

1 HB111
2 135653-1
3 By Representative McClendon
4 RFD: Health
5 First Read: 07-FEB-12
6 PFD: 02/02/2012

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8 SYNOPSIS: Existing state law does not provide
9 standards of care that address the unique health
10 care needs of persons with hemophilia and other
11 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
2 Department of Public Health to adopt rules
3 necessary to implement the provisions set forth in
4 this act.

5
6 A BILL
7 TO BE ENTITLED
8 AN ACT
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10 To establish standards of care that provide for the
11 health care needs of persons with hemophilia and other
12 bleeding disorders; to require pharmacy providers that
13 distribute blood clotting products to meet certain standards;
14 to require health insurers to provide certain benefits; and to
15 require physicians to request screening for certain conditions
16 before performing surgical procedures.

17 BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:

18 Section 1. This act shall be known and may be cited
19 as the Hemophilia Standards of Care Act.

20 Section 2. As used in this act, the following terms
21 shall have the following meanings:

22 (1) 340B PROGRAM. An outpatient pharmacy licensed by
23 the State of Alabama to dispense blood clotting products which
24 is conditionally or fully designated as a covered entity under
25 the Veterans Health Care Act of 1992 (Public Law 102-585, 106
26 Stat. 4943), which enacted Section 340B of the Public Health
27 Service Act (58 Stat. 682, 42 U.S.C. § 256b). The program

1 allows hemophilia treatment centers to purchase prescription
2 drugs, including clotting factor products and other necessary
3 supplies, at discounted prices from pharmaceutical
4 manufacturers for the management of bleeding disorders in the
5 home setting.

6 (2) ANCILLARY INFUSION EQUIPMENT AND SUPPLIES. The
7 equipment and supplies required for infusing blood clotting
8 products into the body. The term includes, but is not limited
9 to, syringes, sterile gauze, and alcohol swabs, tourniquets,
10 medical tape, sharps, or equivalent biohazard waste
11 containers, and cold compression packs.

12 (3) BLEEDING DISORDER. A medical condition
13 characterized by a severe deficiency or absence of one or more
14 essential blood clotting proteins, often called factors,
15 including all forms of hemophilia, von Willebrand's disease
16 and other bleeding disorders which result in uncontrollable
17 bleeding or abnormal blood clotting.

18 (4) BLOOD CLOTTING PRODUCT. An intravenously
19 administered medicine manufactured from human plasma or
20 recombinant biotechnology techniques, approved for
21 distribution by the Food and Drug Administration and which is
22 used for the treatment and prevention of symptoms associated
23 with bleeding disorders. The term includes, but is not limited
24 to, Factors VII, VIII, and IX products; von Willebrand Factor
25 products; bypass products for patients with inhibitors; and
26 activated prothrombin complex concentrates.

1 (5) CLINICAL COAGULATION LABORATORY. A medical
2 facility licensed by the State of Alabama to diagnose bleeding
3 disorders and perform specialized coagulation studies of human
4 blood for patients with bleeding disorders.

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

8 (7) DEPARTMENT. The Alabama Department of Public
9 Health.

10 (8) HEMOPHILIA. A type of bleeding disorder caused
11 by a deficiency of the blood clotting proteins known as
12 Factors I, VII, VIII, IX, XI, and XII.

13 (9) HEMOPHILIA TREATMENT CENTER. A facility which
14 provides comprehensive care for people with bleeding
15 disorders. Some of these centers receive funding from the
16 federal government including, but not limited to, the Centers
17 for Disease Control and Prevention (CDC) and the Health
18 Resources and Services Administration (HRSA).

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

24 (11) INSURER. An entity that is licensed under Title
25 27, Code of Alabama 1975, or an entity that issues an
26 individual or a group health insurance policy pursuant to
27 Article 6 of Chapter 20 of Title 10A, Code of Alabama 1975.

1 (12) INVASIVE UTERINE SURGICAL PROCEDURE. A
2 procedure performed by a physician that involves the insertion
3 of a surgical instrument into the uterus, including, but not
4 limited to, the performance of a hysterectomy or uterine
5 ablation.

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

9 Section 3. A pharmacy that dispenses clotting factor
10 products to individuals with bleeding disorders in the State
11 of Alabama for use in the home shall comply with all of the
12 following requirements:

13 (1) Supply blood clotting products and home nursing
14 services as prescribed by the covered person's treating
15 physician. To make any substitutions of blood clotting
16 products, the provider must first receive prior approval from
17 the treating physician, patient, or the patient's legal
18 guardian if younger than 18.

19 (2) If provided to a hemophilia treatment center or
20 other organization operating as a 340B program, place the
21 therapeutic value of each clotting product above the revenue
22 generating value of each clotting product, on a
23 patient-by-patient basis.

24 (3) Supply all FDA-approved brands of blood clotting
25 products in multiple assay ranges, as applicable, including
26 products manufactured with recombinant biotechnology
27 techniques and those manufactured from human plasma.

1 (4) Supply all necessary ancillary infusion
2 equipment and supplies needed to prepare and infuse the
3 quantity of blood clotting product.

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

8 (6) Ensure that a pharmacist is on call to fill
9 prescriptions for blood clotting products 24 hours a day,
10 seven days a week.

11 (7) Be capable of providing blood clotting products
12 in assays within five percent of the prescribed amount.

13 (8) Ship the prescribed blood clotting products and
14 ancillary infusion equipment to covered persons within 24
15 hours.

16 (9) Provide appropriate and necessary record keeping
17 and documentation, including tracking of lifetime caps.

18 (10) Provide administrative assistance for covered
19 persons to obtain payment for blood clotting products,
20 ancillary infusion equipment and home nursing services.

21 (11) Provide covered persons, upon request, with
22 information about the anticipated out-of-state pocket cost for
23 blood clotting products, ancillary infusion equipment and
24 services that are not otherwise paid for by the health care
25 insurer.

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

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

6 (14) File a plan with the department explaining how
7 the pharmacy will deal with emergencies such as natural
8 disasters or blood clotting product shortages. This plan shall
9 be available to the public upon request.

10 Section 4. For any policy or plan issued or renewed
11 after the effective date of this act, an insurer shall provide
12 coverage for services provided to persons with hemophilia and
13 related bleeding disorders including, but not limited to,
14 physician services as prescribed by the treating physician for
15 inpatient care and outpatient care, blood clotting factor
16 products, and physician fees and diagnostic laboratory
17 services as required under Section 6.

18 Section 5. A physician licensed in the State of
19 Alabama shall request a medical screening for von Willebrand's
20 disease and other bleeding disorders prior to advising an
21 individual that an invasive uterine surgical procedure is the
22 most appropriate treatment for menorrhagia. The medical
23 screening shall be performed at a clinical coagulation
24 laboratory as explained under subdivision (4) of Section 3.

25 Section 6. (a) The department shall compile and
26 distribute, upon request, a list of full-service home care
27 pharmacies which comply with this act.

1 (b) The department may adopt rules pursuant to the
2 Administrative Procedure Act to carry out the purposes of this
3 act.

4 Section 7. Nothing in this act shall apply to the
5 public Hemophilia Treatment Program or any other program
6 administered by the Department of Rehabilitation Services,
7 except the prohibition in subdivision (2) of Section 4.

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