

1 HB420
2 117115-1
3 By Representative Mask
4 RFD: Health
5 First Read: 26-JAN-10

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8 SYNOPSIS: Existing state law does not provide
9 standards of care that adequately address the
10 unique health care needs of persons with hemophilia
11 and other bleeding disorders.

12 This bill would require pharmacy providers
13 that distribute blood clotting products used at
14 home to treat and prevent symptoms associated with
15 bleeding disorders, including all forms of
16 hemophilia, to meet certain specified conditions.

17 This bill would require health insurers to
18 provide certain benefits in their policies for
19 persons with hemophilia and other bleeding
20 disorders.

21 This bill would require physicians to
22 request a medical screening for von Willebrand's
23 disease and other bleeding disorders prior to
24 advising a patient that an invasive uterine
25 surgical procedure is the most appropriate
26 treatment for menorrhagia.

1 This bill would also authorize the State
2 Department of Public Health to adopt rules
3 necessary to implement the act.

4
5 A BILL
6 TO BE ENTITLED
7 AN ACT

8
9 Establishing standards of care for health care needs
10 of persons with hemophilia and other bleeding disorders in
11 Alabama.

12 BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:

13 Section 1. This act shall be known and may be cited
14 as the "Hemophilia Standards of Care Act."

15 Section 2. The Legislature finds and declares the
16 following:

17 (1) Hemophilia is a rare, genetic bleeding disorder
18 and is a chronic, lifelong, incurable disease.

19 (2) Until the 1970's, persons afflicted with severe
20 hemophilia suffered from uncontrollable internal bleeding,
21 crippling orthopedic deformities, and diminished life span.

22 (3) The scientific discovery of highly purified
23 blood clotting factors has enabled many persons with
24 hemophilia to lead normal lives free of pain and crippling
25 arthritis.

26 (4) The blood clotting factors used to treat and
27 control bleeding episodes are expensive and must be injected

1 intravenously, typically several times per week, but this
2 medicine can be self-administered in the patient's home, the
3 preferred method of treatment.

4 (5) In addition to blood clotting factors, patients
5 require expert, specialized medical care at a regional
6 hemophilia treatment program affiliated with a hospital.

7 (6) The Legislature therefore establishes standards
8 of care so that patients with hemophilia and other bleeding
9 disorders can receive necessary and appropriate medical care.

10 Section 3. As used in this act, the following terms
11 shall have the following meanings:

12 (1) 340B PROGRAM. An outpatient pharmacy licensed by
13 the State of Alabama to dispense blood clotting products which
14 is conditionally or fully designated as a covered entity under
15 the Veterans Health Care Act of 1992 (Public Law 102-585, 106
16 Stat. 4943), which enacted Section 340B of the Public Health
17 Service Act (58 Stat. 682, 42 U.S.C. §256b). The program
18 allows hemophilia treatment centers to purchase prescription
19 drugs, including clotting factor products and other necessary
20 supplies, at discounted prices from pharmaceutical
21 manufacturers for the management of bleeding disorders in the
22 home setting.

23 (2) ANCILLARY INFUSION EQUIPMENT AND SUPPLIES. The
24 equipment and supplies required for infusing blood clotting
25 products into the body. The term includes, but is not limited
26 to, syringes, sterile gauze and alcohol swabs, tourniquets,

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

3 (3) BLEEDING DISORDER. A medical condition
4 characterized by a severe deficiency or absence of one or more
5 essential blood clotting proteins, including all forms of
6 hemophilia, von Willebrand's disease, and other bleeding
7 disorders that result in uncontrollable bleeding or abnormal
8 blood clotting.

9 (4) BLOOD CLOTTING PRODUCT. An intravenously
10 administered medicine manufactured from human plasma or
11 recombinant biotechnology techniques, approved for
12 distribution by the Food and Drug Administration and which is
13 used for the treatment and prevention of symptoms associated
14 with bleeding disorders. The term includes, but is not limited
15 to, Factors VII, VIII, and IX products; von Willebrand Factor
16 products; bypass products for patients with inhibitors; and
17 activated prothrombin complex concentrates.

18 (5) CLINICAL COAGULATION LABORATORY. A medical
19 facility licensed by the State of Alabama to diagnose bleeding
20 disorders and perform specialized coagulation studies of human
21 blood for patients with bleeding disorders.

22 (6) COVERED PERSON. An individual who is entitled to
23 receive health care benefits or coverage from a health care
24 insurer.

25 (7) DEPARTMENT. The Department of Public Health.

