REPUBLIC OF THE PHILIPPINES HOUSE OF REPRESENTATIVES Quezon City

SEVENTEENTH CONGRESS First Regular Session

882

HOUSE BILL No.



Introduced by Honorable Benhur B. Lopez Jr.

EXPLANATORY NOTE

Supply has not kept pace with demand

At the outset, Republic Act No. 7170 authorizes the legacy or donation of all or part of a human body after death for specified purposes. The law recognizes that an individual has the option to become a hero, so to speak, via a will or other document he/she himself/herself executed or through the decision of his/her next of kin. Hence, a mechanism has been set up to legitimize the donation of organs to take effect after death.

Moreover, in fulfilment of the country's commitment to the 63rd World Health Assembly and the Istanbul Declaration 2008, the government set up a national system of promoting organ donation from deceased donors and sharing of grafts through the Philippine Network for Organ Sharing or PHILNOS. The network aims at implementing a system of timely referral and processing of potential multiple organ donors, the equitable allocation and efficient procurement and transplantation of organs from them. It bears stressing however again that what presently is being promoted is only deceased organ donation.

But, how about living organ donation?

To date, there is no law passed by Congress addressing this specific concern. True, there is Republic Act No. 9208, otherwise known as the Anti-Trafficking in Persons Act of 2003 which punishes the *exploitative* removal or sale of organs as an act of trafficking. It thus raises the question: how about non-exploitative removal of organs? Thus, a law is necessary to determine precisely when is removal of organ considered exploitative or when it may be considered as a valid act of donation.

The ratio between living and deceased donors cannot be over-emphasized. Statistics show that from 1999 to 2009, there has been an

Philippine Renal Disease Registry; PRDR Annual Report, Philippine Society of Nephrology and Renal Disease Control Program, National Kidney and Transplant Institute, Department of Health, 2010

average of 178 (92.7%) living kidney donors as compared to 14 (7.3%) deceased donors for Filipino recipients. Out of the 178,102 (or 57%) are living non-related donors while 76 (or 43%) are living related donors. Meanwhile, there are 9,184 Filipinos suffering from end-stage renal diseases, and only 477 (or roughly 5%) of whom have undergone kidney transplant². Globally, every year, a million people develop end-stage renal disease but only a fraction of those receive any kind renal placement therapy and even fewer receive kidney transplants³. In fact, currently, there are 48 pay patients and 20 service patients on the active waiting list of the Human Organ Preservation Effort of the National Kidney and Transplant Institute (HOPE-NKTI), while there are 413 pay patients and 95 service patients on the inactive waiting list on the same hospital⁴. Annually, 5 active pay patients, 3 active service patients, 10 inactive pay patients and 10 inactive service patients die while on the waiting list⁵. For this reason, the demand for kidney donation is high.

It is undeniable that there are other successful strategies to expand kidney donor pool including passing presumed-consent law, use of non-heart beating deceased donors, encouraging live donor renal transplantation from genetically-related and emotionally-motivated donors, accepting non-directed kidney donations. Trends, globally however, prove that the waiting list for renal transplants has not significantly declined despite these efforts, with the single exception of the latest strategy, meaning, accepting non-directed type of living donation, which happened in Iran.

It is thus submitted that the availability of the source of the supply of organs should not be restricted to deceased donors but should include living and willing donors. It cannot be denied that living donors far outnumber the deceased ones and this situation can be taken advantaged of, provided proper parameters are observed. These parameters must, in the end, not only increase potential donors but equally important is that, it must help curb or curtail illegal organ commerce that only degrades the person of the donor but may also endanger their very lives leading therefore to exploitation.

In a country such as ours, culture and religion play important roles in decision making. It is however submitted that becoming an organ or tissue donor is a personal decision. A decision that must likewise be guided by the constant fact that organ and tissue donation saves lives and that in no instance should exploitation of either the donor or recipient be countenanced.

