

SENATE
S. No. 2096

*18 NOV 14 P4:59

RECEIVED

Introduced by **Senator Richard J. Gordon**

**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.

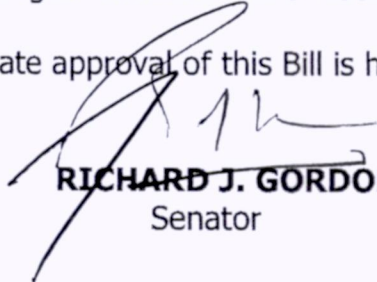
Unlike in other developed countries, kidney donors in the Philippines come mostly from living related donors (95%) and a mere 5% from deceased donors despite efforts made by the government and non-governmental organizations to encourage organ donations.

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.



RICHARD J. GORDON
Senator

*18 NOV 14 P5:00

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

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

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

5 a. Death – The irreversible cessation of circulatory and respiratory functions or
6 the irreversible cessation of functions of the entire brain, including the brain stem. A
7 person shall be medically and legally dead if either:

8 1) In the opinion of the attending physician, based on the acceptable
9 standards of medical practice, there is an absence of natural respiratory and
10 cardiac functions and, attempts at resuscitation would not be successful in
11 restoring those functions. In this case, death shall be deemed to have occurred
12 at the time these functions ceased; or

13 2) In the opinion of the consulting physician, concurred in by the
14 attending physician, that on the basis of acceptable standards of medical
15 practice, there is an irreversible cessation of all brain functions; and considering
16 the absence of such functions, further attempts at resuscitation or continued
17 supportive maintenance would not be successful in resorting such natural

1 functions. In this case, death shall be deemed to have occurred at the time
2 when these conditions first appeared.

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

10 b. Department of Health-Philippine Network for Organ Sharing (DOH-PhilNOS).
11 – An attached organization of the DOH which facilitates and oversees organ donation
12 and transplantation involving deceased donors in the country. It shall serve as the
13 central coordinating body of all deceased organs, tissues, or corneas donation and
14 transplantation procedures.

15 c. Donor. – An individual authorized under this Act to donate organs, tissues,
16 and corneas to a decedent.

17 d. Hospital – A licensed, accredited, and approved hospital under the law,
18 which includes, a hospital operated by the Government.

19 e. Organ Bank Storage Facility – A facility licensed, accredited, or approved
20 under the law for storage of human bodies or parts thereof.

21 f. Organ Procurement Organization. - A non-profit, independent or hospital-
22 based, organization that is duly accredited by the Department of Health (DOH),
23 composed primarily of transplant coordinators and transplant specialists (internists
24 and surgeons), who can identify, evaluate, and maintain potential organ donors and
25 retrieve organs therefrom.

26 g. Part – Includes transplantable organs, tissues, eyes, bones, arteries, blood,
27 other fluids and other portions of the human body.

28 h. Physician or Surgeon – A medical practitioner who is authorized to practice
29 medicine under the laws of the Republic of the Philippines.

30 i. Portable Organ Perfusion Machine - A machine in which one donor organ is
31 connected to receives perfusion and cooling from a special machine perfusion fluid.
32 The organ is perfused continuously during transport with an oxygenated perfusion

1 fluid by a membrane pump that pumps perfusion fluid from the container, into the
2 organ's artery and/or portal vein.

3 j. Transplant Center. – A medical institution with complete transplant facilities
4 and duly accredited by the Department of Health (DOH).

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

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

12 a) During his lifetime, he has registered an objection to the removal of the
13 organ from his body after his death, in accordance to Section 4 of this Act;

14 b) He/she is not a citizen of the Philippines. *Provided that*, Filipinos who have
15 lost their citizenship and obtained citizenship in another country, and are
16 residents in the Philippines, may also be given authority to donate their organs
17 to a living person in need of the same, in accordance with the Opt-In System
18 provided in Section 5 hereof;

19 c) He/she is below eighteen (18) years of age unless the parent or guardian
20 has consented to such removal; or

21 d) He/she is mentally ill, therefore, could not have given a valid consent during
22 his/her lifetime, unless the parent or guardian has consented to such removal.

