transplant patients by private insurers and the public sector;
 - (4) An analysis of the comparative advantages of grants, coverage under existing programs or other means to assure that individuals who need such medications can obtain them.
- (c) Make an assessment of public and private efforts to procure human organs and tissues for transplantation and identification of factors that diminish the number of human organs and tissues available for transplantation;
- (d) Make an assessment of problems in coordinating the procurement of viable human organs and tissues, including skin and bone for transplantation;
- (e) Make recommendations for the education and training of health professionals, including physicians, nurses and hospital and emergency care personnel, with respect to human organ and tissue procurement and transplantation;
- (f) Make recommendation for the education of the general public, health workers, the clergy, law enforcement officers, members of the local fire departments and other agencies and individuals that may be instrumental in affecting human and tissue procurement;
- (g) Make recommendations for assuring equitable access by patients to organ and tissue transplantation and for assuring equitable allocation

- of donated human organs and tissues among transplant centers and among patients medically qualified for an organ and tissue transplant;
- (h) Identify the barriers to the donation of human organs and tissues to patients (with special emphasis upon pediatric patients), including an assessment of:
 - (1) Barriers to the improved identification of human organ and tissue donors and their families and organ and tissue recipients;
 - (2) The number of potential human organ and tissue donors and their geographical distribution;
 - (3) Current health care services provided for patients who need human organ and tissue transplantation and human organ and tissue procurement procedures, systems and programs which affect such patients;
 - (4) Cultural factors affecting the family with respect to the donation of human organs and tissues and;
 - (5) Ethical and economic, issues relating to human organ and tissue needed by chronically-ill patients;
 - (i) Make recommendations for the conduct and coordination of continuing research concerning all aspects of the transplantation of human organs and tissues;
 - (j) Make an analysis of the factors involved in insurance reimbursement for transplant procedures by private insurers and the public sector;
 - (k) Make an analysis of the manner in which human organ and tissue transplantation technology is diffused among and adopted by qualified medical centers, including a specification of the number and geographical distribution of qualified medical centers using such technology is sufficient or excessive and of whether the public has sufficient access to medical procedures using such technology;
 - (l) Make an assessment of the feasibility of establishing and of the likely effectiveness of a national and tissue donors.

SEC. 16. *Designation of Hospitals and Medical Centers.* The Secretary of Health may, upon the recommendation of the Task Force, designate hospitals and medical equipped with the appropriate state-of-the-art facilities as training centers for Human organ procurement and transplantation.

SEC. 17. *Reports.* Not later than three (3) months after the Task Force is established, shall transmit a report to the Secretary of Health and to Congress its assessments of immune-suppressive medications to prevent organ and tissue rejection.

Not later than six (6) months after the date on which the Task Force is established, the Task Force shall transmit a final report to the Secretary of Health and the Congress, which shall include:

1. A description of any finding and conclusion of the Task Force made pursuant to any study conducted under this Act;
2. Such recommendation as the Task Force considers appropriate;

SEC. 18. *Penalty.* Any person who shall buy and sell human organs or tissues for profit-marketing shall, upon conviction suffer the penalty of imprisonment for not less than two (2) years nor more than five (5) years and to

pay a fine of not less than Ten Thousand Pesos (P10,000.00), nor more than Fifty Thousand Pesos (P50,000.00) at the discretion of the court, if the offender is a public officer, he shall, in addition, suffer the penalty of perpetual absolute disqualification from holding a public office. If the offender is an alien, he shall be deported further proceedings.

A Doctor of Medicine or any health professionals who has no knowledge of any for-profit marketing transactions shall be free from any liability.

SEC. 19. Appropriation. The sum of Three Million Pesos (P3,000,000.00) not otherwise appropriated from the funds of the National Treasury is hereby appropriated to implement the provisions of this Act. Thereafter, the same shall be included in the General Appropriations Act.

SEC. 20. Rules and Regulations. The Secretary of Health, after consultation with health professionals, both government and private and non-governmental health organizations shall promulgate such rules and regulations as may be necessary for the proper implementation of this Act.

SEC. 21. Repealing Clause. All laws, decrees, ordinances, rules and regulations, executive or administrative orders, and other presidential issuances inconsistent with the provisions of this Act are hereby repealed, amended or modified accordingly.

SEC. 22. Separability Clause. The provisions of this Act are hereby deemed separable. If any provision hereof should be declared invalid or unconstitutional, the remaining provisions shall remain in full force and effect.

SEC. 23. Effectivity. This Act shall, take effect after fifteen (15) days following its publication in at least two (2) newspapers of general circulation.

Approved,