

NINETEENTH CONGRESS OF THE
REPUBLIC OF THE PHILIPPINES
First Regular Session



Senate
Office of the Secretary

'22 JUL 18 P5:13

SENATE

RECEIVED BY

S. B. NO. 744

Introduced by **SENATOR JOEL VILLANUEVA**

**AN ACT PROVIDING A STANDARD OF CARE FOR THE
TREATMENT OF PERSONS WITH BLEEDING DISORDERS,
ESTABLISHING TREATMENT CENTERS AND
APPROPRIATING FUNDS THEREFOR**

EXPLANATORY NOTE

The global incidence of hemophilia is still unknown, but medical experts estimated that there are around 400,000 individuals diagnosed with it.¹ Based on the World Federation of Hemophilia Report on the 2020 Annual Global Survey, the Philippines has only around 1,604 persons that have been registered as persons with hemophilia, and 46 with von Willebrand disease.² There are estimates that the number of Filipinos with hemophilia may reach 10,000, and prevalence of von Willebrand Disease is estimated to be equivalent to 1% of the population.³ The gap in estimates and recorded data may partly be due to the lack of awareness and understanding on this group of medical conditions.

Bleeding disorder is a genetic condition where the blood does not clot properly. It is caused by deficiency of proteins in the blood called clotting factors. There are 13 factors in the blood, and when one of it is missing or is deficient, it results in a bleeding disorder.

¹ Makati Medical Center, Hemophilia: A Rare Genetic Blood Disease, April 6, 2020, accessible at <https://www.makatimed.net.ph/blogs/hemophilia-a-rare-genetic-blood-disease/> (last accessed July 17, 2022).

² World Federation of Hemophilia, Report on the Annual Global Survey 2020, October 2021, accessible at https://www1.wfh.org/publications/files/pdf-2045.pdf?_ga=2.227444824.496073867.1658053117-2081625859.1658053117&_gl=1*o99f5e*_ga*MjA4MTYyNTQ1OS4xNiU4MDUzMTE3*_ga_7974KH9LH5*MTY1ODA1MzExNi4xLjEuMTY1ODA1NDQ2My4w (last accessed July 17, 2022).

³ Hemophilia Advocates Philippines, accessible at <https://www.hemophilia.ph/> (last accessed July 17, 2022).

People with bleeding disorders can bleed for longer than normal, and some may experience spontaneous bleeding into joints, muscles, or other parts of their bodies. Women with bleeding disorders may experience menorrhagia (excessive menstruation) and post-partum hemorrhage, on top of other bleeding problems.

The most known of this group of medical conditions is Hemophilia, classified as Hemophilia A (Factor VIII deficiency) and Hemophilia B (Factor IX deficiency), which occurs mostly in males. But the most prevalent is von Willebrand Disease (deficiency in von Willebrand factor), which affects around 1 percent of the population – both males and females. Other factor deficiency disorders are: I, II, V, VII, X, XI, XIII. (Source: World Federation of Hemophilia)

Bleeding disorders like Hemophilia, von Willebrand Disease and other factor deficiencies are usually inherited and genetic. Thus, there may be multiple members in a family affected by the condition and they will have it for life. There is no known cure yet for bleeding disorders.

The World Health Organization and the Department of Health cited post-partum hemorrhage as one of the top causes of maternal deaths. Incidentally, the Philippines did not meet the Millennium Development Goal on maternal health. It is very possible that a big percentage of those mothers who died of post-partum hemorrhage had undiagnosed bleeding disorders.

Bleeding disorders are treated by replacing the missing or deficient factors either through blood products such as cryo-precipitate, cryo-supernate, fresh frozen plasma, packed red blood cells (RBC) and whole blood or by manufactured plasma-derived factor concentrates and recombinant (genetically engineered) factor concentrates.

The cost of treatment is very high, and therefore, inaccessible to majority of Filipino patients. For example, it was reported that “a mild bleed in the joints can cost Php30,000 to Php50,000 per treatment,” and “severe bleeds like those in internal organs...may reach hundreds of thousands if not millions.”⁴ Many of them suffer with chronic pain and deformities in the joints because of lack of access to proper treatment. Availability of factor concentrates in the country is also inconsistent. Other countries like India and Malaysia give free treatment to their citizens who have bleeding disorders. This bill seeks to provide medical and financial support to patients affected with this condition.

The immediate passage of this bill is earnestly sought.


SENATOR JOEL VILLANUEVA

⁴ Inquirer, Many Filipinos with hemophilia can't get treatment, April 20, 2015, *accessible at* <https://newsinfo.inquirer.net/686539/many-filipinos-with-hemophilia-cant-get-treatment> (last accessed July 17, 2022).

