

Introduced by Senator Pavley

February 8, 2010

An act to add Article 5 (commencing with Section 125286.1) to Chapter 2 of Part 5 of Division 106 of the Health and Safety Code, relating to genetic disease services.

LEGISLATIVE COUNSEL'S DIGEST

SB 971, as introduced, Pavley. Bleeding disorders: blood clotting products.

Existing law, the Holden-Moscone-Garamendi Genetically Handicapped Person's Program, requires the Director of Health Care Services to establish and administer a program for the medical care of persons with genetically handicapping conditions, including hemophilia.

This bill would impose specified requirements on providers of blood clotting products for home use used for the treatment and prevention of symptoms associated with bleeding disorders, including all forms of hemophilia. This bill would require the California State Board of Pharmacy to administer and enforce these provisions.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

- 1 SECTION 1. Article 5 (commencing with Section 125286.1)
- 2 is added to Chapter 2 of Part 5 of Division 106 of the Health and
- 3 Safety Code, to read:

Article 5. Standards of Service for Providers of Blood Clotting
Products for Home Use Act

125286.1. This article shall be known, and may be cited, as the Standards of Service for Providers of Blood Clotting Products for Home Use Act.

125286.2. The Legislature hereby finds and declares all of the following:

(a) Hemophilia is a rare, hereditary, bleeding disorder affecting at least 4,000 persons in California and is a chronic, lifelong, and incurable, but treatable, disease.

(b) Von Willebrand disease is a human bleeding disorder caused by a hereditary deficiency or abnormality of the von Willebrand Factor in human blood, which is a protein that helps clot blood. Von Willebrand disease is a chronic, lifelong, incurable, but treatable, disease affecting at least 360,000 Californians.

(c) Until the 1970s, people with severe hemophilia suffered from uncontrollable internal bleeding, crippling orthopedic deformities, and a shortened lifespan. More recently, the production of highly purified blood clotting factors have provided people with hemophilia and other bleeding disorders with the opportunity to lead normal lives, free of pain and crippling arthritis.

(d) The preferred method of treatment of hemophilia today is intravenous injection, or infusion, of prescription blood clotting products several times per week, along with case management and specialized medical care at a federally designated regional hemophilia treatment center.

(e) Pharmacies and other entities specializing in the delivery of blood clotting products and related equipment, supplies, and services for home use form a growing enterprise in California. All of these entities are licensed by the state or are located at federally designated regional hemophilia treatment centers, or both.

(f) Timely access to federally designated regional hemophilia centers and appropriate products and services in the home, including infusion of blood clotting products and related equipment, and supplies and services for persons with hemophilia and other bleeding disorders, reduces mortality and bleeding-related hospitalizations, and is extremely cost effective, according to the federal Centers for Disease Control and Prevention and the Medical

1 and Scientific Advisory Council of the National Hemophilia
2 Foundation.

3 (g) Eligible persons with hemophilia or other bleeding disorders
4 may receive treatment through the Genetically Handicapped
5 Persons Program, the California Children’s Services Program, and
6 Medi-Cal. Access to quality blood clotting products for home use
7 and related equipment, supplies, and services for people with
8 hemophilia or other bleeding disorders promotes cost containment
9 in each of these publicly funded programs as well as in the health
10 insurance and health care industries more generally.

11 (h) For the benefit of persons with hemophilia or other bleeding
12 disorders, as well as for cost containment in health care, the
13 purposes of this article are to do the following:

14 (1) Establish standards of service for entities that deliver blood
15 clotting products and related equipment, supplies, and services for
16 home use.

17 (2) Promote access to a full range of essential, cost effective,
18 lifesaving, blood clotting products and related equipment, supplies,
19 and high-quality services for home use for persons with hemophilia
20 and other bleeding disorders.

21 125286.3. Unless context otherwise requires, the following
22 definitions shall apply for purposes of this article:

23 (a) “340B Program” means an outpatient pharmacy licensed to
24 dispense blood clotting products in California and that is
25 conditionally or fully designated as a covered entity under the
26 Veterans Health Care Act of 1992 (Public Law 102-585), which
27 enacted Section 340B of the Public Health Service Act (41 U.S.C.
28 Sec. 201 et seq.).

29 (b) “Assay” means the amount of a particular constituent of a
30 mixture or of the biological or pharmacological potency of a drug.

31 (c) “Ancillary infusion equipment and supplies” means the
32 equipment and supplies required to infuse a blood clotting product
33 into a human vein, including, but not limited to, syringes, needles,
34 sterile gauze, field pads, gloves, alcohol swabs, numbing creams,
35 tourniquets, medical tape, sharps or equivalent biohazard waste
36 containers, and cold compression packs.

37 (d) “Bleeding disorder” means a medical condition characterized
38 by a severe deficiency or absence of one or more essential blood
39 clotting proteins in the human blood, often called “factors,”

1 including all forms of hemophilia and other bleeding disorders
2 that result in uncontrollable bleeding or abnormal blood clotting.

3 (e) “Blood clotting product” means an intravenously
4 administered medicine manufactured from human plasma or
5 recombinant biotechnology techniques, approved for distribution
6 by the federal Food and Drug Administration, that is used for the
7 treatment and prevention of symptoms associated with bleeding
8 disorders. Blood clotting products include, but are not limited to,
9 Factor VII, Factor VIIa, Factor VIII, and Factor IX products, von
10 Willebrand Factor products, bypass products for patients with
11 inhibitors, and activated prothrombin complex concentrates.

12 (f) “Consumer” means a person needing a blood clotting product
13 for home use.

