
THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 620 Session of
2009

INTRODUCED BY CURRY, GRUCELA, DeLUCA, ARGALL, BARRAR, BELFANTI, BEYER, BISHOP, BRENNAN, BROWN, BUXTON, CALTAGIRONE, CLYMER, COHEN, D. COSTA, P. COSTA, CREIGHTON, DALEY, DALLY, DERMODY, DeWEESE, DiGIROLAMO, DONATUCCI, FABRIZIO, FLECK, FRANKEL, FREEMAN, GEIST, GEORGE, GERBER, GIBBONS, GINGRICH, GOODMAN, GRELL, HALUSKA, HARHAI, HARKINS, HARPER, HENNESSEY, HESS, JOSEPHS, KESSLER, KILLION, KIRKLAND, KORTZ, KULA, MAHER, MANN, MARKOSEK, MARSICO, McCALL, McILVAINE SMITH, MELIO, MICOZZIE, MILNE, MUNDY, MURT, MYERS, D. O'BRIEN, M. O'BRIEN, O'NEILL, PARKER, PHILLIPS, READSHAW, REICHLEY, ROCK, ROHRER, ROSS, SAMUELSON, SANTONI, SCAVELLO, SCHRODER, SHAPIRO, SIPTROTH, K. SMITH, SOLOBAY, SONNEY, STEVENSON, J. TAYLOR, R. TAYLOR, TRUE, VULAKOVICH, WALKO, WANSACZ, WATSON, WILLIAMS, YOUNGBLOOD, SABATINA, HORNAMAN, STERN AND VEREB, FEBRUARY 26, 2009

REFERRED TO COMMITTEE ON INSURANCE, FEBRUARY 26, 2009

AN ACT

1 Providing a standard of care for the treatment of persons with
2 bleeding disorders.

3 The General Assembly of the Commonwealth of Pennsylvania
4 hereby enacts as follows:

5 Section 1. Short title.

6 This act shall be known and may be cited as the Hemophilia
7 Standards of Care Act.

8 Section 2. Declaration of policy.

9 The General Assembly finds and declares as follows:

10 (1) Hemophilia is a rare, hereditary bleeding disorder
11 affecting at least 1,700 individuals in this Commonwealth. It

1 is a chronic, lifelong, incurable disease.

2 (2) Until the 1970s, persons afflicted with severe
3 hemophilia suffered from uncontrollable internal bleeding,
4 crippling orthopedic deformities and a diminished lifespan.

5 (3) The scientific discovery of highly purified blood
6 clotting factors has enabled many persons with hemophilia the
7 opportunity to lead normal lives free of pain and crippling
8 arthritis.

9 (4) The blood clotting factors are expensive and must be
10 injected intravenously several times per week, but this
11 medicine can be administered in the patient's home, the
12 preferred method of treatment.

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

16 (6) The purpose of this act is to establish a standard
17 of care so that patients with severe bleeding disorders can
18 receive necessary and appropriate medical care.

19 Section 3. Definitions.

20 The following words and phrases when used in this act shall
21 have the meanings given to them in this section unless the
22 context clearly indicates otherwise:

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

29 "Ancillary infusion equipment and supplies." The equipment
30 and supplies required to infuse a blood clotting product into a

1 human vein, including, but not limited to, syringes, needles,
2 sterile gauze and alcohol swabs, tourniquets, medical tape,
3 sharps or equivalent biohazard waste containers and cold
4 compression packs.

5 "Bleeding disorder." A medical condition characterized by a
6 severe deficiency or absence of one or more essential blood
7 clotting proteins in the human blood, often called factors,
8 including all forms of hemophilia, von Willebrand disease and
9 other bleeding disorders which result in uncontrollable bleeding
10 or abnormal blood clotting.

11 "Blood clotting product." An intravenously administered
12 medicine manufactured from human plasma or recombinant
13 biotechnology techniques, approved for distribution by the Food
14 and Drug Administration and which is used for the treatment and
15 prevention of symptoms associated with bleeding disorders. The
16 term includes, but is not limited to:

- 17 (1) Factor VIIa, Factor VIII and Factor IX products.
- 18 (2) Von Willebrand Factor products.
- 19 (3) Prothrombin complex concentrates.
- 20 (4) Activated prothrombin complex concentrates.
- 21 (5) Other products approved by the FDA for the treatment
22 of bleeding disorders and associated inhibitors.

23 "Clinical coagulation laboratory." A laboratory affiliated
24 with a State-recognized hemophilia program which is able to
25 diagnose bleeding disorders and perform specialized coagulation
26 studies of human blood for patients with bleeding disorders.