1 (8) HEMOPHILIA. A type of bleeding disorder caused
2 by a deficiency of the blood clotting proteins known as
3 Factors I, VII, VIII, IX, XI, or XII.

4 (9) HEMOPHILIA TREATMENT CENTER. A facility which
5 provides comprehensive care for people with bleeding
6 disorders. Some of these centers receive funding from the
7 federal government including, but not limited to, Centers for
8 Disease Control and Prevention and the Health Resources and
9 Services Administration.

10 (10) HOMECARE COMPANY. Any outpatient pharmacy other
11 than a 340B program licensed by the State of Alabama to
12 provide blood clotting products, ancillary infusion equipment,
13 home nursing services, and patient assistance for the
14 management of bleeding disorders in the home setting.

15 (11) INSURER. An entity that issues an individual or
16 a group health insurance policy pursuant to Article 6 of
17 Chapter 4 of Title 10 or Title 27, Code of Alabama 1975.

18 (12) INVASIVE UTERINE SURGICAL PROCEDURE. A
19 procedure performed by a physician that involves the insertion
20 of a surgical instrument into the uterus, including, but not
21 limited to, the performance of a hysterectomy or uterine
22 ablation.

23 (13) VON WILLEBRAND DISEASE. A type of bleeding
24 disorder caused by a deficiency of a blood clotting protein
25 known as the von Willebrand Factor.

26 Section 4. A pharmacy that dispenses clotting factor
27 products to individuals with bleeding disorders in the State

1 of Alabama for use in the home shall comply with the following
2 requirements:

3 (1) Supply blood clotting products and home nursing
4 services as prescribed by the covered person's treating
5 physician. To make any substitutions of blood clotting
6 products, the provider must first receive prior approval from
7 the treating physician of the patient or the patient's legal
8 guardian, if the patient is under the age of 18.

9 (2) Supply all FDA-approved brands of blood clotting
10 products in multiple assay ranges, as applicable, including
11 products manufactured with recombinant biotechnology
12 techniques and those manufactured from human plasma.

13 (3) Supply all necessary ancillary infusion
14 equipment and supplies needed to prepare and infuse the
15 quantity of blood clotting product.

16 (4) Provide, directly or through a reliable
17 third-party agency, home infusion nursing services whenever
18 these services are prescribed or deemed necessary by the
19 treating physician.

20 (5) Ensure that a pharmacist is on call to fill
21 prescriptions for blood clotting products 24 hours a day,
22 seven days a week.

23 (6) Be capable of providing blood clotting products
24 in assays within five percent of the prescribed amount.

25 (7) Ship the prescribed blood clotting products and
26 ancillary infusion equipment to covered persons within 24
27 hours.

1 (8) Provide appropriate and necessary recordkeeping
2 and documentation, including tracking of lifetime caps.

3 (9) Provide administrative assistance for covered
4 persons to obtain payment for blood clotting products,
5 ancillary infusion equipment, and home nursing services.

6 (10) Provide covered persons, upon request, with
7 information about the anticipated out-of-pocket cost for blood
8 clotting products, ancillary infusion equipment, and services
9 that are nor otherwise paid for by the health care insurer.

10 (11) Notify covered persons and prescribers of
11 recalls and withdrawals of blood clotting products and
12 ancillary infusion equipment as soon as practical.

13 (12) Provide covered persons with containers or the
14 equivalent for the removal and disposal of medical waste.

15 (13) File a plan with the department explaining how
16 the pharmacy will deal with emergencies such as natural
17 disasters or blood clotting product shortages. This plan shall
18 be available upon request to the public.

19 Section 5. All entities licensed as an insurer shall
20 provide coverage for services provided to persons with
21 hemophilia and related bleeding disorders including, but not
22 limited to, physician services as prescribed by the treating
23 physician for inpatient care and outpatient care, blood
24 clotting factor products, and physician fees and diagnostic
25 laboratory services as required under Section 6.

26 Section 6. (a) A physician licensed in the State of
27 Alabama shall request a medical screening for von Willebrand's

1 disease and other bleeding disorders prior to advising an
2 individual that an invasive uterine surgical procedure is the
3 most appropriate treatment for menorrhagia.

4 (b) A medical screening under subsection (a) shall
5 be performed at a clinical coagulation laboratory as defined
6 under subdivision (5) of Section 3.

7 Section 7. The department may compile and
8 distribute, upon request, a list of full-service home care
9 pharmacies that comply with this act. The department may adopt
10 rules pursuant to the Administrative Procedure Act to carry
11 out the purposes of this act.

12 Section 8. This act shall become effective on the
13 first day of the third month following its passage and
14 approval by the Governor, or its otherwise becoming law.