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FUNDS THEREFOR**

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

1 **SECTION 1. Short Title.** – This Act shall be known as the “*Bleeding*
2 *Disorder Standards of Care Act.*”
3

4 **SEC. 2. Declaration of Policy.** – It is hereby declared the policy of the
5 State:
6

- 7 a) To ensure the adequate treatment of hemophilia at the lowest
8 possible cost and endeavor to make them available for free to
9 indigent patients;
10
11 b) To ensure the establishment of treatment centers in public
12 hospitals; and
13
14 c) To establish a standard of care so that patients with severe
15 bleeding disorders can receive necessary and appropriate medical
16 care.
17

18 **SEC. 3. Definition of Terms.** – The following words and phrases when
19 used in this Act shall have the meanings given to them in this Section unless
20 the context clearly indicates otherwise:
21

- 22 a) **Bleeding Disorder** refers to a medical condition characterized by
23 a severe deficiency or absence of one or more essential blood

1 clotting proteins in the human blood, often called factors, including
2 all forms of hemophilia, von Willebrand disease, and other bleeding
3 disorders which result in uncontrollable bleeding or abnormal blood
4 clotting;

5
6 b) **Blood clotting product** refers to an intravenously administered
7 medicine manufactured from human plasma, recombinant
8 biotechnology techniques and other processes, approved for
9 distribution by the Food and Drugs Administration (FDA), and which
10 is used for the treatment and prevention of symptoms associated
11 with bleeding disorders. The term includes, but is not limited to:

- 12 1) Factor VIIa, Factor VIII and Factor IX products;
- 13 2) Von Willebrand Factor products;
- 14 3) Prothrombin complex concentrates;
- 15 4) Activated prothrombin complex concentrates; and
- 16 5) Other products approved by the BFAD for the treatment of
17 bleeding disorders and associated inhibitors.
18

19
20 c) **Financially Incapacitated Patient** refers to a patient who is not
21 classified as indigent, but who demonstrates clear inability to pay
22 or spend for necessary expenditures for services or medical
23 treatment, laboratory testing of blood and/or coagulation studies, or
24 blood coagulating products and/or ancillary infusion equipment, as
25 assessed by the Department of Social Welfare and Development
26 (DSWD), local government social worker or the medical social
27 worker of the health facility;
28

29 d) **Indigent Patient** refers to a patient who has no visible means of
30 income, or whose income is insufficient for the subsistence of his
31 or her family, as assessed by the DSWD, local government social
32 worker or the medical social worker of the health facility;
33

34 e) **DOH** refers to the Department of Health.
35

36 f) **Hemophilia** refers to a human bleeding disorder caused by a
37 hereditary deficiency of the Factor VIII, Factor IX or Factor XI blood
38 clotting protein in human blood.
39

40 g) **von Willebrand disease** refers to a human bleeding disorder
41 caused by a hereditary deficiency or abnormality of the von
42 Willebrand Factor in human blood.
43

44 **SEC. 4. State Treatment Facilities.** – The State shall establish
45 hemophilia treatment facilities in key cities and regions nationwide in
46 designated hospitals with Cancer and Hematology Departments.
47

48 Each Hemophilia Treatment Facility shall provide to all hemophilia
49 patients:
50

- 1 a) Care by qualified hematologists and medical doctors and shall also
2 provide free of charge the necessary blood clotting products and
3 ancillary infusion equipment necessary for the infusion of such
4 blood clotting products;
5
6 b) A room exclusively for hemophilia patients; and
7
8 c) A clinical coagulation laboratory for the screening, diagnosis,
9 provisional diagnosis and treatment of bleeding disorders or
10 suspected bleeding disorders and such services shall be provided
11 free of charge to all indigent patients and financially incapacitated
12 patients.
13

14 **SEC. 5. Funding.** – The amount necessary for the initial implementation
15 of this Act shall be sourced from the current budget of the DOH. Thereafter, the
16 funds necessary for the continuous implementation of this Act in the ensuing
17 years shall be included in the General Appropriations Act.
18

19 The funds given to the treatment facilities shall be used as follows:
20

- 21 a) Five percent (5%) shall be used for the maintenance of the rooms
22 that will be used exclusively for hemophilia patients;
23
24 b) Ninety percent (90%) shall be used exclusively for necessary
25 blood clotting products and ancillary infusion equipment necessary
26 for the infusion of such blood clotting products to hemophilia
27 patients; and
28
29 c) Five percent (5%) shall be used for blood screening of hemophilia
30 patients.
31

32 Each treatment facility established under this Act shall submit an annual
33 report to the DOH on the utilization of the amount given to it.
34

35 **SEC. 6. Implementing Rules and Regulations.** – Within sixty (60) days
36 from the approval of this Act, the DOH, in consultation with hemophilia groups
37 and other relevant stakeholders, shall promulgate the rules and regulations to
38 implement the provisions of this Act.
39

40 **SEC. 7. Separability Clause.** – If for any reason, any provision of this
41 Act is declared unconstitutional or invalid, the other parts or provisions hereof
42 which are not affected thereby shall continue to be in full force and effect.
43

44 **SEC. 8. Effectivity Clause.** – This Act shall take effect fifteen (15) days
45 after its publication in the Official Gazette or in at least two (2) newspapers of
46 general circulation.
47

48 **Approved,**
49