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

1 The DOH-PhilNOS shall establish and maintain a National Register which shall
2 contain all Filipino citizens and all Filipinos who opted-out not to donate any organ,
3 tissue, or cornea after their death. Such register shall be updated real-time.

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

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

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

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

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

- 30 a. A person who has not registered any objection at any given time with the
31 DOH-PhilNOS in respect of any organ shall be prioritized;

1 b. A person who has registered his objection with the DOH-PhilNOS, in respect
2 of any organ, but who has withdrawn such objection shall have priority over a
3 person who has registered such objection; and

4 c. A person who has registered his objection with the DOH-PhilNOS shall be
5 given least priority.

6 *Sec. 7. Roles and Functions of the DOH-PhilNOS.* - In addition to the roles and
7 functions of the DOH-PhilNOS, as provided by DOH Administrative Order No. 2010-
8 0018, DOH Administrative Order No. 2010-0019, and other laws, rules, and/or
9 regulations, it shall have the following roles and functions:

10 a. Act as the central coordinating body to ensure that all donor organs, tissues,
11 and cornea are allocated according to established criteria;

12 b. Implement the policies on deceased donor allocation;

13 c. Maintain a National Registry and local registries in each region, with
14 computer-based database and linked to Transplant Centers, to include:

15 (i) Registry of all kidney transplants performed in the country;

16 (ii) Registry of all Filipino citizens, in coordination with the Philippine Statistics
17 Authority (PSA) and Civil Registry Offices;

18 (iii) Registry of all Filipinos seeking organ, tissues, and corneas transplant;
19 and

20 (iv) Registry of all Filipinos who opt not to donate any organ, tissue, or
21 cornea, as prescribed in Section 5 of this Act; and

22 d. Such other roles and functions, as may be deemed necessary by the DOH.

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

25 *Sec. 8. Organ Donation Ethics Committee.* – Every Hospital and Transplant
26 Center, shall designate an organ donation ethics committee to ensure that the rights
27 and welfare of the organ donors and their families are protected.

28 *Sec. 9. Persons Authorized to Perform the Removal and Transplant of Organs,*
29 *Tissues, and Corneas.* – Only authorized physicians or surgeons in a hospital or
30 Transplant Center shall remove and/or transplant any organ which is authorized to be
31 removed and/or transplanted pursuant to this Act. *Provided that,* the removal of
32 corneal tissues shall be performed only by ophthalmic surgeons and ophthalmic

1 technicians trained in the methodology of such procedure and duly certified by the
2 accredited National Association of Ophthalmologists.

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

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

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

14 a. Selling of Organs. To enter into a contract or arrangement under which a
15 person agrees, for valuable consideration, whether given or to be given to
16 himself or to another person, to the sale or supply of any organ, tissue or cornea
17 from his body or from the body of another person, whether before or after his
18 death or the death of the other person, as the case may be;

19 b. Buying of Organs. To give or offer to give valuable consideration for the sale
20 or supply of, or for an offer to sell or supply, any organ from the body of another
21 person;

22 c. Performing organ removal and/or transplantation of an unauthorized person.
23 To remove and / or transplant any organ, tissue or cornea of a person without
24 an authorized physician or surgeon;

25 d. Advertising and promoting buying and selling of organs. No person shall
26 issue or cause to be issued any advertisement relating to the buying or selling
27 of any organ, tissue or cornea in the Philippines; and

28 e. Destroying, forging, mutilating, and altering registries. To willfully destroy,
29 forge, mutilate, or make any unauthorized alteration in any of the registries of
30 the DOH-PhilNOS.

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

1 a. Any person found guilty of committing any of the acts enumerated in Section
2 12 (a), (b) and (c) shall suffer the penalty of imprisonment of twenty (20) years
3 and a fine of not less than One million pesos (P1,000,000.00) but not more
4 than Two million pesos (P2,000,000.00);

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

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

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

20 Sec. 16. *Appropriation.* – The amount of Four Hundred Million Pesos (P400,000,
21 000.00) shall be appropriated for the management and implementation of this Act which
22 shall be included in the General Appropriations Act (GAA).

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

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

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

32 *Approved,*