27 "Covered person." An individual who is entitled to receive
28 health care benefits or coverage from a health care insurer.

29 "Department." The Department of Health of the Commonwealth.

30 "Drug formulary." A schedule of prescription drugs or

1 preferred therapeutic agents, including blood clotting products,
2 approved for use by a health care insurer or its agent, which
3 will be covered and dispensed through participating pharmacies.

4 "FDA." The United States Food and Drug Administration.

5 "Full-service home care pharmacy." A vendor or provider of
6 blood clotting products, ancillary infusion equipment, home
7 nursing services and patient assistance for the management of
8 bleeding disorders in the home setting that does the following:

9 (1) Supplies blood clotting products and home nursing
10 services as prescribed by the covered person's treating
11 physician and does not make any substitutions of blood
12 clotting products without the prior approval of the treating
13 physician.

14 (2) Supplies all FDA-approved brands of blood clotting
15 products in multiple assay ranges, low, medium and high, as
16 applicable, including products manufactured from human plasma
17 and those manufactured with recombinant biotechnology
18 techniques.

19 (3) Supplies all needed ancillary infusion equipment and
20 supplies.

21 (4) Provides directly or through a reliable third-party
22 agency home nursing services, whenever the services are
23 prescribed and deemed necessary by the treating physician.

24 (5) Upon receiving a prescription, ships the prescribed
25 blood clotting products and ancillary infusion equipment to
26 the covered person within three business days.

27 (6) Provides a pharmacist on call, available at all
28 times to fill prescriptions for blood clotting products.

29 (7) Provides appropriate and necessary recordkeeping and
30 documentation.

1 (8) Provides administrative assistance for covered
2 persons to obtain payment for blood clotting products,
3 ancillary infusion equipment and home nursing services.

4 (9) Provides covered persons, upon request, with
5 information about the anticipated out-of-pocket costs for
6 blood clotting products, ancillary infusion equipment and
7 services that are not otherwise paid for by the health care
8 insurer.

9 (10) Provides patient notification of recalls and
10 withdrawals of blood clotting products and ancillary infusion
11 equipment as soon as practical.

12 (11) Provides sharps containers or the equivalent for
13 the removal and disposal of medical waste.

14 (12) Is certified by the Department of Health.

15 "Health care insurer." An entity that issues an individual
16 or a group health insurance policy.

17 "Health insurance policy."

18 (1) An individual or group health insurance policy,
19 subscriber contract, certificate or plan which provides
20 medical or health care coverage by a health care facility or
21 licensed health care provider and which is offered by or is
22 governed under this act or any of the following:

23 (i) The act of May 17, 1921 (P.L.682, No.284), known
24 as The Insurance Company Law of 1921.

25 (ii) The act of December 29, 1972 (P.L.1701, No.
26 364), known as the Health Maintenance Organization Act.

27 (iii) The act of May 18, 1976 (P.L.123, No.54),
28 known as the Individual Accident and Sickness Insurance
29 Minimum Standards Act.

30 (iv) 40 Pa.C.S. Ch. 61 (relating to hospital plan

1 corporations).

2 (v) 40 Pa.C.S. Ch. 63 (relating to professional
3 health services plan corporations).

4 (2) The term does not include any of the following types
5 of insurance, alone or in combination with each other:

6 (i) Hospital indemnity.

7 (ii) Accident only policies.

8 (iii) Specified disease policies.

9 (iv) Disability income policies.

10 (v) Dental plans.

11 (vi) Vision plans.

12 (vii) CHAMPUS supplement.

13 (viii) Long-term care policies.

14 (ix) Other limited benefit plans.

15 "Hemophilia." A human bleeding disorder caused by a
16 hereditary deficiency of the Factor VIII, Factor IX or Factor XI
17 blood clotting protein in human blood.

18 "Home nursing services." Specialized nursing care provided
19 in the home setting to assist a patient in the reconstitution
20 and administration of blood clotting products.

21 "Invasive uterine surgical procedure." Any procedure
22 performed by a physician licensed in this Commonwealth that
23 involves the insertion of a surgical instrument into the human
24 uterus, including, but not limited to, the performance of a
25 hysterectomy or uterine ablation.

26 "Menorrhagia." Excessive uterine or menstrual bleeding.

27 "Participating pharmacy." An entity which enters into an
28 agreement with a health care insurer to dispense blood clotting
29 products, ancillary infusion equipment and supplies to
30 individuals with bleeding disorders.

1 "Pharmacy." A full-service home care pharmacy, a mail-order
2 pharmacy, 340B program or other dispensing pharmacy that is
3 licensed by the Commonwealth to dispense blood clotting
4 products, ancillary infusion equipment and, in the case of full-
5 service home care pharmacies, home nursing services.

