

1 SB92
2 135653-1
3 By Senator Ward
4 RFD: Health
5 First Read: 07-FEB-12
6 PFD: 01/20/2012

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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

1 Service Act (58 Stat. 682, 42 U.S.C. § 256b). The program
2 allows hemophilia treatment centers to purchase prescription
3 drugs, including clotting factor products and other necessary
4 supplies, at discounted prices from pharmaceutical
5 manufacturers for the management of bleeding disorders in the
6 home setting.

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

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

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

1 products; bypass products for patients with inhibitors; and
2 activated prothrombin complex concentrates.

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

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

10 (7) DEPARTMENT. The Alabama Department of Public
11 Health.

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

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

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

1 (11) INSURER. An entity that is licensed under Title
2 27, Code of Alabama 1975, or an entity that issues an
3 individual or a group health insurance policy pursuant to
4 Article 6 of Chapter 20 of Title 10A, Code of Alabama 1975.

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

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

13 Section 3. A pharmacy that dispenses clotting factor
14 products to individuals with bleeding disorders in the State
15 of Alabama for use in the home shall comply with all of the
16 following requirements:

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

23 (2) If provided to a hemophilia treatment center or
24 other organization operating as a 340B program, place the
25 therapeutic value of each clotting product above the revenue

1 generating value of each clotting product, on a
2 patient-by-patient basis.

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

7 (4) Supply all necessary ancillary infusion
8 equipment and supplies needed to prepare and infuse the
9 quantity of blood clotting product.

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

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

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

19 (8) Ship the prescribed blood clotting products and
20 ancillary infusion equipment to covered persons within 24
21 hours.

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

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

1 (11) Provide covered persons, upon request, with
2 information about the anticipated out-of-state pocket cost for
3 blood clotting products, ancillary infusion equipment and
4 services that are not otherwise paid for by the health care
5 insurer.

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

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

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

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

23 Section 5. A physician licensed in the State of
24 Alabama shall request a medical screening for von Willebrand's
25 disease and other bleeding disorders prior to advising an
26 individual that an invasive uterine surgical procedure is the

1 most appropriate treatment for menorrhagia. The medical
2 screening shall be performed at a clinical coagulation
3 laboratory as explained under subdivision (4) of Section 3.

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

7 (b) The department may adopt rules pursuant to the
8 Administrative Procedure Act to carry out the purposes of this
9 act.

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

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