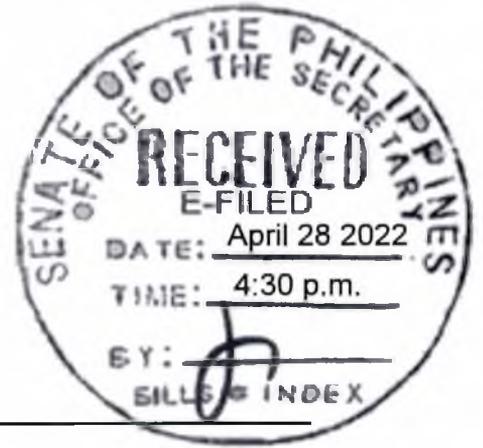


EIGHTEENTH CONGRESS OF THE)
REPUBLIC OF THE PHILIPPINES)
Third Regular Session)

SENATE
S.B. No. **2515**



Introduced by **SENATOR IMEE R. MARCOS**

**AN ACT PROMOTING AND REGULATING THE DONATION OF UMBILICAL
CORD BLOOD, APPROPRIATING FUNDS THEREFOR,
AND FOR OTHER PURPOSES**

EXPLANATORY NOTE

Section 15, Article II of the 1987 Constitution states that "*the State shall protect and promote the right to health of the people and instill health consciousness among them.*"

An umbilical cord blood is the blood from a baby that remains in the umbilical cord and placenta after birth. According to studies, an umbilical cord blood contains special cells called "*hematopoietic stem cells*". Hematopoietic stem cells are immature cells that can develop into all types of blood cells, such as red blood cells, white blood cells, and platelets. Hematopoietic stem cells are the same type of blood-forming stem cells present in a bone marrow transplant. They may help treat over 70 types of diseases. It is for this reason that other States have institutionalized the collection of umbilical cord blood.

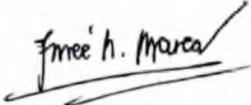
People are given the option to choose whether or not to donate and have cord blood collected after giving birth. Cord blood collection is beneficial to both the mother and the baby. After cord blood samples are collected, cord blood banks freeze and store them for future use.

Other States practice cord blood banking to collect potential life-saving stem cells from the umbilical cord and placenta and storing them for future use. They can treat cancer, blood diseases like anemia, and some immune system disorders, which disrupt your body's ability to defend itself. The fluid is easy to collect and has 10 times more stem cells than those collected from bone marrow. Furthermore, stem cells from

cord blood rarely carry any infectious disease and, are half as likely to be rejected as adult stem cells.

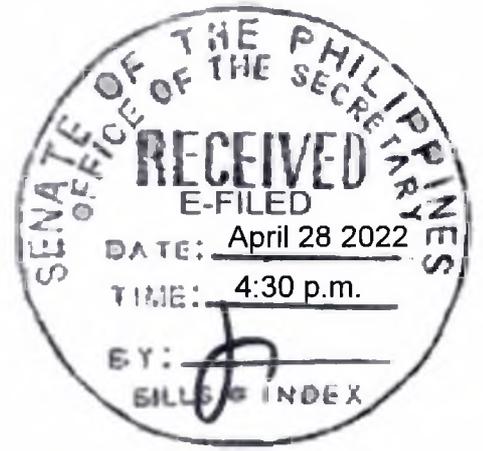
Thus, this bill aims to promote and regulate the system of umbilical cord blood banking in the country and provide protection to its donors and hope to its recipients. This bill also intends, among others, to inform expectant families about the potential uses of umbilical cord blood, within existing prenatal screening program, and offer standardized, objective information to all maternity patients about public and private cord blood banking. Further, with the rise of infectious diseases and terminal illnesses, the State must adopt proactive methods in safeguarding the health of its citizens.

In view of the foregoing, the passage of this bill is earnestly sought.



IMEE R. MARCOS

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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 "*Umbilical Cord Blood*
2 *Donation Act.*"

3

4 **SEC. 2. Declaration of Policy.** – It is hereby declared the policy of the State to
5 protect and promote the right to health of the people and instill health consciousness
6 among them. For this reason, the State aims to educate pregnant women regarding
7 the potential benefits of umbilical cord blood banking and to provide opportunities for
8 the donation and storage of umbilical cord blood when desired by a pregnant woman
9 thereby adopting proactive methods in treating diseases such as cancer, anemia, and
10 blood diseases, among others.

