

AMENDED IN ASSEMBLY AUGUST 9, 2010

AMENDED IN ASSEMBLY JUNE 23, 2010

AMENDED IN ASSEMBLY JUNE 15, 2010

AMENDED IN SENATE MAY 28, 2010

AMENDED IN SENATE MAY 12, 2010

AMENDED IN SENATE MAY 3, 2010

AMENDED IN SENATE APRIL 21, 2010

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, as described, whose products are 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:

4
5 Article 5. Standards of Service for Providers of Blood Clotting
6 Products for Home Use Act
7

8 125286.1. This article shall be known, and may be cited, as
9 the Standards of Service for Providers of Blood Clotting Products
10 for Home Use Act.

11 125286.2. The Legislature hereby finds and declares all of the
12 following:

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

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

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

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

1 (e) Pharmacies and other entities specializing in the delivery of
2 blood clotting products and related equipment, supplies, and
3 services for home use form a growing enterprise in California.

4 (f) Timely access to federally designated regional hemophilia
5 centers and appropriate products and services in the home,
6 including infusion of blood clotting products and related
7 equipment, and supplies and services for persons with hemophilia
8 and other bleeding disorders, reduces mortality and bleeding-related
9 hospitalizations, ~~and is extremely cost effective~~, according to the
10 federal Centers for Disease Control and Prevention and the Medical
11 and Scientific Advisory Council of the National Hemophilia
12 Foundation.

13 (g) Eligible persons with hemophilia or other bleeding disorders
14 may receive treatment through the Genetically Handicapped
15 Persons Program, the California Children's Services Program, and
16 the Medi-Cal program. ~~Access to quality blood clotting products
17 for home use and related equipment, supplies, and services for
18 people with hemophilia or other bleeding disorders promotes cost
19 containment in each of these publicly funded programs as well as
20 in the health insurance and health care industries more generally.~~

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

24 (1) Establish standards of service for entities that deliver blood
25 clotting products and related equipment, supplies, and services for
26 home use.

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

31 125286.3. Unless the context otherwise requires, the following
32 definitions shall apply for purposes of this article:

33 (a) "Assay" means the amount of a particular constituent of a
34 mixture or of the biological or pharmacological potency of a drug.

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

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

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

(e) “Emergency” means care as defined in Section 1317.1.

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

(g) “Hemophilia treatment center” means a facility for the treatment of bleeding disorders, including, but not limited to, hemophilia, that receives funding specifically for the treatment of patients with bleeding disorders from federal government sources, including, but not limited to, the federal Centers for Disease Control and Prevention and the federal Health Resources and Services Administration (HRSA) of the United States Department of Health and Human Services.

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

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

(j) “Patient” means a person needing a blood clotting product for home use.

(k) (1) “Provider of blood clotting products for home use” means all the following pharmacies, except as described in Section 125286.6, that dispense blood clotting factors for home use:

- 1 (A) Hospital pharmacies.
- 2 (B) Health system pharmacies.
- 3 (C) Pharmacies affiliated with hemophilia treatment centers.
- 4 (D) Specialty home care pharmacies.
- 5 (E) Retail pharmacies.

6 (2) The providers described in this subdivision may also provide
7 home nursing services for persons with bleeding disorders.

8 (3) The providers described in this subdivision shall include a
9 health care service plan and all its affiliated providers if the health
10 care service plan exclusively contracts with a single medical group
11 in a specified geographic area to provide professional services to
12 its enrollees.

13 125286.4. Each provider of blood clotting products for home
14 use shall meet all of the following requirements:

15 (a) Have sufficient knowledge and understanding of bleeding
16 disorders to accurately follow the instructions of the prescribing
17 physician and ensure high-quality service for the patient and the
18 medical and psychosocial management thereof, including, but not
19 limited to, home therapy.

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

25 (c) Have access to knowledgeable pharmacy staffing on call 24
26 hours a day, to initiate emergency requests for clotting factors.

27 (d) Have the ability to obtain all brands of blood clotting
28 products approved by the federal Food and Drug Administration
29 in multiple assay ranges (low, medium, and high, as applicable)
30 and vial sizes, including products manufactured from human
31 plasma and those manufactured with recombinant biotechnology
32 techniques, provided manufacturer supply exists and payer
33 authorization is obtained.

34 (e) Supply all necessary ancillary infusion equipment and
35 supplies with each prescription, as needed.

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

1 (g) When home nursing services are necessary, as determined
2 by the treating physician, provide these services either directly or
3 through a qualified third party with experience in treating bleeding
4 disorders and coordinate pharmacy services with the third party
5 when one is used to provide home nursing services.

6 (h) Upon receiving approved authorization for a nonemergency
7 prescription, provided manufacturer supply exists, ship the
8 prescribed blood clotting products and ancillary infusion equipment
9 and supplies to the patient within two business days or less for
10 established and new patients.

11 (i) Upon receiving approved authorization to dispense a
12 prescription for an emergency situation, provided manufacturer
13 supply exists, deliver prescribed blood products, ancillary infusion
14 equipment and supplies, medications, and home nursing services
15 to the patient within 12 hours for patients living within 100 miles
16 of a major metropolitan airport, and within one day for patients
17 living more than 100 miles from a major metropolitan airport.

18 (j) Maintain 24-hour on call service seven days a week for every
19 day of the year, adequately screen phone calls for emergencies,
20 and acknowledge all phone calls within one hour or less.

21 (k) Provide patients who have ordered their products with a
22 designated contact phone number for reporting problems with a
23 delivery and respond to these calls within a reasonable time period.

24 (l) Provide patients with notification of Class 1 and Class 2
25 recalls and withdrawals of blood clotting products and ancillary
26 infusion equipment within 24 hours of the provider of blood
27 clotting products for home use receiving notification and participate
28 in the National Patient Notification System for blood clotting
29 product recalls.

30 (m) Provide language interpretive services over the phone or in
31 person, as needed by the patient.

32 (n) Have a detailed plan for meeting the requirements of this
33 article in the event of a natural or manmade disaster or other
34 disruption of normal business operations.

35 (o) Provide the patient with a sharps container and instructions
36 on how to dispose of medical waste sharps. However, the provider
37 of blood clotting products shall not be liable for any acts or
38 omissions of the patient in the handling and disposal of medical
39 waste.

1 (p) Provide appropriate and necessary recordkeeping and
2 documentation as required by state and federal law and retain
3 copies of the patient's prescriptions.

4 (q) Comply with the privacy and confidentiality requirements
5 of the Health Insurance Portability and Accountability Act of 1996
6 (HIPAA).

7 125286.5. The California State Board of Pharmacy shall
8 administer and enforce this article.

9 125286.6. Nothing in this article shall apply to either hospital
10 pharmacies or health system pharmacies that dispense blood
11 clotting products due only to emergency, urgent care, or inpatient
12 encounters, or if an inpatient is discharged with a supply of blood
13 clotting products for home use.