

Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

EIGHTEENTH CONGRESS
First Regular Session

HOUSE BILL NO. 1491



Introduced by: Hon. Angelina "Helen" D.L. Tan, M.D.

AN ACT
PROVIDING FOR AN "OPT-OUT" SYSTEM OF ORGAN DONATION AND TRANSPLANTATION, AMENDING REPUBLIC ACT NO. 7170 OTHERWISE KNOWN AS THE "ORGAN DONATION ACT OF 1991," PROMOTING THE RIGHT TO HEALTH, PROVIDING PENALTIES THEREFOR, AND FOR OTHER PURPOSES

EXPLANATORY NOTE

Article II, Section 15 of the 1987 Constitution provides that, "the State shall protect and promote the right to health of the people and instill health consciousness among them." There is an increasing number of kidney disease which affect Filipinos. End Stage Renal Disease (ESRD) which is a consequence of underlying diseases such as diabetes mellitus and hypertension increased the demand for medications and treatments such as the hemodialysis.

In the Philippines, the estimated average cost of hemodialysis is P3,000 per session. If the patient is on it for three times a week, the total cost would be P468,000 a year. However, this amount does not include other medications and laboratories that an average patient would need. To address this concern, government medical institutions offer free or low-cost dialysis treatments to Filipinos. Just recently, the Philippine Red Cross extended its arms to lessen the suffering of people afflicted with kidney failure by providing a modern state-of-the-art dialysis center with quality healthcare.

Despite the availability of dialysis machines, kidney transplantation is still the treatment of choice for ESRD because it offers a better-quality life and long-term survival. The estimated life expectancy post-transplant is 17.19 years compared to only 5.48 years, if the patient remains on dialysis. Moreover, the difference in the total quality of life in terms of physical, social, emotional, spiritual, and financial aspects between transplant vis-à-vis dialysis patients was determined to be 18.12% greater in transplant patients.

Unlike in other developed countries, kidney donors in the Philippines come mostly from living related donors (95%) and a mere 5% from deceased donors despite efforts made by the government and non-governmental organizations to encourage organ donations.

The incentive for systematic reform of organ and tissue donation has arisen internationally because of the increased incidence of end stage organ failure and the corresponding growth in need for transplants. Several countries have responded to this challenge by implementing strategies to increase organ and tissue donation, and now, have established reform models. The "Opt-In" or "Opt-Out" donation models are the more known. "Opt-In" donation system means that only those with explicit consent are considered as donors. While, "Opt-Out" donation system means that everyone is treated as a donor unless they specifically object to do so. Both strategies allow individuals (or their next of kin) power to determine what happens to their cadaveric organs: the difference between them is the "default" treatment of someone who has expressed no wish either way. Opt-Out strategies are likely to increase donation rates because those who do not register a preference either way will be treated as donors. Opt-Out organ donation systems are often called "presumed consent".

In recent years, technical, social, and public opinion in many countries has shifted towards the view that Opt-Out provisions can help promote organ donation. Two components of transplantation legislation – presumed consent and allocation priority – are thought to increase the donor population by decreasing the ease of opting out and giving registered donors priority among the pool of individuals in need of organ transplant. The joint implementation of these components is believed to yield beneficial effects. Explicit Opt-Out laws have long been among the major interventions used to increase the pool of potential donors in countries such as Austria, Belgium, the Czech Republic, Finland, France, Greece, Hungary, Israel, Italy, Luxembourg, Norway, Poland, Slovenia, Spain, Sweden and Turkey. There is evidence that supports the association between presumed consent and increased donation rates and that countries with Opt-Out laws have rates 25 to 35% higher than those in countries requiring explicit consent. However, presumed consent appears to be only one of several factors. Other factors include potential donor availability, transplantation infrastructure, health care spending, and public attitudes, as well as familial consent and donor registries.

If a person can be an organ recipient, they should also be able to give an organ and vice versa. This principle is consistent with the view that a fair concept of justice calls for reciprocal altruism, because organs may be considered a scarce societal resource — i.e. the demand for donated organs is higher than the supply of such organs. It also justifies the perceived unfair action of free-riders: those who are willing to receive an organ but unwilling to donate one. Moral duty must be the foundation of our organ donation laws. This duty places a legal obligation on any citizen to contribute to the system they stand to benefit from. It is this context that this Opt-Out system of organ donation is sought to be approved in substitution of the voluntary organ donation system existing under the "Organ Donation Act of 1991."