² For 2009

³ Dr. Luc Noel, Coordinator of WHO's clinical procedure team, as quoted in WHO Bulletin entitled "Dilemma over live-donor transplantation"

⁴ Answer of HOPE-NKTI dated 30 September 2010 to query of the bill proponent

⁵ ibid

This bill, in the higher interest of public health, therefore primarily ensures that the availability of organs and tissues, for donation, from living and willing donors, is carefully supervised and regulated. Supervision and regulation which includes the grant of reasonable support to donors, to include medical care, or educational, economic or livelihood projects, or other forms of assistance to promote the well-being of these donors.

In view of the foregoing, the approval of this proposed measure is earnestly sought.

BENHUR B. LOPEZ JR.

Party list, YACAP

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AN ACT REGULATING THE DONATION AND TRANSPLANTATION OF HUMAN ORGANS AND TISSUES FROM LIVING DONORS

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 "LIVING ORGAN DONORS ACT of 2016."

- SECTION 2. Declaration of Policies. It is hereby declared the policy of the State to promote and protect the health of its people and, in line with this policy, the State shall enact measures creating programs including but not limited to:
- (A) Recognizing and regulating the donation of human organs and tissues of living donors to prevent their exploitation and, more importantly, ensure their legal entitlement to reasonable medical support and other forms of assistance;
- (B) Granting patients with end-stage diseases access to human organs for transplantation but at the same time ensuring that there is equitable distribution in the allocation of available organs among qualified recipients;
- (C) Encouraging donation of human organs and tissues, most especially the directed living donation, without giving endue prejudice to nondirected directed living donation, and taking into consideration respect for the dignity of human life, beneficence and non-maleficence, solidarity and volunteerism, justice and equity;
- (D) Developing and maintaining a national registry and reporting system of donors and recipients of human organs and tissues, and the continuous evaluation of the system.

SECTION 3. Definition of Terms. As used in this act, the following terms shall have the following meanings:

"Human Organ or Tissue" refers to the kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, skin, nerve, muscle tissue and any other human organ or tissue that may be transplanted to another living person.

"Donation of an organ or tissue" refers to a voluntary act of a person to give his organs or tissues gratuitously in favor of another, who accepts it. In this case, the recipient shall have no demandable or enforceable right over the organ or tissue donated, but he may, after the donation has been performed and in gratitude or acknowledgement of the donation, give anything of value to the donor.

"Related Donors" refers to relatives by consanguinity up to the fourth civil degree.

"Non-Related Donors" include the following:

(A) Those who are related by consanguinity beyond the fourth civil degree;

(B) Those who are related within the fourth degree of affinity;

(C) Those not related by consanguinity or affinity but bear emotional ties with the organ or tissue recipient (e.g. friends, employees or employers, colleagues, fiance/fiancee); and

(D) Strangers.

"Directed living donors" - refer to a donor who has a specific recipient in mind whom would want to donate to.

"Non-directed living donors" - refer to donors who would donate to whoever matches on a list of waiting patients for organ transplant.

"Transplant Facility" – facility or hospital in which the transplant shall be performed.

"Indigent" – refers to an individual who has been certified by the local branch of the Department of Social Welfare and Development of the area in which he/she is a resident to be belonging to that sector living or earning below the poverty threshold as determined from time to time by the National Economic and Development Authority.

"Medical care" – refers to medicines and laboratory examinations necessary to be made for purposes of, and pursuant to, transplantation. It however does not include expenses for the treatment of unrelated medical illness that is discovered during evaluation procedures.

SECTION 4. Acceptable Living Donations – Any individual, at least twenty one years of age, of sound mind, who underwent screening and counselling procedures and has been found suitable as living donor based on the physical and psychological evaluation and assessments made by the physicians of the transplant facility who are not in anyway directly connected with the transplant, and thus fully understands the risks, benefits and consequences of

transplanting organs and tissues from his/her body, may so donate by way of written consent to such removal for purposes of transplanting the same to another living human body. Such informed consent shall be in a document witnessed by a relative of the donor and two (2) physicians neither of whom shall be a member of the team of medical practitioners who will effect the removal of the organ or tissue from the donor's body nor the physician or transplant team attending to the recipient of the organ to be removed.