14 (g) “Emergency” means a situation in which a prudent layperson
15 could reasonably believe that the consumer’s condition requires
16 immediate medical attention.

17 (h) “Hemophilia” means a human bleeding disorder caused by
18 a hereditary deficiency of the Factors I, II, V, VIII, IX, XI, XII,
19 or XIII blood clotting protein in human blood.

20 (i) “Hemophilia treatment center” means a facility for the
21 treatment of bleeding disorders, including, but not limited to,
22 hemophilia, that receives funding from the federal government
23 sources, including, but not limited to, the federal Centers for
24 Disease Control and Prevention and the federal Health Resources
25 and Services Administration (HRSA) of the United States
26 Department of Health and Human Services.

27 (j) “Home nursing services” means specialized nursing care
28 provided in the home setting to assist a patient in the reconstitution
29 and administration of blood clotting products.

30 (k) “Home use” means infusion or other use of a blood clotting
31 product in a place other than a state-recognized hemophilia
32 treatment center. Places where home use occurs include, without
33 limitation, a home or physician office.

34 (l) “Provider of blood clotting products for home use” means a
35 seller and provider of blood clotting products, ancillary infusion
36 equipment, home nursing services, and patient assistance for the
37 management of bleeding disorders for home use. These providers
38 include, without limitation, 340B programs, other pharmacies,
39 and, when treatment is not provided onsite, hemophilia treatment
40 centers.

1 125286.4. Each provider of blood clotting products for home
2 use shall meet all of the following requirements:

3 (a) Have sufficient knowledge and understanding of bleeding
4 disorders and the medical and psychosocial management thereof,
5 including, but not limited to, home therapy.

6 (b) Have sufficient clinical experience providing services to
7 persons with bleeding disorders and a sufficient nonclinical
8 understanding of bleeding disorders that enables the provider to
9 know when patients have an appropriate supply of clotting factor
10 on hand and about proper refrigeration of clotting factors.

11 (c) Ensure that its customer service staff meets the requirements
12 of subdivisions (a) and (b).

13 (d) Have a pharmacist available at all times, 24 hours a day,
14 seven days a week, every day of the year, either onsite or on call,
15 to fill prescriptions for blood clotting products.

16 (e) Supply blood clotting products and home nursing services,
17 as prescribed by the consumer's treating physician, and, pursuant
18 to Section 4073 of the Business and Professions Code, not make
19 any substitutions of blood clotting products or assay amounts.

20 (f) Ask the prescribing physician which specific blood clotting
21 product is intended whenever a prescription does not indicate the
22 specific product and then use the product named in the physician's
23 response.

24 (g) Supply all brands of blood clotting products approved by
25 the federal Food and Drug Administration in multiple assay ranges
26 (low, medium, and high, as applicable) and vial sizes, including
27 products manufactured from human plasma and those manufactured
28 with recombinant biotechnology techniques.

29 (h) Supply all necessary ancillary infusion equipment and
30 supplies with each prescription, as needed.

31 (i) Maintain adequate stocks of blood clotting products and
32 ancillary infusion equipment and supplies.

33 (j) Store and ship, or otherwise deliver, all blood clotting
34 products in conformity with all state and federally mandated
35 standards, including, but not limited to, the standards set forth in
36 the product's approved package insert (PI).

37 (k) When home nursing services are prescribed by the treating
38 physician, provide these services either directly or through a
39 qualified third party with experience in infusing bleeding disorders

1 and coordinate pharmacy services with the third party when one
2 is used to provide home nursing services.

3 (l) Upon receiving a nonemergency prescription, ship the
4 prescribed blood clotting products and ancillary infusion equipment
5 and supplies to the consumer within:

6 (1) Two business days or less for established consumers.

7 (2) Three business days or less for new consumers.

8 (m) Upon receiving a prescription for an emergency situation,
9 deliver prescribed blood products, ancillary infusion equipment
10 and supplies, medications, and home nursing services to the
11 consumer within 12 hours after receipt of the prescription.

12 (n) Maintain 24-hour oncall service seven days a week for every
13 day of the year, adequately screen phone calls for emergencies,
14 and respond to all phone calls within one hour or less.

15 (o) Provide consumers who have ordered their products with a
16 designated contact phone number for reporting problems with a
17 delivery and respond to these calls immediately.

18 (p) Provide patients with notification of recalls and withdrawals
19 of blood clotting products and ancillary infusion equipment within
20 24 hours and participate in the National Patient Notification System
21 for blood clotting product recalls.

22 (q) Provide language translation services, both over the phone
23 and in person, as needed by the consumer.

24 (r) Have a detailed plan for meeting the requirements of this
25 article in the event of a natural or manmade disaster or other
26 disruption of normal business operations.

27 (s) Provide for proper collection, removal, and disposal of
28 hazardous waste pursuant to state and federal law, including, but
29 not limited to, sharps containers for the removal and disposal of
30 medical waste.

31 (t) Clearly inform the consumer of his or her copay, deductible,
32 and coinsurance payment responsibilities each time he or she orders
33 a blood clotting product.

34 (u) Provide consumers with a copy of all billing invoices.

35 (v) Provide appropriate and necessary recordkeeping and
36 documentation as required by state and federal law and retain
37 copies of the patient's prescriptions.

38 (w) Comply with the privacy and confidentiality requirements
39 of the Health Insurance Portability and Accountability Act of 1996
40 (HIPAA).

1 125286.5. The California State Board of Pharmacy shall
2 administer and enforce this article.

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