In view of the foregoing, the immediate approval of this Bill is hereby sought.



ANGELINA "HELEN" D.L. TAN, M.D.
4th District, Quezon

Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

EIGHTEENTH CONGRESS
First Regular Session

HOUSE BILL NO. 1491

Introduced by: Hon. Angelina "Helen" D.L. Tan, M.D.

AN ACT
PROVIDING FOR AN "OPT-OUT" SYSTEM OF ORGAN DONATION AND TRANSPLANTATION, AMENDING REPUBLIC ACT NO. 7170 OTHERWISE KNOWN AS THE "ORGAN DONATION ACT OF 1991," PROMOTING THE RIGHT TO HEALTH, PROVIDING PENALTIES THEREFOR, AND FOR OTHER PURPOSES

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

SECTION 1. *Short Title.* – This Act shall be known as the "Organ Donation Act of 2018."

SEC. 2. *Definitions.* – For purposes of this Act, the following terms shall be defined as follows:

- a. Death – The irreversible cessation of circulatory and respiratory functions or the irreversible cessation of functions of the entire brain, including the brain stem. A person shall be medically and legally dead if either:
 - 1) In the opinion of the attending physician, based on the acceptable standards of medical practice, there is an absence of natural respiratory and cardiac functions and, attempts at resuscitation would not be successful in restoring those functions. In this case, death shall be deemed to have occurred at the time these functions ceased; or
 - 2) In the opinion of the consulting physician, concurred in by the attending physician, that on the basis of acceptable standards of medical practice, there is an irreversible cessation of all brain functions; and considering the absence of such functions, further attempts at resuscitation or continued supportive maintenance would not be successful in resorting such natural functions. In this case, death shall be deemed to have occurred at the time when these conditions first appeared.

Provided that, the death of the person shall be determined in accordance with the Brain Death Criteria, as provided by the Philippine Neurological Association (PNA), which shall be declared by two (2) different physicians who are both not part of the Transplant team. The physicians are preferably, but not limited to, a neurologist, neurosurgeon, internist, or anesthesiologist shall determine and establish brain death based on existing guidelines. The death shall be recorded in the patient's medical record.

- b. Department of Health-Philippine Network for Organ Sharing (DOH-PhilNOS). – An attached organization of the DOH which facilitates and oversees organ donation and transplantation involving deceased donors in the country. It shall serve as the central coordinating body of all deceased organs, tissues, or corneas donation and transplantation procedures.
- c. Donor. – An individual authorized under this Act to donate organs, tissues, and corneas to a decedent.

- d. Hospital – A licensed, accredited, and approved hospital under the law, which includes, a hospital operated by the Government.
- e. Organ Bank Storage Facility – A facility licensed, accredited, or approved under the law for storage of human bodies or parts thereof.
- f. Organ Procurement Organization. – A non-profit, independent or hospital-based, organization that is duly accredited by the Department of Health (DOH), composed primarily of transplant coordinators and transplant specialists (internists and surgeons), who can identify, evaluate, and maintain potential organ donors and retrieve organs therefrom.
- g. Part – Includes transplantable organs, tissues, eyes, bones, arteries, blood, other fluids and other portions of the human body.
- h. Physician or Surgeon – A medical practitioner who is authorized to practice medicine under the laws of the Republic of the Philippines.
- i. Portable Organ Perfusion. – A machine in which one donor organ is connected to receives perfusion and cooling from a special machine perfusion fluid. The organ is perfused continuously during transport with an oxygenated perfusion fluid by a membrane pump that pumps perfusion fluid from the container, into the organ's artery and/or portal vein.
- j. Transplant Center. – A medical institution with complete transplant facilities and duly accredited by the Department of Health (DOH).

SEC. 3. *Removal of Organ After Death.* – The designated physician or surgeon of a hospital or Transplant Center may, subject to and in accordance with this section, authorize, in writing, the removal of any part of the body of a person who has died in the hospital or Center for the purpose of transplantation of the organ to the body of a living person.

