# EIGHTEENTH CONGRESS OF THE REPUBLIC OF THE PHILIPPINES

First Regular Session

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### SENATE S.B. NO. <u>834</u>

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Introduced by Senator Maria Lourdes Nancy S. Binay

### AN ACT

# ESTABLISHING A STANDARD OF CARE AND TREATMENT CENTERS FOR PERSONS WITH BLEEDING DISORDERS, AND APPROPRIATING FUNDS THEREFOR

#### EXPLANATORY NOTE

Article II, Section 15 of the 1987 Philippine Constitution provides:

"The State shall protect and promote the right to health of the people and instill health consciousness among them."

Article XIII, Section 11 of the 1987 Philippine Constitution provides:

"The State shall adopt and integrated and comprehensive approach to health development which shall endeavor to make essential goods, health and other social services available to all the people at affordable cost. There shall be priority for the needs of the underprivileged sick, elderly, disabled, women, and children. The State shall endeavor to provide free medical care to paupers."

A bleeding disorder is a condition that affects the way that blood normally clots. Bleeding disorders can cause abnormal bleeding both outside and inside the body. According to the World Federation of Hemophilia, the most common types of bleeding disorders are hemophilia and von Willebrand disease (VWD). Hemophilia is a bleeding disorder that affects approximately 1 in 10,000 people. People with hemophilia do not have enough clotting factor VIII or IX in their blood which results in longer periods of bleeding.

The von Willebrand disease (VWD) is a bleeding disorder caused by a deficiency of the von Willebrand factor (VWF), which is a type of protein that helps blood platelets clump together. Low functioning levels of VWF disables platelets to clot properly and leads to prolonged bleeding.

In the Philippines, approximately one million Filipinos have VWD or another type of bleeding disorder while around 10,000 Filipinos are hemophiliacs. As a result of lack of information and awareness, there are patients of bleeding disorders that died without receiving diagnosis or treatment.

This bill seeks to establish hemophilia treatment facilities nationwide in designated hospitals with Cancer and Hematology Departments to provide free of charge blood clotting products, room exclusivity for hemophilia patients, and clinical coagulation laboratories.

In view of the foregoing the immediate passage of this measure is earnestly sought.

ARIA LOURDES NAMCY S. BINAY Senator

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#### SENATE S.B. NO. <u>83</u>4

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## AN ACT

## ESTABLISHING A STANDARD OF CARE AND TREATMENT CENTERS FOR PERSONS WITH BLEEDING DISORDERS, AND APPROPRIATING 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 of 2019."
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4	Sec. 2. Declaration of Policy It is hereby declared the policy of the State
5	to:
6	(a) Ensure the adequate treatment of hemophilia at the lowest
7	possible cost and endeavor to make them available for free
8	to indigent patients;
9	(b) Ensure the establishment of treatment centers in public
10	hospitals; and
11	(c) Establish a standard of care so that patients with severe
12	bleeding disorders can receive necessary and appropriate
13	medical care.
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15	Sec. 3. Definition of Terms As used in this Act, the terms:
16	(a) "Bleeding Disorder" shall refer to a medical condition
17	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 uncontrolled bleeding or abnormal blood clotting;

- (b) "Blood Clotting product" shall mean 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:
  - (1) Factor VIIa, Factor VIII and Factor IX products;
  - (2) Von Willebrand Factor products;

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- (3) Prothrombin complex concentrates;
- (4) Activated prothrombin complex concentrates; and
- (5) Other products approved by the BFAD for the treatment of bleeding disorders and associated inhibitors;
- (c) "Indigent Patient" shall mean any patient deemed unable to
  pay for services or medical treatment, laboratory testing of
  blood and/or coagulation studies, or blood coagulating
  product and/or ancillary infusion equipment;
- 23 (d) "DOH" shall refer to the Department of Health;

(e) "BFAD" shall refer to the Bureau of Food and Drugs;

- (f) "Hemophilia" shall refer to a human bleeding disorder
  caused by a hereditary deficiency of the Factor VIII, Factor
  XI or Factor XI blood clotting protein in human blood; and
- (g) "von Willebrand disease" shall refer to a human bleeding
   disorder caused by a hereditary deficiency or abnormality of
   the von Willebrand Factor in human blood;

Sec. 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 hemophiliapatients:

(a) 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;

(b) A room exclusively for hemophilia patients; and

- (c) 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.
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16 Sec. 5. *Funding.* – The amount necessary for the initial implementation of 17 this Act shall be sourced from the current budget of the Department of Health. 18 Thereafter, the funds necessary for the continuous implementation of this Act in 19 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.

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

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6 Sec. 7. *Separability Clause.* – If for any reason, any provision of this Act is 7 declared unconstitutional or invalid, the other parts or provisions hereof which 8 are not affected thereby shall continue to be in full force and effect.

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10Sec. 8. *Effectivity Clause.* – This Act shall take effect fifteen (15) days11following its publication in at least two (2) newspapers of national circulation.

Approved,