

ASSEMBLY, No. 2180

STATE OF NEW JERSEY

215th LEGISLATURE

INTRODUCED FEBRUARY 2, 2012

Sponsored by:

Assemblyman HERB CONAWAY, JR.

District 7 (Burlington)

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District 32 (Bergen and Hudson)

Assemblywoman SHAVONDA E. SUMTER

District 35 (Bergen and Passaic)

Assemblywoman L. GRACE SPENCER

District 29 (Essex)

SYNOPSIS

Establishes “Bleeding Disorders Treatment Fund.”

CURRENT VERSION OF TEXT

As introduced.



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

1 AN ACT establishing the “Bleeding Disorders Treatment Fund” and
2 supplementing Title 26 of the Revised Statutes.

3
4 **BE IT ENACTED** *by the Senate and General Assembly of the State*
5 *of New Jersey:*

6
7 1. The Legislature finds and declares that:

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

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

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

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

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

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

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

40 h. Given these circumstances with regard to the unique nature
41 of hemophilia among congenital disorders and the critical need to
42 ensure continued funding to preserve the existing system of
43 comprehensive treatment centers for hemophilia and other related
44 bleeding disorders in New Jersey and the life-enhancing and life-
45 saving care that they provide, it is in the public interest for the State
46 to enact legislation that will secure additional revenues from a
47 rebate on clotting factor sold in this State in order to address the

1 immediate funding needs of the State and federally recognized
2 hemophilia treatment centers in New Jersey.

3

4 2. As used in this act:

5 “Association” means the Hemophilia Association of New Jersey.

6 “Bleeding disorder” means a quantitative or qualitative
7 abnormality in the physiologic processes which bring about
8 hemostasis.

9 “Clotting factor” means specific and specialized protein
10 molecules present in blood plasma that are essential for hemostasis.

11 “Department” means the Department of Health and Senior
12 Services.

13 “Fund” means the “Bleeding Disorders Treatment Fund”
14 established pursuant to this act.

15 “Hemophilia treatment center” means a specialized care center,
16 defined and recognized by the department and the federal Maternal
17 and Child Health Bureau and the federal Centers for Disease
18 Control and Prevention, for patients with hemophilia and other
19 bleeding disorders.

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

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

30 “Platelets” means fragments of special blood cells that have
31 several functions relating to the arrest of bleeding.

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

37

38 3. a. The “Bleeding Disorders Treatment Fund” is established
39 as a nonlapsing, revolving fund. The fund shall be administered by
40 the department, and shall be credited with rebates collected
41 pursuant to section 4 of this act, and any monies appropriated or
42 otherwise made available for the purposes of this act; except that
43 the department may deduct from the rebates collected pursuant to
44 section 4 of this act the administrative costs reasonably incurred by
45 the department to effectuate the purposes of this act, including, but
46 not limited to, costs incurred to collect those rebates and to collect
47 data pursuant to section 4 of this act.

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

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

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

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

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

28 (a) is a section 340B center; or

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

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

39

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

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

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

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

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

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

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

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

28 (2) The department shall safeguard from public disclosure the
29 confidentiality of any data submitted by a manufacturer or home
30 care company that the manufacturer or home care company
31 designates as being proprietary.

32 (3) The semi-annual report shall be submitted within 60 days
33 following the close of the preceding semi-annual reporting period;
34 and the manufacturer and home care company shall remit, with the
35 semi-annual report, payment of the rebate due for the preceding
36 semi-annual period.

37
38 5. The Commissioner of Health and Senior Services, pursuant
39 to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-
40 1 et seq.), shall adopt rules and regulations to effectuate the
41 purposes of this act in consultation with the Hemophilia Association
42 of New Jersey and the manufacturer with the largest market share of
43 clotting factor sold in this State, as determined by the
44 commissioner.

45
46 6. This act shall take effect on the 180th day after enactment,
47 but the Commissioner of Health and Senior Services may take such
48 anticipatory administrative action in advance thereof as shall be

1 necessary for the implementation of this act.

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3

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STATEMENT

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6 This bill establishes the “Bleeding Disorders Treatment Fund” to
7 support certain hemophilia treatment centers.

8 The substitute requires manufacturers and home care companies
9 to enter into agreements with the Department of Health and Senior
10 Services (DHSS) to pay a rebate for each unit of clotting factor that
11 they sell for use by patients with bleeding disorders residing in New
12 Jersey.

13 The bill charges DHSS with the administration of the fund,
14 which will serve as the repository of monies collected under rebate
15 agreements.

16 The bill stipulates that at least 60% of the monies available in the
17 fund in any calendar year must be used to fund the operating
18 expenses of hemophilia treatment centers, and that the balance of
19 the fund must be used to support the purchase of insurance policies
20 and patient-related services provided by the Hemophilia
21 Association of New Jersey.

22 The bill requires the State Treasurer to credit to the fund such
23 grants of monies as may be received from the federal government,
24 corporations, foundations, or other private sector sources for the
25 purposes of the fund.

26 The bill requires the rebate paid by manufacturers to be 6% of
27 the average manufacturer’s price for clotting factor sold in New
28 Jersey, and the rebate paid by home care companies to be 2% of the
29 sales price of each unit of clotting factor sold in New Jersey. The
30 bill does not require a rebate for clotting factor sold in New Jersey
31 which is subject to a discount mandated by federal law or
32 regulation, including under section 340B of the Public Health
33 Service Act, and for clotting factor sold to Medicare or Medicaid
34 patients.

35 The bill requires DHSS to collect the rebates and to deposit the
36 proceeds into the fund, except as otherwise utilized for DHSS
37 administrative expenses, as provided by the bill.

38 The bill requires manufacturers and home care companies to file
39 a semi-annual report with DHSS for each six-month period after the
40 effective date of the bill identifying data necessary to calculate the
41 rebate due for that six-month period.

42 The bill requires the Commissioner of Health and Senior
43 Services to adopt rules and regulations to effectuate the purposes of
44 the bill in consultation with the Hemophilia Association of New
45 Jersey and the manufacturer with the largest market share of
46 clotting factor sold in this State, as determined by the
47 commissioner.

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1 The bill takes effect on the 180th day after its enactment, and
2 applies the rebate to sales of clotting factor beginning on the first
3 day of the next calendar quarter after that effective date. The bill
4 authorizes the commissioner to take anticipatory administrative
5 action in advance of the effective date as necessary for its
6 implementation.