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ASSEMBLY, No. 2180

STATE OF NEW JERSEY

215th LEGISLATURE

INTRODUCED FEBRUARY 2, 2012

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SYNOPSIS

Establishes “Bleeding Disorders Treatment Fund.”

CURRENT VERSION OF TEXT

As reported by the Assembly Health and Senior Services Committee on February 7, 2013, with amendments.

(Sponsorship Updated As Of: 9/28/2012)

AN ACT establishing the "Bleeding Disorders Treatment Fund" and supplementing Title 26 of the Revised Statutes.

BE IT ENACTED *by the Senate and General Assembly of the State of New Jersey:*

1. The Legislature finds and declares that:

a. Hemophilia is a congenital bleeding disorder that affects more than 800 males in New Jersey;

b. Hemophilia and other related bleeding disorders are characterized by lifelong frequent spontaneous bleeds in the joints and internal organs that cause excruciating pain, crippling multiple joint damage, and often death for children or adolescents with hemophilia;

c. With the establishment of federally funded comprehensive treatment centers for hemophilia and other related bleeding disorders in 1975 and the availability of clotting factor concentrates, the lives and health of individuals with hemophilia and other related bleeding disorders have vastly improved, allowing normal and productive life styles and 40% less mortality for those receiving comprehensive care from the State designated hemophilia treatment centers in New Jersey;

d. Hemophilia is unique among all congenital disorders in that a hemophilic patient depends upon the coordinated, multi-specialty comprehensive care of a treatment center for all of his medical needs from birth to death;

e. Although the cost of maintaining the comprehensive treatment centers accounts for only 5% to 10% of the total medical cost of hemophilia care, with clotting factor accounting for most of the rest, without the treatment centers, the care of persons with hemophilia would again become fragmented, suboptimal, and unreliable;

f. During the past 15 years, federal funding support for the comprehensive treatment centers has steadily declined and now meets less than 10% of the costs incurred by the centers;

g. With the likely discontinuance of federal and State funding support for the care of hemophilia and other related bleeding disorders in the foreseeable future, the survival of these treatment centers and the care of their patients are in jeopardy; and

h. Given these circumstances with regard to the unique nature of hemophilia among congenital disorders and the critical need to ensure continued funding to preserve the existing system of comprehensive treatment centers for hemophilia and other related bleeding disorders in New Jersey and the life-enhancing and life-saving care that they provide, it is in the public interest for the State

EXPLANATION – Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted in the law.

Matter underlined thus is new matter.
Matter enclosed in superscript numerals has been adopted as follows:
[1]Assembly AHE committee amendments adopted February 7, 2013.

to enact legislation that will secure additional revenues from a rebate on clotting factor sold in this State in order to address the immediate funding needs of the State and federally recognized hemophilia treatment centers in New Jersey.

2. As used in this act:

"Association" means the Hemophilia Association of New Jersey.

"Bleeding disorder" means a quantitative or qualitative abnormality in the physiologic processes which bring about hemostasis.

"Clotting factor" means specific and specialized protein molecules present in blood plasma that are essential for hemostasis.

"Department" means the Department of Health [1][and Senior Services][1].

"Fund" means the "Bleeding Disorders Treatment Fund" established pursuant to this act.

"Hemophilia treatment center" means a specialized care center, defined and recognized by the department and the federal Maternal and Child Health Bureau and the federal Centers for Disease Control and Prevention, for patients with hemophilia and other bleeding disorders.

"Hemostasis" means the normal blood clot formation needed to arrest excessive or prolonged bleeding when blood vessels are damaged due to an injury during normal daily activity or from significant trauma or surgery, which involves the physiological processes of clot formation that require integrated interactions of the lining of the blood vessels, platelets, and clotting factors.

"Home care company" means a provider of home treatment services for bleeding episodes associated with hemophilia that meets the standards set forth in section 1 of P.L.2000, c.121 (C.26:2S-10.1).

"Platelets" means fragments of special blood cells that have several functions relating to the arrest of bleeding.

"Section 340B center" means a hemophilia treatment center that is eligible to receive discounted outpatient prescription drug prices from pharmaceutical manufacturers under the federal Public Health Service 340B drug pricing program established pursuant to the federal "Veterans Health Care Act of 1992," Pub.L.102-585.

