

AMENDED IN SENATE APRIL 7, 2010

SENATE BILL

No. 971

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 amended, 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)

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

32 (c)

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

39 (d)

1 (c) “Bleeding disorder” means a medical condition characterized
2 by a ~~severe~~ deficiency or absence of one or more essential blood
3 clotting proteins in the human blood, often called “factors,”
4 including all forms of hemophilia and other bleeding disorders
5 that result in uncontrollable bleeding or abnormal blood clotting
6 *without treatment*.

7 ~~(e)~~

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

17 ~~(f)~~

18 (e) “Consumer” means a person needing a blood clotting product
19 for home use.

20 ~~(g)~~

21 (f) “Emergency” means a situation in which a prudent layperson
22 could reasonably believe that the consumer’s condition requires
23 immediate medical attention.

24 ~~(h)~~

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

28 ~~(i)~~

29 (h) “Hemophilia treatment center” means a facility for the
30 treatment of bleeding disorders, including, but not limited to,
31 hemophilia, that receives funding from the federal government
32 sources, including, but not limited to, the federal Centers for
33 Disease Control and Prevention and the federal Health Resources
34 and Services Administration (HRSA) of the United States
35 Department of Health and Human Services.

36 ~~(j)~~

37 (i) “Home nursing services” means specialized nursing care
38 provided in the home setting to assist a patient in the reconstitution
39 and administration of blood clotting products.

40 ~~(k)~~

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

~~(i)~~

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

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

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

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

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

~~(d) Have a pharmacist available at all times; knowledgeable pharmacy staffing on call 24 hours a day, seven days a week, every day of the year, either onsite or on call, to fill prescriptions for blood clotting products; to initiate emergency requests for clotting factors.~~

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

~~(f) Ask the~~ The prescribing physician *shall indicate* which specific blood clotting product is intended whenever a prescription ~~does not indicate the specific product and then use the product named in the physician’s response.~~ *is written.*

(g) Supply all brands of blood clotting products approved by the federal Food and Drug Administration in multiple assay ranges (low, medium, and high, as applicable) and vial sizes, including

1 products manufactured from human plasma and those manufactured
2 with recombinant biotechnology techniques, *provided manufacturer*
3 *supply exists and payer authorization is approved.*

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

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

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

12 (k) When home nursing services are prescribed by the treating
13 physician, provide these services either directly or through a
14 qualified third party with experience in infusing bleeding disorders
15 and coordinate pharmacy services with the third party when one
16 is used to provide home nursing services.

17 (l) Upon receiving *approved authorization for* a nonemergency
18 prescription, ship the prescribed blood clotting products and
19 ancillary infusion equipment and supplies to the consumer within:
20 *two business days or less for established and new consumers.*

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

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

23 (m) Upon receiving *approved authorization to dispense* a
24 prescription for an emergency situation, deliver prescribed blood
25 products, ancillary infusion equipment and supplies, medications,
26 and home nursing services to the consumer within 12 hours ~~after~~
27 ~~receipt of the prescription~~ *for patients living within 100 miles of*
28 *a major metropolitan airport, and within one day for patients*
29 *living more than 100 miles from a major metropolitan airport.*

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

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

36 (p) Provide patients with notification of recalls and withdrawals
37 of blood clotting products and ancillary infusion equipment within
38 24 hours and participate in the National Patient Notification System
39 for blood clotting product recalls.

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

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

6 (s) Provide for proper collection, removal, and disposal of
7 hazardous waste pursuant to state and federal law, including, but
8 not limited to, sharps containers for the removal and disposal of
9 medical waste.

10 (t) ~~Clearly inform the~~ *Inform a* consumer of his or her copay,
11 deductible, and coinsurance payment responsibilities ~~each time he~~
12 ~~or she orders a blood clotting product.~~ *initially and when changed*
13 *by the consumer's insurance, health plan, or other third-party*
14 *payer.*

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

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

19 (w) Comply with the privacy and confidentiality requirements
20 of the Health Insurance Portability and Accountability Act of 1996
21 (HIPAA).

22 125286.5. The California State Board of Pharmacy shall
23 administer and enforce this article.