In no instance shall a minor be made a donor of any organ or tissue to anybody. Further, no transplant shall be undertaken if it will result in a physical and/or psychological harm to the donor. Furthermore, an individual is allowed to donate only one organ/tissue in his/her lifetime. Finally, a foreigner is not allowed to become a recipient of any organ/tissue unless it can be shown that he/she is a former Filipino citizen or that the potential donor is related to the said former Filipino foreigner by consanguinity within the fourth degree.

SECTION 5. Choice of type of donation – It shall be the choice of the donor whether to make a non-directed or directed type of donation, taking into consideration the following:

A. In making a non-directed type of living donation, a non-indigent donor is to proceed to an accredited transplant facility of his/her choice, bringing with him a verified certification from two (2) physicians to the effect that he/she is physically and medically fit to donate the organ of his/her choice. The said transplant facility shall then conduct the required pre-transplant psychological screening to determine his/her suitability for donation. The cost of the screening shall be free of charge. It later on found suitable to make the donation, the transplant facility shall then register the name of the potential donor in the Philippine Organ Donor and Recipient Registry System (PODRRS) maintained by the Department of Health for matching with a recipient.

In a case of an indigent donor intending to make a non-directed living donation, he/she shall proceed to an accredited government transplant facility which shall conduct initially a psychological screening, as adverted to in Section 4 hereof to determine his mental fitness to make such a donation. If found suitable, the same government transplant facility shall subject the potential donor to a test to determine his physical fitness to undergo the donation. In both cases of screening and physical testing, the procedure shall be free of charge. If the potential donor is finally found psychologically, mentally and physically fit to make the donation, his/her name shall then be registered by the same transplant facility in the PODRRS for matching with a recipient.

It is understood that a non-directed living donor makes such donation out of mere altruism but a grateful recipient who after the transplant, had knowledge of the identity of his/her donor, is not precluded from giving financial assistance to the latter.

B. In making a directed type of living donation, the potential donor shall undergo psychological, mental and physical tests to determine his/her fitness to become a donor, the costs of all of which shall be borne by the intended recipient, unless the recipient is an indigent in which case the said tests shall be conducted free charge in the government transplant facility in which the indigent is to be scheduled for transplant.

SECTION 6. Requirement of registration – All patients in need of transplant shall also register themselves in the Philippine Organ Donor and Recipient Registry System (PODRRS) maintained by the Department of Health (DOH).

SECTION 7. Duty of non-indigent recipients – In all cases of living donation, whether directed or non-directed, and notwithstanding any agreement to the contrary, it shall be the responsibility of the non-indigent recipient to shoulder the cost of the transplantation procedure and pre and post-operation medical care of the donor, who has been found suitable mentally and physically to make the donation.

Further, the recipient shall cause the name of the donor to be registered in the registry of the PODRRS. Furthermore, the recipient is obliged to shoulder the expenses of travel and housing, if any, and lost wages, if applicable and other related expenses in connection with the donation. Finally, the recipient shall be made to answer financially, wholly or partly depending on their agreement, for any subsequent disease that may be developed by the donor in connection with the organ or tissue donated.

Nothing in this Act however shall proscribe the voluntary act of the recipient in providing additional assistance to the family of the family of the donor either through livelihood projects and/or educational support to the family of the donor.

SECTION 8. Duty of the State – if the organ or tissue recipient is indigent, as certified to by the local branch of the Department of Social Welfare and Development of the area where the recipient is a resident, the actual transplant shall be made in any of the accredited government transplant facilities and the pre and post operation medical care of the donor shall be shouldered by the said transplant facility while the expenses of travel and housing, if any, and lost wages, if applicable, shall be shouldered by the local government of which the recipient is a resident.

The local government unit concerned as well as the district representative of the place where the donor is a resident shall likewise, as far as practicable, provide preferential assistance in terms of educational, scholarship or other non-monetary benefits to the family of the donor and/or his next of kin.

SECTION 9. Duty of donors – In all cases, it shall be the duty of the donor, for his own protection, to ensure and verify that his name is registered in the national registry of donors maintained by the PODRRS.

