

SENATE

'19 JUL 18 P 1 :27

S. B. NO. 610

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Introduced by **SENATOR JOEL VILLANUEVA**

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**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. This is partly 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.

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.

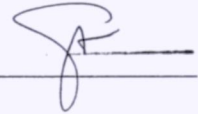
The immediate passage of this bill is earnestly sought.

  
SENATOR JOEL VILLANUEVA

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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 Disorder  
2 Standards of Care Act.”  
3

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

6 a) To ensure the adequate treatment of hemophilia at the lowest possible  
7 cost and endeavor to make them available for free to indigent patients;  
8

9 b) To ensure the establishment of treatment centers in public hospitals; and  
10

11 c) To establish a standard of care so that patients with severe bleeding  
12 disorders can receive necessary and appropriate medical care.  
13

14 **SEC. 3. Definitions.** – The following words and phrases when used in this  
15 Act shall have the meanings given to them in this Section unless the context  
16 clearly indicates otherwise:  
17

18 a) **Bleeding Disorder** refers to a medical condition characterized by a  
19 severe deficiency or absence of one or more essential blood clotting  
20 proteins in the human blood, often called factors, including all forms of  
21 hemophilia, von Willebrand disease and other bleeding disorders which  
22 result in uncontrollable bleeding or abnormal blood clotting.  
23



- 1 b) **Blood clotting product** refers to an intravenously administered  
2 medicine manufactured from human plasma, recombinant biotechnology  
3 techniques and other processes, approved for distribution by the Food  
4 and Drugs Administration (FDA) and which is used for the treatment and  
5 prevention of symptoms associated with bleeding disorders. The term  
6 includes, but is not limited to:  
7  
8 1) Factor VIIa, Factor VIII and Factor IX products;  
9 2) Von Willebrand Factor products;  
10 3) Prothrombin complex concentrates;  
11 4) Activated prothrombin complex concentrates;  
12 5) Other products approved by the BFAD for the treatment of bleeding  
13 disorders and associated inhibitors.  
14  
15 c) **Indigent Patient** refers to any patient deemed unable to pay for services  
16 and or medical treatment, laboratory testing of blood and/or coagulation  
17 studies, or blood coagulating products and/or ancillary infusion  
18 equipment.  
19  
20 d) **DOH** refers to the Department of Health.  
21  
22 e) **Hemophilia** refers to a human bleeding disorder caused by a hereditary  
23 deficiency of the Factor VIII, Factor IX or Factor XI blood clotting protein  
24 in human blood.  
25  
26 f) **von Willebrand disease** refers to a human bleeding disorder caused by  
27 a hereditary deficiency or abnormality of the von Willebrand Factor in  
28 human blood.  
29

30 **SEC. 4. State Treatment Facilities.** – The State shall establish hemophilia  
31 treatment facilities in key cities and regions nationwide in designated hospitals  
32 with Cancer and Hematology Departments.  
33

34 Each Hemophilia Treatment Facility shall provide to all hemophilia patients:  
35

- 36 a) Care by qualified hematologists and medical doctors and shall also  
37 provide free of charge the necessary blood clotting products and  
38 ancillary infusion equipment necessary for the infusion of such blood  
39 clotting products;  
40  
41 b) A room exclusively for hemophilia patients; and  
42  
43 c) A clinical coagulation laboratory for the screening, diagnosis, provisional  
44 diagnosis and treatment of bleeding disorders or suspected bleeding  
45 disorders and such services shall be provided free of charge to all  
46 indigent patients.  
47

48 **SEC. 5. Funding.** – The amount necessary for the initial implementation of  
49 this Act shall be sourced from the current budget of the DOH. Thereafter, the

1 funds necessary for the continuous implementation of this Act in the ensuing  
2 years shall be included in the General Appropriations Act.

3

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

5

6 a) five percent (5%) shall be used for the maintenance of the rooms that  
7 will be used exclusively for hemophilia patients;

8

9 b) ninety percent (90%) shall be used exclusively for necessary blood  
10 clotting products and ancillary infusion equipment necessary for the  
11 infusion of such blood clotting products to hemophilia patients; and

12

13 c) five percent (5%) shall be used for blood screening of hemophilia  
14 patients.

15

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

18

19 **SEC. 6. Implementing Rules and Regulations.** – Within sixty (60) days from  
20 the approval of this Act, the Department of Health (DOH), in consultation with  
21 hemophilia groups and other relevant stakeholders, shall promulgate the  
22 Implementing Rules and Regulations (IRR) to carry out the provisions of this  
23 Act.

24

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

28

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

32

33 **Approved,**

34