11

12 **SEC. 3. Definition of Terms.** – For purposes of this Act, the following shall be
13 defined as:

- 14 a. "*Department*" shall mean the Department of Health (DOH);
15 b. "*Health Care Facility*" shall mean as an institution providing health care
16 services to a pregnant woman that are directly related to her pregnancy,
17 including a hospital, clinic or other inpatient center, outpatient facility or
18 diagnostic or treatment center that is licensed by the Department of Health;

- 1 c. "Health Care Provider" shall mean as a person who is licensed, certified, or
2 otherwise authorized by law to provide or render health care services to
3 pregnant women in the ordinary course of business or practice of a
4 profession but is limited to a medical physician, osteopathic physician,
5 certified nurse practitioner and certified nurse-midwife; *and*
6 d. "Umbilical Cord Blood" shall mean as the blood that remains in the umbilical
7 cord and placenta after the birth of a newborn child.
8

9 **SEC. 4. Option to Donate Umbilical Cord Blood.** – All health care providers
10 providing health care services to a pregnant woman by the end of the second trimester
11 (28th week), which health care services are directly related to her pregnancy, shall
12 advise her of options to donate umbilical cord blood following the delivery of a newborn
13 child, by providing standardized objective information about cord blood banking that is
14 sufficient to allow a pregnant woman to make an informed decision on whether to
15 participate in a public or private umbilical cord blood banking program.
16

17 This shall include information on the free family banking and sibling donor
18 programs where there is an existing medical need by a family member, among others.
19 Provision in a timely manner of publications prepared by the Department, as provided
20 in Section 6 of this Act, shall constitute compliance with this Section.
21

22 **SEC. 5. Exemption.** – Nothing in this Section shall impose an obligation upon a
23 health care provider to inform a pregnant woman regarding her umbilical cord blood
24 banking options if such information conflicts with *bona fide* religious beliefs of the
25 health care provider or the pregnant woman.
26

27 **SEC. 6. Information Dissemination.** – The Department shall, on its official
28 website and other publications, make available to health care providers printable
29 publications regarding umbilical cord blood banking which shall include the following
30 information, among others:

- 1 (1) An explanation of the differences between public and private umbilical cord
- 2 blood banking;
- 3 (2) The medical processes involved in the collection of umbilical cord blood;
- 4 (3) The medical risks to a mother and her newborn child of umbilical cord
- 5 blood collection;
- 6 (4) The current and potential future medical uses and benefits of umbilical
- 7 cord blood collection to a mother, her newborn child and her biological family;
- 8 (5) The current and potential future medical uses and benefits of umbilical
- 9 cord blood collection to persons who are not biologically related to a mother or
- 10 her newborn child;
- 11 (6) Any costs that may be incurred by a pregnant woman who chooses to
- 12 make an umbilical cord blood donation;
- 13 (7) The average costs of public and private umbilical cord blood banking;
- 14 (8) Options for ownership and future use of the donated material; *and*
- 15 (9) The availability of umbilical cord blood donations in the country.

16

17 **SEC. 7. *Donation of umbilical cord blood.* –**

18 (a) *Arrangements for donations* – Unless it is medically inadvisable, all health

19 care facilities and health care providers treating a pregnant woman during the delivery

20 of a newborn child shall, if requested by that woman, permit and assist her to arrange

21 for an umbilical cord blood donation.

22 (b) *Exceptions relating to health of mother* – Nothing in this section imposes an

23 obligation upon a health care facility or health care provider to permit an umbilical cord

24 blood donation if, in the professional judgment of a health care provider, the donation

25 of umbilical cord blood would threaten the health of the mother or the newborn child.

26 (c) *Exceptions relating to religion* – Nothing in this section imposes an obligation

27 upon a health care facility or health care provider to permit an umbilical cord blood

28 donation if the donation conflicts with *bona fide* religious beliefs of the health care

29 facility or health care provider.

30 *Provided that*, if a health care facility or health care provider declines to engage

31 in umbilical cord blood donation, under reasonable circumstances, such fact shall be

1 made known to pregnant patients of that facility or provider, as soon as reasonably
2 feasible.

3

4 **SEC. 8. *Creation of a Committee.*** – There shall be established, within the
5 Department, an implementing committee to provide guidance and policy suggestions
6 to the Department on the implementation of the Umbilical Cord Blood Collection
7 Program created pursuant to this Act.

8 The implementing committee shall be chaired by the Secretary of Health or his
9 duly authorized representative with six (6) members, as follows: one (1) representative
10 from the Department, one (1) representative from the Department of Science and
11 Technology (DOST), two (2) representatives from the academe, two (2)
12 representatives from the private sector, all of whom with at least ten (10) years practice
13 in the medical field or medical sciences.

14 The Department shall use its existing authority to promote and implement the
15 collection, storage, retrieval, and distribution of the umbilical cord blood.