6 "Policy." A written document or contract that provides
7 health care coverage and health care benefits for a covered
8 person.

9 "Prescription" or "prescription drug." A drug or a blood
10 clotting product dispensed by order of a health care provider
11 with prescriptive authority under the laws of this Commonwealth.

12 "State-recognized hemophilia program." A facility and
13 program for the treatment of bleeding disorders that receive
14 funding from the Commonwealth as part of the Hemophilia Program
15 administered by the Division of Child and Adult Health Services
16 in the Department of Health.

17 "von Willebrand disease." A human bleeding disorder caused
18 by a hereditary deficiency or abnormality of the von Willebrand
19 Factor in human blood.

20 Section 4. Coverage.

21 (a) Products.--A health care insurer shall contract with
22 pharmacies that will provide blood clotting products as
23 prescribed by the covered person's treating physician. The
24 pharmacies shall not make any substitutions of blood clotting
25 products without the prior approval of the treating physician.

26 (b) Payments.--

27 (1) A health care insurer shall provide payment for all
28 FDA-approved brands of blood clotting products in multiple
29 assay ranges, low, medium and high, as applicable, including
30 products manufactured from human plasma and those

1 manufactured with recombinant biotechnology techniques.

2 (2) A health care insurer shall provide payment for
3 blood clotting products as prescribed by the treating
4 physician for in-patient care, out-patient care and the home
5 treatment of bleeding disorders.

6 (c) Drug formulary.--If a health care insurer has a drug
7 formulary, including a formulary relating to specialty
8 pharmaceutical therapies, all FDA-approved blood clotting
9 products shall be included in the formulary.

10 (d) Preauthorization.--If a health care insurer requires
11 preapproval or preauthorization of a prescription for blood
12 clotting products prior to the dispensing of the same,
13 preapproval or preauthorization shall be completed within 24
14 hours or one business day, whichever is later. However, if the
15 circumstances are deemed urgent by the treating physician, then
16 preapproval or preauthorization shall be administered upon the
17 request of the treating physician.

18 (e) Ancillary infusion equipment.--When dispensing blood
19 clotting products to individuals with bleeding disorders in this
20 Commonwealth, a pharmacy shall supply ancillary infusion
21 equipment sufficient to prepare and infuse the quantity of blood
22 clotting product being dispensed.

23 Section 5. Pharmacies.

24 (a) Choice of pharmacies.--A health care insurer shall
25 provide to a covered person a choice of at least three full-
26 service home care pharmacies which demonstrate full compliance
27 with this act.

28 (b) Using other pharmacies.--A patient with hemophilia may
29 obtain blood clotting products and ancillary infusion equipment
30 from any other participating pharmacy and from the 340B program

1 affiliated with the patient's State-recognized hemophilia
2 program.

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

6 Section 6. State-recognized hemophilia programs.

7 A health care insurer shall provide coverage for the
8 following services provided to persons with bleeding disorders
9 by a State-recognized hemophilia program:

10 (1) Physician services.

11 (2) Blood clotting products, if available, from a 340B
12 program or similar program associated with a State-recognized
13 hemophilia program.

14 (3) Clinical laboratory services at a hospital with a
15 State-recognized hemophilia program when a covered person's
16 treating physician determines that the use of the hospital's
17 clinical coagulation laboratory is medically necessary for
18 the screening, diagnosis, provisional diagnosis and treatment
19 of bleeding disorders or suspected bleeding disorders. The
20 term medically necessary includes, but is not limited to,
21 circumstances deemed urgent by the treating physician.

22 Section 7. Medical screening.

23 (a) Required screening.--A physician licensed in this
24 Commonwealth to provide obstetrical and gynecological services
25 shall request a medical screening for von Willebrand disease and
26 other bleeding disorders prior to advising an individual that an
27 invasive uterine surgical procedure is the most appropriate
28 treatment for menorrhagia.

29 (b) Place of screening.--The medical screening referenced in
30 subsection (a) shall be performed at a clinical coagulation

1 laboratory associated with a State-recognized hemophilia
2 program.

3 (c) Coverage for screening.--A health care insurer shall
4 provide coverage for the medical screening required under
5 subsection (a), including, but not limited to, physician's fees
6 and diagnostic laboratory services.

7 Section 8. Applicability.

8 All health care insurers shall comply with the provisions of
9 this act.

10 Section 9. Regulations.

11 The department may adopt regulations to carry out the
12 provisions of this act.

13 Section 10. Effective date.

14 This act shall take effect in 60 days.