No authority shall be given for the removal of the organ from the body of any deceased person if:

- a. During his lifetime, he has registered an objection to the removal of the organ from his body after his death, in accordance to Section 4 of this Act;
- b. He/she is not a citizen of the Philippines. Provided that, Filipinos who have lost their citizenship and obtained citizenship in another country, and are residents in the Philippines, may also be given authority to donate their organs to a living person in need of the same, in accordance with the Opt-In System provided in Section 5 hereof;
- c. He/she is below eighteen (18) years of age unless the parent or guardian has consented to such removal; or
- d. He/she is mentally ill, therefore, could not have given a valid consent during his/her lifetime, unless the parent or guardian has consented to such removal.

SEC. 4. *Opt-Out System.* – Upon the effectivity of this Act, any person who objects to the removal of any part or organ from his body after his death may register his objection, in respect of that organ, with the Department of Health - Philippine Network for Organ Sharing (PhilNOS), which may be done through the National Registry or local registries which shall thereafter be established in each region. Upon the receipt of DOH-PhilNOS of the duly signed written objection, it shall issue a certification and an opt-out card to the person which shall serve as a proof that his objection was duly recorded and registered.

The DOH-PhilNOS shall establish and maintain a National Register which shall contain all Filipino citizens and all Filipinos who opted-out not to donate any organ, tissue, or cornea after

their death. Such register shall be updated real-time.

Any person who has registered his objection with the DOH-PhilNOS in respect of any organ may withdraw his objection anytime in the prescribed form, as may be determined by the DOH-PhilNOS. Upon receipt of the withdrawal of a person, the DOH-PhilNOS shall issue the person an acknowledgement in the prescribed form and shall immediately remove the objection from the National Register.

SEC. 5. *Opt-In System.* – Upon the effectivity of this Act, any natural-born Filipino who has lost his or her citizenship and obtained citizenship in another country, but who is a resident of the Philippines, and who desires to donate his or her organ, may register such desire, in respect of that organ, with the Department of Health - Philippine Network for Organ Sharing (PhilNOS), which may be done through the National Registry or local registries which shall thereafter be established in each region. Upon the receipt of DOH-PhilNOS of the duly signed written opt-in, it shall issue a certification and an opt-in card to the person which shall serve as a proof that his or her desire was duly recorded and registered.

The DOH-PhilNOS shall establish and maintain a National Register which shall contain all such persons who opted-in to donate any organ, tissue, or cornea after their death. Such register shall be updated real-time.

Any person covered by this Section who has registered his or her opt-in with the DOH-PhilNOS, in respect of any organ, may cancel his or her registration anytime in the prescribed form, as may be determined by the DOH-PhilNOS. Upon receipt of the cancellation of a person, the DOH-PhilNOS shall issue the person an acknowledgement in the prescribed form and shall immediately remove his or her name from the National Register.

SEC. 6. *Proposed Recipients of Organs.* - In the selection of a proposed recipient of any organ removed pursuant to Section 4 of this Act, the following circumstances shall be considered:

- a. A person who has not registered any objection at any given time with the DOH-PhilNOS in respect of any organ shall be prioritized;
- b. A person who has registered his objection with the DOH-PhilNOS, in respect of any organ, but who has withdrawn such objection shall have priority over a person who has registered such objection; and
- c. A person who has registered his objection with the DOH-PhilNOS shall be given least priority.

SEC. 7. *Roles and Functions of the DOH-PhilNOS.* - In addition to the roles and functions of the DOH-PhilNOS, as provided by DOH Administrative Order No. 2010-0018, DOH Administrative Order No. 2010-0019, and other laws, rules, and/or regulations, it shall have the following roles and functions:

- a. Act as the central coordinating body to ensure that all donor organs, tissues, and cornea are allocated according to established criteria;
- b. Implement the policies on deceased donor allocation;
- c. Maintain a National Registry and local registries in each region, with computer-based database and linked to Transplant Centers, to include:
 - (i) Registry of all kidney transplants performed in the country;
 - (ii) Registry of all Filipino citizens, in coordination with the Philippine Statistics Authority (PSA) and Civil Registry Offices;

- (iii) Registry of all Filipinos seeking organ, tissues, and corneas transplant; and
- (iv) Registry of all Filipinos who opt not to donate any organ, tissue, or cornea, as prescribed in Section 5 of this Act; and
- d. Such other roles and functions, as may be deemed necessary by the DOH.

