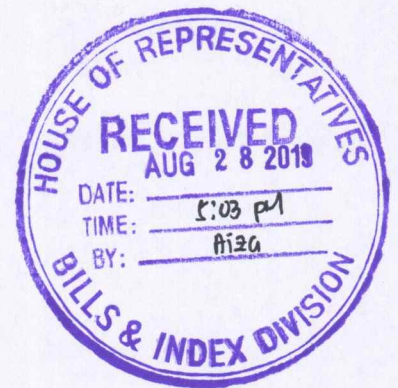


Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

EIGHTEENTH CONGRESS
First Regular Session

House Bill No. 4237



Introduced by REP. BERNADETTE "BH" HERRERA-DY

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

EXPLANATORY NOTE

In the Philippines, about one million Filipinos are affected by Hemophilia, von Willebrand Disease and other bleeding disorders. However, only around 1,500 have been registered with the Philippine Hemophilia Foundation. There is also an obvious 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.

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.

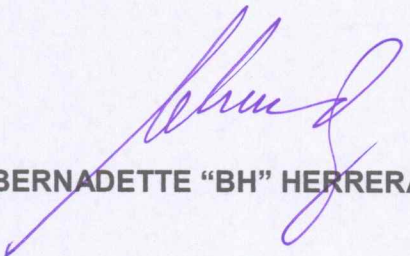
The World Health Organization and the Department of Health cited post-partum hemorrhage as one of the top causes of maternal deaths. Incidentally, the Philippines did not meet the Millennium Development Goal on maternal health. It is very possible that a big percentage of those mothers who died of post-partum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



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

Section 1. Short Title. – This Act shall be known as the "*Bleeding Disorder Standards of Care Act of 2019.*"

Section 2. Declaration of Policy. – It is hereby declared the policy of the State:

- (1) To ensure the adequate treatment of hemophilia at the lowest possible cost and endeavor to make them available for free to indigent patients;
- (2) To ensure the establishment of treatment centers in public hospitals; and
- (3) To establish a standard of care so that patients with severe bleeding disorders can receive necessary and appropriate medical care.

Section 3. Definitions. – The following words and phrases when used in this Act shall have the meanings given to them in this Section unless the context clearly indicates otherwise:

- (1) "**Bleeding Disorder**" - A medical condition characterized by a severe deficiency or absence of one or more essential blood clotting proteins in the human blood, often called factors, including all forms of hemophilia, von Willebrand disease and other bleeding disorders which result in uncontrollable bleeding or abnormal blood clotting.
- (2) "**Blood clotting product**" - An intravenously administered medicine manufactured from human plasma, recombinant biotechnology techniques and other processes, approved for distribution by the BFAD and which is used for the treatment and prevention of symptoms associated with bleeding disorders. The term includes, but is not limited to:
 - (A) Factor VII, Factor VIII and Factor IX products;
 - (B) Von Willebrand Factor products;
 - (C) Prothrombin complex concentrates;
 - (D) Activated prothrombin complex concentrates;
 - (E) Other products approved by the BFAD for the treatment of bleeding disorders and associated inhibitors.
- (3) "**Indigent Patient**" – Any patient deemed unable to pay for services and or medical treatment, laboratory testing of blood and/or coagulation studies, or blood coagulating products and/or ancillary infusion equipment.
- (4) "**DOH**" – refers to the Department of Health.

- (5) **"BFAD"** – refers to the Bureau of Food and Drugs.
- (6) **"Hemophilia"** – A human bleeding disorder caused by a hereditary deficiency of the Factor VIII, Factor IX or Factor XI blood clotting protein in human blood.
- (7) **"von Willebrand disease"** – A human bleeding disorder caused by a hereditary deficiency or abnormality of the von Willebrand Factor in human blood.

Section 4. State Treatment Facilities. – The State shall establish hemophilia treatment facilities in key cities and regions nationwide in designated hospitals with Cancer and Hematology Departments.

Each Hemophilia Treatment Facilities shall provide to all hemophilia patients:

- (1) Care by qualified hematologists and medical doctors and shall also provide free of charge the necessary blood clotting products and ancillary infusion equipment necessary for the infusion of such blood clotting products;
- (2) A room exclusively for hemophilia patients; and
- (3) A clinical coagulation laboratory for the screening, diagnosis, provisional diagnosis and treatment of bleeding disorders or suspected bleeding disorders and such services shall be provided free of charge to all indigent patients.

Section 5. Funding. – The amount necessary for the initial implementation of this Act shall be sourced from the current budget of the Department of Health. Thereafter, the funds necessary for the continuous implementation of this Act in the ensuing years shall be included in the General Appropriations Act.

The treatment facilities are allowed to use five percent (5%) of the amount given to it for the maintenance of the rooms that will be used exclusively for hemophilia patients. However, ninety percent (90%) of the amount shall be used exclusively for necessary blood clotting products and ancillary infusion equipment necessary for the infusion of such blood clotting products to hemophilia patients. The remaining five percent (5%) shall be used for blood screening of hemophilia patients.

Each treatment facility shall submit an annual report to the DOH on how the amount given to it is used.

Section 6. Regulations. – Within sixty (60) days from the approval of this Act, the Department of Health (DOH) shall, in consultation with hemophilia groups, promulgate the Implementing Rules and Regulations (IRR) to carry out the provisions of this Act.

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

Section 8. Effectivity Clause. – This Act shall take effect on the fifteenth day following its publication in at least two (2) daily papers of national circulation.

Approved,