

Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

Seventeenth Congress
Third Regular Session



HOUSE BILL No. 8613

Introduced by **Rep. MARLYN B. ALONTE**

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

In recent years, the demand for donated organs is higher than the supply of such, that human organs can already be considered a scarce societal resource. The surge in demand is brought about by the increase in cases of kidney diseases.

More and more Filipinos are diagnosed with End Stage Renal Disease (ESRD), the last stage of chronic kidney disease. At this point, the kidneys' functions have reached an advanced state and can no longer support one's body needs. The most common treatment for ESRD is hemodialysis, which can cost a patient having the treatment three times a week about P468,000 for a whole year. This does not include medications, laboratories, and other treatment fees.

Although dialysis centers are abundant in the country, kidney transplantation is still the treatment that offers better quality of life as well as longer survival for patients. A transplant helps a patient live for an estimated 17 more years after the treatment, as compared to just over 5 years for those who remain on dialysis treatment. Studies also show that quality of life—physical, social, emotional, spiritual, and financial—post-kidney transplant is 18.12% greater than those of dialysis patients.

But here's the sad truth: the Philippines needs to step up in its bid to increase organ donation rates. Unlike in other developed countries, 95% of kidney donors in the Philippines are from living donors, while only 5% are from deceased donors although efforts are made by government and non-government organizations to encourage more people to donate.

This Act provides an "Opt-Out" system in organ donation and transplantation. In this donation system, everyone is treated as a donor unless they specifically object to being one. It will allow individuals or their next of kin to determine what happens to their cadaveric organs. Those who do not register a preference will still be treated as a donor, often called "presumed consent". This process will likely increase the rate of donations, as opposed to the "Opt-In" donation system which only counts those who explicitly gave their consent to donate.

The "Opt-Out" donation system has been used by different countries—namely, Austria, Belgium, the Czech Republic, Finland, France, Greece, Hungary, Israel, Italy, Luxembourg, Norway, Poland, Slovenia, Spain, Sweden and Turkey—to increase the potential pool of organ donors. 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. But this is not to say that presumed consent is the sole factor to the increase. Other factors include potential donor availability, transplantation infrastructure, health care spending, and public attitudes, as well as familial consent and donor registries.

The benefits mentioned above are the reasons this Act seeks to substitute the voluntary organ donation system with the "Opt-Out" donation system under the "Organ Donation Act of 1991."

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



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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:*

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

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

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

10 b. Department of Health-Philippine Network for Organ Sharing (DOH-
11 PhilNOS). – An attached organization of the DOH which facilitates and oversees
12 organ donation and transplantation involving deceased donors in the country. It
13 shall serve as the central coordinating body of all deceased organs, tissues, or
14 corneas donation and 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. - 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
7 section, authorize, in writing, the removal of any part of the body of a person who
8 has died in the **hospital or** Center for the purpose of transplantation of the organ to
9 the body of 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
17 organs to a living person in need of the same, in accordance with the Opt-In
18 System 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
22 during his/her lifetime, unless the parent or guardian has consented to such
23 removal.

24 Sec. 4. *Opt-Out System.* – Upon the effectivity of this Act, any person who
25 objects to the removal of any part or organ from his body after his death may
26 register his objection, in respect of that organ, with the Department of Health -
27 Philippine Network for Organ Sharing (PhilNOS), which may be done through the
28 National Registry or local registries which shall thereafter be established in each
29 region. Upon the receipt of DOH-PhilNOS of the duly signed written objection, it shall
30 issue a certification and an opt-out card to the person which shall serve as a proof
31 that his 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
11 country, but who is a resident of the Philippines, and who desires to donate his or
12 her organ, may register such desire, in respect of that organ, with the Department
13 of Health - Philippine Network for Organ Sharing (PhilNOS), which may be done
14 through the National Registry or local registries which shall thereafter be established
15 in each region. Upon the receipt of DOH-PhilNOS of the duly signed written opt-in, it
16 shall issue a certification and an opt-in card to the person which shall serve as a
17 proof that 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
23 anytime in the prescribed form, as may be determined by the DOH-PhilNOS. Upon
24 receipt of 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
28 recipient of any organ removed pursuant to Section 4 of this Act, the following
29 circumstances 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
2 respect of any organ, but who has withdrawn such objection shall have
3 priority over a 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
7 and functions of the DOH-PhilNOS, as provided by DOH Administrative Order No.
8 2010-0018, 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,
11 tissues, 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
17 Statistics 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
31 be 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
10 be covered by the Philippine Health Insurance Corporation (PhilHealth). *Provided*
11 *that*, the assistance given by Philhealth shall be determined through fair and
12 transparent 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
17 cornea from his body or from the body of another person, whether before or
18 after his 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
20 sale or supply of, or for an offer to sell or supply, any organ from the body of
21 another person;

22 c. Performing organ removal and/or transplantation of an unauthorized
23 person. To remove and / or transplant any organ, tissue or cornea of a
24 person without 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
2 Section 12 (a), (b) and (c) shall suffer the penalty of imprisonment of twenty
3 (20) years and a fine of not less than One million pesos (P1,000,000.00) but
4 not more 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
7 not less than One hundred thousand pesos (P100,000.00) but not more than
8 Five 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
11 cooperation with institutions, such as the National Kidney and Transplant Institute
12 (NKTi), civic and non-government health organizations and other health related
13 agencies, involved in the donation and transplantation of human organs, shall
14 undertake public education and information campaign program on organ donation
15 and transplantation.

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

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

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

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

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

4 *Approved,*