Provided that, the DOH-PhilNOS shall operate in coordination with Organ Procurement Organizations, duly accredited by the DOH.

SEC. 8. *Organ Donation Ethics Committee.* – Every hospital and transplant center shall designate an organ donation ethics committee to ensure that the rights and welfare of the organ donors and their families are protected.

SEC. 9. *Persons Authorized to Perform the Removal and Transplant of Organs, Tissues, and Corneas.* – Only authorized physicians or surgeons in a hospital or Transplant Center shall remove and/or transplant any organ which is authorized to be removed and/or transplanted pursuant to this Act. Provided that, the removal of corneal tissues shall be performed only by ophthalmic surgeons and ophthalmic technicians trained in the methodology of such procedure and duly certified by the accredited National Association of Ophthalmologists.

SEC. 10. *Transport of Donated Organs, Tissues, and Corneas.* – In order to maintain the quality and integrity of an organ for transplantation, to ensure traceability, and to minimize any potential risk, it is vital that donor organs and their accompanying blood and tissue samples are packaged, labelled, and transported to the Transplant Center appropriately, and in a timely manner through portable organ perfusion machines.

SEC. 11. *PhilHealth Assistance.* – Organ transplantation, under this Act, shall be covered by the Philippine Health Insurance Corporation (PhilHealth). Provided that, the assistance given by Philhealth shall be determined through fair and transparent assessment process.

SEC. 12. *Prohibited Acts.* - The following acts shall be prohibited:

- a. Selling of Organs. To enter into a contract or arrangement under which 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 organ, tissue or cornea 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 may be;
- b. Buying of Organs. To give or offer to give valuable consideration for the sale or supply of, or for an offer to sell or supply, any organ from the body of another person;
- c. Performing organ removal and/or transplantation of an unauthorized person. To remove and / or transplant any organ, tissue or cornea of a person without an authorized physician or surgeon;
- d. Advertising and promoting buying and selling of organs. No person shall issue or cause to be issued any advertisement relating to the buying or selling of any organ, tissue or cornea in the Philippines; and
- e. Destroying, forging, mutilating, and altering registries. To willfully destroy, forge, mutilate, or make any unauthorized alteration in any of the registries of the DOH-PhilNOS.

SEC. 13. *Penalties* - The following penalties are hereby provided:

- a. Any person found guilty of committing any of the acts enumerated in Section 12 (a), (b) and (c) shall suffer the penalty of imprisonment of twenty (20) years and a fine of not

less than One million pesos (P1,000,000.00) but not more than Two million pesos (P2,000,000.00);

- b. Any person found guilty of committing any of the acts under Section 12 (d) and (e) shall suffer the penalty of imprisonment of two (2) years and a fine not less than One hundred thousand pesos (P100,000.00) but not more than Five hundred thousand pesos (P500,000.00).

SEC. 14. *Education and Information Campaign on Organ Donation.* – In order that the public shall obtain the maximum benefits from this Act, the DOH, in cooperation with institutions, such as the National Kidney and Transplant Institute (NKTi), civic and non-government health organizations and other health related agencies, involved in the donation and transplantation of human organs, shall undertake public education and information campaign program on organ donation and transplantation.

SEC. 15. *Implementing Rules and Regulations.* – Within ninety (90) days after the effectivity of this Act, the Secretary of Health, in coordination with the National Kidney and Transplant Institute (NKTi) and other medical and healthcare professionals, in government, private, and non-governmental health organizations shall promulgate such rules and regulations as may be necessary and proper to implement this Act.

SEC. 16. *Appropriation.* – The amount of Four Hundred Million Pesos (P400,000, 000.00) shall be appropriated for the management and implementation of this Act which shall be included in the General Appropriations Act (GAA).

SEC. 17. *Repealing Clause.* – All laws, decrees, orders, rules and regulations or other issuances or parts thereof inconsistent with the provisions of this Act are hereby repealed or modified accordingly.

SEC. 18. *Separability Clause.* – If any portion or provision of this Act is declared unconstitutional, the remainder of this Act or any provision not affected thereby shall remain in force and effect.

SEC. 19. *Effectivity.* – This Act shall take effect after fifteen (15) days following the completion of its publication either in the Official Gazette or in a newspaper of general circulation.

Approved,