3. a. The "Bleeding Disorders Treatment Fund" is established as a nonlapsing, revolving fund. The fund shall be administered by the department, and shall be credited with rebates collected pursuant to section 4 of this act, and any monies appropriated or otherwise made available for the purposes of this act; except that the department may deduct from the rebates collected pursuant to section 4 of this act the administrative costs reasonably incurred by the department to effectuate the purposes of this act, including, but

not limited to, costs incurred to collect those rebates and to collect data pursuant to section 4 of this act.

b. The monies in the fund are specifically dedicated and shall be applied to the purpose of supporting hemophilia treatment centers as set forth in this act.

c. The State Treasurer is the custodian of the fund. The monies in the fund, pending their application to the purposes provided in this act, may be invested and reinvested as are other trust funds in the custody of the State Treasurer, in the manner provided by law. Net earnings received from the investment or deposit of monies in the fund shall be paid into the fund for the purpose of supplementing or replenishing the fund.

d. The principal purposes of the fund shall be to help ensure the long-term financial viability of hemophilia treatment centers located in the State that are not section 340B centers and to provide an ongoing source of funds to support the purchase of insurance policies and other patient-related services provided by or through the Hemophilia Association of New Jersey for New Jersey residents with bleeding disorders.

(1) No less than 60% of the monies available in the fund in any calendar year shall be used to fund the operating expenses of the hemophilia treatment centers, and the balance shall be used to support the purchase of insurance policies and patient-related services provided by the association.

(2) The monies available in the fund shall be distributed to hemophilia treatment centers and the association in accordance with criteria to be established by the department and based upon the populations served; except that none of these monies shall be made available to a hemophilia treatment center which:

(a) is a section 340B center; or

(b) executes an agreement with a third party, or employs a physician who agrees to a contract with a third party, which restricts the access of patients being treated at that hemophilia treatment center to less than the full range of hemophilia clotting factors then generally available to patients.

e. In addition to those monies otherwise credited to the fund pursuant to this act, the State Treasurer shall credit to the fund such grants of monies as may be received from the federal government, corporations, foundations, or other private sector sources for the purposes of the fund.

4. a. Except as provided herein, each manufacturer of clotting factor shall be required to enter into an agreement with the department to pay a rebate, as provided in this section, for each unit of clotting factor that it sells for use by patients with bleeding disorders residing in this State.

(1) The rebate shall be equal to 6% of the average manufacturer's price for that unit of clotting factor sold in this State.

(2) The rebate agreement shall not apply to any unit of clotting factor sold in New Jersey which is then already subject to a discount mandated by federal law or regulation, specifically including that received by a section 340B center, and clotting factor sold to a person covered by the federal Medicare program established pursuant to Title XVIII of the "Social Security Act," Pub.L.89-97 (42 U.S.C. s.1395 et seq.) or by the Medicaid program pursuant to P.L.1968, c.413 (C.30:4D-1 et seq.).

b. Each home care company that sells clotting factor to patients residing in this State shall be required to enter into an agreement with the department to pay a rebate equal to 2% of the sales price of each unit of clotting factor sold in this State, which assessment shall be in addition to the rebate payable by the manufacturer.

c. The rebate agreement provided for under this section shall apply to the sale of clotting factor beginning on the first day of the next calendar quarter after the effective date of this act.

d. Proceeds from the rebates shall be collected by the department and deposited in the fund, except as otherwise utilized for the administrative expenses of the department, as provided in section 3 of this act.

e. Each manufacturer and home care company shall file a semi-annual report with the department for each six-month period subsequent to the effective date of this act identifying therein the necessary data to calculate the rebate due with respect to that six-month period.

(1) The report shall be in such form as may be specified by the department.

(2) **[1]**[The department shall safeguard from public disclosure the confidentiality of any data submitted by a]** A**[1]** manufacturer or home care company **[1]**[that the manufacturer or home care company designates as being]** may certify that data included in its semi-annual report filed with the department is**[1]** proprietary **[1]**commercial information**[1]**. **[1]**That certification shall include all information that the Commissioner of Health deems necessary for the department to determine whether the data is proprietary commercial information. If the department determines that the data is proprietary commercial information, the department shall not disclose or make public the data, and shall make a determination that the data is not a "government record" subject to public access or inspection within the meaning of P.L.1963, c.73 (C.47:1A-1 et seq.) and section 1 of P.L.1995, c.23 (C.47:1A-1.1).**[1]**

(3) The semi-annual report shall be submitted within 60 days following the close of the preceding semi-annual reporting period; and the manufacturer and home care company shall remit, with the

semi-annual report, payment of the rebate due for the preceding semi-annual period.

5. The Commissioner of Health [1]⟦and Senior Services⟧[1], pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), shall adopt rules and regulations to effectuate the purposes of this act in consultation with the Hemophilia Association of New Jersey and the manufacturer with the largest market share of clotting factor sold in this State, as determined by the commissioner.

6. This act shall take effect on the [1]⟦180th day after⟧ first day of the seventh month next following the date of[1] enactment, but the Commissioner of Health [1]⟦and Senior Services⟧[1] may take such anticipatory administrative action in advance thereof as shall be necessary for the implementation of this act.