16

17 **SEC. 9. *Functions.*** – The committee shall have the following functions:

- 18 (a) Define and identify qualified umbilical cord blood collection entities;
19 (b) Design a competitive process to identify qualified participants licensed or
20 accredited to harvest umbilical cord blood in a manner that complies with
21 existing laws, rules and regulations;
22 (c) Establish a criteria for determining which units of umbilical cord blood may be
23 used for research and/or transplant, and policy to address circumstances under
24 which umbilical cord blood may be used for either purpose;
25 (d) Create collection targets for ethnically diverse populations in accordance with
26 identified deficiencies in inventories;
27 (e) Consider a medical contingency response program to prepare for and respond
28 effectively to biological, chemical, or radiological attacks, and other public
29 health emergencies requiring treatment with umbilical cord blood;

- 1 (f) Develop a public awareness campaign and increase hospital participation in the
2 collection and storage efforts, and identify sources to offset the financial impact
3 on hospitals;
- 4 (g) Determine and conduct training programs for health care providers relative to
5 the handling, labeling, transporting, and storing of the umbilical cord blood,
6 among others;
- 7 (h) Determine policy on obtaining patient consent and timing of consent in relation
8 to existing laws and standards of care;
- 9 (i) Ascertain whether current laws and guidelines applicable to donor
10 confidentiality and security of donor information are sufficient and what other
11 additional requirements or guidelines are necessary;
- 12 (j) Determine whether a sibling donor component would help achieve the overall
13 inventory goals of the program;
- 14 (k) Explore feasibility of operating the Umbilical Cord Blood Collection Program as
15 a self-funding program;
- 16 (l) Ensure that the Umbilical Cord Blood Collection Program does not conflict with
17 other national and international efforts to generate an adequate, high-quality
18 inventory; *and*
- 19 (m) Such other function/s that may be necessary for the implementation of this
20 Act.

21

22 **SEC. 10.** *Establishment of Umbilical Cord Blood Storage Facilities.* – One (1)
23 year after the effectivity of this Act, all hospitals should have a facility where cord blood
24 can be stored. Provided that, if existing hospital blood storage facilities are capable of
25 storing cord blood, the hospital involved is deemed to have complied with the provisions
26 of this Act.

27

28 **SEC. 11.** *Umbilical Cord Blood Collection Program.* – Within one year from the
29 effectivity of this Act, the DOH shall establish the Umbilical Cord Blood Collection
30 Program for the purpose of collecting and storing umbilical cord blood for public use,
31 human transplantation, and research.

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SEC. 12. Confidentiality. – A health care provider or any employee of medical or research facility shall comply with, and shall be subject to existing penalties for violations of all laws with respect to the confidentiality and protection of any information contained in the umbilical cord blood inventory and relative to the patients.

All information collected pursuant to the Umbilical Cord Blood Collection Program shall be confidential, and shall be used solely for the purposes of this Act. Access to confidential information shall be limited to authorized persons who agree, in writing, to maintain the confidentiality of that information.

SEC. 13. Punishable Act. – Any person who, in violation Sec. 13 of this Act, uses or discloses any information relevant to the Umbilical Cord Blood Collection Program and any patient thereof shall be subject to a civil liability of not exceeding one hundred thousand pesos (Php 100,000.00). Provided that, the penalty provided for in this provision shall not be construed as to limit or otherwise restrict any remedy, provisional or otherwise, provided by existing laws.

Notwithstanding the restrictions of this Act, any individual to whom the confidential information pertains to shall have access to his or her own personal records.

SEC. 14. Implementing Rules and Regulations. – The Department shall promulgate the necessary implementing rules and regulations within sixty (60) days following the effectivity of this Act.

SEC. 15. Appropriations. – The amount needed to initially implement the provisions of this Act shall be charged against the appropriations of the current year of the Department. Thereafter, such sums, as may be necessary, for its continued implementation shall be included in the annual General Appropriations Act.

1 **SEC. 16. *Repealing Clause.*** – Any law, presidential decree or issuance, executive
2 order, letter of instruction, administrative order, rule or regulation contrary to, or
3 inconsistent with the provisions of this Act is hereby repealed, modified or amended
4 accordingly.

5

6 **SEC. 17. *Separability Clause.*** - If any provision or part hereof is held invalid or
7 unconstitutional, the remainder of the law or the provision not otherwise affected shall
8 remain valid and subsisting.

9

10 **SEC. 18. *Effectivity Clause.*** – This Act shall take effect fifteen (15) days after
11 its publication in at least two (2) newspapers of general circulation.

Approved,