

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, except as provided.

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

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

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

1 including infusion of blood clotting products and related
2 equipment, and supplies and services for persons with hemophilia
3 and other bleeding disorders, reduces mortality and bleeding-related
4 hospitalizations, and is extremely cost effective, according to the
5 federal Centers for Disease Control and Prevention and the Medical
6 and Scientific Advisory Council of the National Hemophilia
7 Foundation.

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

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

19 (1) Establish standards of service for entities that deliver blood
20 clotting products and related equipment, supplies, and services for
21 home use.

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

26 125286.3. (a) Unless the context otherwise requires, the
27 following definitions shall apply for purposes of this article:

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

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

36 (3) “Bleeding disorder” means a medical condition characterized
37 by a deficiency or absence of one or more essential blood clotting
38 proteins in the human blood, often called “factors,” including all
39 forms of hemophilia and other bleeding disorders that result in

1 uncontrollable bleeding or abnormal blood clotting without
2 treatment.

3 (4) “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 (5) “Consumer” means a person needing a blood clotting product
13 for home use.

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

17 (7) “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 (8) “Hemophilia treatment center” means a facility for the
21 treatment of bleeding disorders, including, but not limited to,
22 hemophilia, that receives funding from federal government sources,
23 including, but not limited to, the federal Centers for Disease
24 Control and Prevention and the federal Health Resources and
25 Services Administration (HRSA) of the United States Department
26 of Health and Human Services.

27 (9) “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 (10) “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’s office~~ *other nonclinical setting*.

34 (b) (1) For purposes of this article, a “provider of blood clotting
35 products for home use” shall be a provider of blood clotting
36 products and ancillary infusion equipment for home use and
37 consumer assistance for the management of bleeding disorders
38 and may include, but is not limited to, any of the following:

39 (A) Hospital pharmacies.

40 (B) Health system pharmacies.

1 (C) Pharmacies affiliated with hemophilia treatment centers.

2 (D) Specialty home care pharmacies.

3 (E) Retail pharmacies.

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

6 125286.4. Each provider of blood clotting products for home
7 use shall meet all of the following requirements:

8 (a) Have sufficient knowledge and understanding of bleeding
9 disorders to accurately follow the instructions of the prescribing
10 physician and ensure high-quality service for the consumer and
11 the medical and psychosocial management thereof, including, but
12 not limited to, home therapy.

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

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

20 (d) Have knowledgeable pharmacy staffing on call 24 hours a
21 day, to initiate emergency requests for clotting factors.

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

26 (f) The prescribing physician shall indicate which specific blood
27 clotting product is intended whenever a prescription is written.

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

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

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

38 (j) Store and ship, or otherwise deliver, all blood clotting
39 products in conformity with all state and federally mandated

1 standards, including, but not limited to, the standards set forth in
2 the product's approved package insert (PI).

3 (k) When home nursing services are prescribed by the treating
4 physician, provide these services either directly or through a
5 qualified third party with experience in infusing bleeding disorders
6 and coordinate pharmacy services with the third party when one
7 is used to provide home nursing services.

8 (l) Upon receiving approved authorization for a nonemergency
9 prescription, ship the prescribed blood clotting products and
10 ancillary infusion equipment and supplies to the consumer within
11 two business days or less for established and new consumers.

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

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

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

25 (p) Provide patients with notification of recalls and withdrawals
26 of blood clotting products and ancillary infusion equipment within
27 24 hours and participate in the National Patient Notification System
28 for blood clotting product recalls.

29 (q) Provide language translation services, ~~both~~ over the phone
30 ~~and~~ or in person, as needed by the consumer.

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

34 (s) Provide for proper collection, removal, and disposal of
35 hazardous waste pursuant to state and federal law, including, but
36 not limited to, sharps containers for the removal and disposal of
37 medical waste.

38 (t) Inform a consumer of his or her copay, deductible, and
39 coinsurance payment responsibilities initially and when changed
40 by the consumer's insurance, health plan, or other third-party payer.

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

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

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

8 125286.5. (a) Except as provided in subdivision (b), the
9 California State Board of Pharmacy shall administer and enforce
10 this article.

11 (b) The California State Board of Pharmacy shall not administer
12 ~~and~~ or enforce subdivision (f) of Section 125286.4.