

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**

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**Introduced by Senator Pavley**

February 8, 2010

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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 in human blood, which is a protein that helps clot blood.  
19 Von Willebrand disease is a chronic, lifelong, incurable, but  
20 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.

32 (e) Pharmacies and other entities specializing in the delivery of  
33 blood clotting products and related equipment, supplies, and  
34 services for home use form a growing enterprise in California. ~~All~~

1 of these entities are licensed by the state or are located at federally  
2 designated regional hemophilia treatment centers, or both.

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

12 (g) Eligible persons with hemophilia or other bleeding disorders  
13 may receive treatment through the Genetically Handicapped  
14 Persons Program, the California Children’s Services Program, and  
15 ~~Medi-Cal~~ *the Medi-Cal program*. Access to quality blood clotting  
16 products for home use and related equipment, supplies, and services  
17 for people with hemophilia or other bleeding disorders promotes  
18 cost containment in each of these publicly funded programs as  
19 well as in the health insurance and health care industries more  
20 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. ~~(a)~~—Unless the context otherwise requires, the  
32 following definitions shall apply for purposes of this article:

33 ~~(1)~~

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

36 ~~(2)~~

37 (b) “Ancillary infusion equipment and supplies” means the  
38 equipment and supplies required to infuse a blood clotting product  
39 into a human vein, including, but not limited to, syringes, needles,  
40 sterile gauze, field pads, gloves, alcohol swabs, numbing creams,

1 tourniquets, medical tape, sharps or equivalent biohazard waste  
2 containers, and cold compression packs.

3 ~~(3)~~

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

10 ~~(4)~~

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

20 ~~(5) “Emergency” means a situation in which a prudent layperson  
21 could reasonably believe that the patient’s condition requires  
22 immediate medical attention.~~

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

24 ~~(6)~~

25 (f) “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 ~~(7)~~

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

37 ~~(8)~~

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

1     ~~(9)~~

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

7     ~~(10)~~

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

10    ~~(b) (1) For purposes of this article, a “provider~~

11    ~~(k) (1) “Provider of blood clotting products for home use” shall~~  
12 ~~be a provider of blood clotting products and ancillary infusion~~  
13 ~~equipment for home use and patient assistance for the management~~  
14 ~~of bleeding disorders and may include, but is not limited to, any~~  
15 ~~of the following: means all the following pharmacies, except as~~  
16 ~~described in Section 125286.6, that dispense blood clotting factors~~  
17 ~~for home use:~~

18    (A) Hospital pharmacies.

19    (B) Health system pharmacies.

20    (C) Pharmacies affiliated with hemophilia treatment centers.

21    (D) Specialty home care pharmacies.

22    (E) Retail pharmacies.

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

25    (3) *The providers described in this subdivision shall include a*  
26 *health care service plan and all its affiliated providers if the health*  
27 *care service plan exclusively contracts with a single medical group*  
28 *in a specified geographic area to provide professional services to*  
29 *its enrollees.*

30    125286.4. Each provider of blood clotting products for home  
31 use shall meet all of the following requirements:

32    (a) Have sufficient knowledge and understanding of bleeding  
33 disorders to accurately follow the instructions of the prescribing  
34 physician and ensure high-quality service for the patient and the  
35 medical and psychosocial management thereof, including, but not  
36 limited to, home therapy.

37    (b) Have *access to a provider with sufficient clinical experience*  
38 *providing services to persons with bleeding disorders* ~~and a~~  
39 ~~sufficient nonclinical understanding of bleeding disorders~~ that  
40 enables the provider to know when patients have an appropriate

- 1 supply of clotting factor on hand and about proper *storage and*  
2 refrigeration of clotting factors.
- 3 ~~(e) Ensure that its customer service staff meets the requirements~~  
4 ~~of subdivisions (a) and (b).~~
- 5 ~~(d) Have~~  
6 *(c) Have access to knowledgeable pharmacy staffing on call 24*  
7 *hours a day, to initiate emergency requests for clotting factors.*
- 8 ~~(e)~~  
9 *(d) Have the ability to obtain all brands of blood clotting*  
10 *products approved by the federal Food and Drug Administration*  
11 *in multiple assay ranges (low, medium, and high, as applicable)*  
12 *and vial sizes, including products manufactured from human*  
13 *plasma and those manufactured with recombinant biotechnology*  
14 *techniques, provided manufacturer supply exists and payer*  
15 *authorization is obtained.*
- 16 ~~(f)~~  
17 *(e) Supply all necessary ancillary infusion equipment and*  
18 *supplies with each prescription, as needed.*
- 19 ~~(g)~~  
20 *(f) Store and ship, or otherwise deliver, all blood clotting*  
21 *products in conformity with all state and federally mandated*  
22 *standards, including, but not limited to, the standards set forth in*  
23 *the product's approved package insert (PI).*
- 24 ~~(h)~~  
25 *(g) When home nursing services are ~~prescribed~~ necessary, as*  
26 *determined by the treating physician, provide these services either*  
27 *directly or through a qualified third party with experience in*  
28 *infusing treating bleeding disorders and coordinate pharmacy*  
29 *services with the third party when one is used to provide home*  
30 *nursing services.*
- 31 ~~(i)~~  
32 *(h) Upon receiving approved authorization for a nonemergency*  
33 *prescription, provided manufacturer supply exists, ship the*  
34 *prescribed blood clotting products and ancillary infusion equipment*  
35 *and supplies to the patient within two business days or less for*  
36 *established and new patients.*
- 37 ~~(j)~~  
38 *(i) Upon receiving approved authorization to dispense a*  
39 *prescription for an emergency situation, provided manufacturer*  
40 *supply exists, deliver prescribed blood products, ancillary infusion*

1 equipment and supplies, medications, and home nursing services  
2 to the patient within 12 hours for patients living within 100 miles  
3 of a major metropolitan airport, and within one day for patients  
4 living more than 100 miles from a major metropolitan airport.

5 ~~(k)~~

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

9 ~~(t)~~

10 (k) Provide patients who have ordered their products with a  
11 designated contact phone number for reporting problems with a  
12 delivery and respond to these calls ~~immediately~~ *within a reasonable*  
13 *time period.*

14 ~~(m)~~

15 (l) Provide patients with notification of *Class 1 and Class 2*  
16 recalls and withdrawals of blood clotting products and ancillary  
17 infusion equipment within 24 hours *of the provider of blood*  
18 *clotting products for home use receiving notification* and participate  
19 in the National Patient Notification System for blood clotting  
20 product recalls.

21 ~~(n)~~

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

24 ~~(o)~~

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

28 ~~(p)~~

29 (o) Provide for proper collection, removal, and disposal of  
30 ~~hazardous waste pursuant to state and federal law, including, but~~  
31 ~~not limited to, sharps containers for the removal and disposal of~~  
32 ~~medical waste: medical waste pursuant to the Medical Waste~~  
33 *Management Act (Part 14 (commencing with Section 117600) of*  
34 *Division 104).*

35 ~~(q)~~

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

39 ~~(r)~~

1 (q) Comply with the privacy and confidentiality requirements  
2 of the Health Insurance Portability and Accountability Act of 1996  
3 (HIPAA).

4 125286.5. The California State Board of Pharmacy shall  
5 administer and enforce this article.

6 125286.6. Nothing in this article shall apply to either hospital  
7 pharmacies or health system pharmacies that dispense blood  
8 clotting products due only to emergency, urgent care, or inpatient  
9 encounters, or if an inpatient is discharged with a supply of blood  
10 clotting products for home use.

O