SECTION 10. Incentives for donors — An organ or tissue donor shall be entitled to a leave of absence with pay for the period of his confinement for purposes of actual transplantation and post-transplant recovery for a period not to exceed fifteen (15) working days.

Should the donor develop a disability, as defined under the Social Security and Government Service Insurance System charters, resulting from the transplantation procedure, he/she shall be entitled to a disability pay, as therein defined and computed.

Further, should the donor eventually develop a disease or sickness necessitating a transplant, the said donor shall be given priority in the registry of potential recipients.

Furthermore, airline companies are to provide at least 10% discount on airfare of potential donors, on their way to and from the actual transplant operation, who have been found suitable, mentally and physically to make the donation.

Finally, pharmaceutical companies and their distributors are directed to ensure that at least a 10% discount is likewise provided for post-transplant and transplant-related medicines personally consumable by the donors.

SECTION 11. Unlawful Act. It is hereby declared unlawful and punishable in its severest form any act of any third person tending to broken, negotiate or engage in transactions that will lead or cause to be lead the transplant of any organ from one person to another, whether for a fee or for free.

SECTION 12. Philippine Network for Organ Sharing – The Department of Health-established Philippine Network for Organ Sharing (PHILNOS) which promotes organ donation from deceased donors is hereby recognized but in addition, it shall also come up with mechanisms and guidelines on living organ donors, as herein provided.

The DOH shall report to Congress before June 30 of every year the analysis of information derived from the registry.

SECTION 13. Regulatory Authority – The Department of Health shall be responsible for:

(A) Implementing the provisions of this Act;

(B) Issuing guidelines relative to the process of donor-screening and evaluation as well as donor and recipient pre and post transplant counselling.

(C) Issuing guidelines on the accreditation of transplant facilities, whether government or private, thereby ensuring that all necessary equipment and facilities are available as well as guaranteeing that the transplant team have the necessary expertise and experience in conducting the same;

(D) Issuing guidelines relative to the duties of hospitals and their respective physicians relative to the conduct of transplant and all its necessary incidents.

SECTION 14. Penalties for Violation (A) A non-indigent recipient who fails to perform any of the mandatory duties mentioned in Section 7 hereof as well as the local chief executive and responsible officers of the local government unit concerned, the officials and employees of hospitals and companies directly involved under Section 8 and 10 respectively hereof shall be held individually liable and suffer the following penalties:

- (1) Fine of not less than One Hundred Thousand Pesos (\$\bar{P}\$100,000.00) but not exceeding Five Hundred Thousand Pesos (\$\bar{P}\$500,000.00) or imprisonment of not less than one year but not more than five years, or both, at the discretion of the Court.
- (2) For any subsequent violation in case of public and private corporations, a fine of not less than Two Hundred Thousand Pesos (₱200,000.00) but not exceeding Six Hundred Thousand Pesos (₱600,000.00) or imprisonment for not less than two years but not more than six years, or both, at the discretion of the court.

Upon filing of an appropriate complaint, and after due notice and hearing, the proper authorities may also cause the cancellation or revocation of the business permit, permit to operate, franchise and other similar privileges granted to any business entity that fails to abide by the provisions of this Act.

- (B) Any person found guilty of violating the provision of Section 11 hereof shall be penalized with imprisonment for not less than six (6) years nor more than twelve (12) years and fine in an amount not less than five hundred thousand pesos (\$\bar{2}500,000.00\$) nor more than one million pesos.
- **SECTION 15.** Funding. An amount not exceeding annually is hereby set aside from the charity funds of the Philippine Charity Sweepstakes Office to cover the financial requirements of this Act.
- **SECTION 16.** Repealing Clause. All Acts or parts of Acts, executive orders and their implementing rules inconsistent with the provisions of this Act are hereby repealed, amended or modified accordingly.
- **SECTION 17.** Separability Clause. If any provision of this Act is declared invalid, the remainder of this Act or any provisions not affected thereby shall remain in force and in effect.
- **SECTION 18.** Effectivity. This Act shall take effect after fifteen days from publication in two newspapers of general circulation.