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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 1705 Session of 2005

INTRODUCED BY BALDWIN, CORNELL, ROSS, BAKER, BEBKO-JONES, BELFANTI, BUNT, CLYMER, CRAHALLA, CREIGHTON, GEIST, KILLION, MANN, NAILOR, RUBLEY AND WATSON, JUNE 20, 2005

REFERRED TO COMMITTEE ON HEALTH AND HUMAN SERVICES, JUNE 20, 2005

AN ACT

Providing for health care coverage for the treatment of people with bleeding disorders.

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

Section 1. Short title.

This act shall be known and may be cited as the Hemophilia Health Care Act.

Section 2. Purpose.

(a) Bleeding disorder.--Hemophilia is a rare, hereditary bleeding disorder affecting at least 1,700 individuals in this Commonwealth. It is a chronic, lifelong, incurable disease. Until the 1970s, persons afflicted with severe hemophilia suffered from uncontrollable internal bleeding, crippling orthopedic deformities and a shortened lifespan. Moving forward, the scientific discovery of highly purified blood clotting factors has enabled most persons with hemophilia the opportunity to lead normal lives, free of pain and crippling arthritis. The

blood clotting factors are expensive and must be injected intravenously several times per week, but this medicine can be administered in the patient's home, the preferred method of treatment. In addition to clotting factor, patients require expert, specialized medical care at a regional hemophilia treatment center based in a hospital.

(b) Costs.--Due to the high cost of treatment for hemophilia and the generally escalating costs of medical care nationwide, health insurers have attempted to contain costs wherever possible. In recent years the cost containment objective has focused on rationing access to medical care for patients with hemophilia. Initially, rationing medical care by various methods might reduce the cost of providing care for these patients; however, rationing and limiting care in the short term eventually leads to higher medical costs, more frequent hospitalizations and a lower quality of life for patients. In the treatment of hemophilia, limiting medical care leads to higher medical costs, not savings. This is the consensus of treating physicians, the Centers for Disease Control and Prevention (CDC) and the Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation.

(c) Preservation of coverage.--The purpose of this act is to preserve access to a full range of essential, lifesaving medical care so that patients with severe bleeding disorders can remain healthy, productive citizens of this Commonwealth.

Section 3. Definitions.

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

"340B Program." An outpatient pharmacy licensed by the

Commonwealth to dispense blood clotting products and which is conditionally or fully designated as a covered entity under the Veterans Health Care Act of 1992 (Public Law 102-585, 106 Stat. 4943), which enacted section 340B of the Public Health Service Act (58 Stat. 682, 42 U.S.C. § 201 et seq.).

"Ancillary infusion equipment and supplies." The equipment and supplies required to infuse a blood clotting product into a human vein, including, but not limited to, syringes, needles, sterile gauze and alcohol swabs, tourniquets, medical tape, sharps or equivalent biohazard waste containers and cold compression packs.

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

"Blood clotting product." An intravenously administered medicine manufactured from human plasma or recombinant biotechnology techniques, approved for distribution by the United States Food and Drug Administration and which is used for the treatment and prevention of symptoms associated with bleeding disorders. Blood clotting products include, but are not limited to, Factor VII, Factor VIIa, Factor VIII and Factor IX products, von Willebrand Factor products, bypass products for patients with inhibitors and activated prothrombin complex concentrates.

"Clinical laboratory." A hospital-based laboratory affiliated with a State-recognized hemophilia program which is able to diagnose bleeding disorders and perform specialized

coagulation studies of human blood for patients with bleeding disorders.

"Contract." A written document that provides health care coverage and health care benefits for a covered person.

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

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

"Drug formulary." A schedule of prescription drugs, including blood clotting products, approved for use by a health care insurer or its agent, which will be covered and dispensed through participating pharmacies.

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

"Full-service home care provider." A seller and provider of blood clotting products, ancillary infusion equipment, home nursing services and patient assistance for the management of bleeding disorders in the home setting.

"Health care insurer." A person, corporation, agency of the Commonwealth or other entity that offers administrative, indemnity or payment services for health care in exchange for a premium or service charge under a program of health care services or as a government-administered medical assistance program, including:

(1) An insurance company, association or exchange with a certificate of authority to issue health insurance policies in this Commonwealth under sections 616 through 630 of the act of May 17, 1921 (P.L.682, No.284), known as The Insurance Company Law of 1921.

(2) A hospital plan corporation as defined in 40 Pa.C.S. Ch. 61 (relating to hospital plan corporations).

(3) A professional health services plan corporation as

defined in 40 Pa.C.S. Ch. 63 (relating to professional health services plan corporations).

(4) A health maintenance organization.

(5) A preferred provider organization.

(6) A managed care organization.

(7) A fraternal benefit society.

(8) A beneficial society.

(9) A fully insured employee health and welfare benefits plan and its third-party administrator.

(10) The Department of Public Welfare, including, but not limited to, programs authorized under 55 Pa. Code (relating to public welfare).

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

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

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

"Menorrhagia." Excessive uterine bleeding occurring at the regular intervals of menstruation, the period of flow being of greater than usual duration.

"Participating laboratory." A clinical laboratory or the affiliated hospital that enters into an agreement with a health care insurer to provide services to covered persons with bleeding disorders.

"Participating provider." An entity that enters into an agreement with a health care insurer to serve as a provider to individuals with bleeding disorders.

"Provider." A full-service home care provider, mail-order pharmacy, 340B Program, hospital or other dispensing pharmacy that is licensed by the Commonwealth to dispense blood clotting products, ancillary infusion equipment and, in the case of full-service home care providers, home nursing services.

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

"Von Willebrand Disease." A human bleeding disorder caused by a hereditary deficiency or abnormality of the von Willebrand factor in human blood.

Section 4. General coverage provisions.

(a) General provisions.--A health care insurer which issues a health insurance policy or contract or offers a managed care plan shall provide benefits and health care services for inpatient care, outpatient care and the home treatment of bleeding disorders.

(b) Products.--Every provider shall supply blood clotting products as prescribed by the covered person's treating physician and not make any substitutions of blood clotting products without the prior approval of the treating physician.

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

manufactured with recombinant biotechnology techniques.

(d) Drug formulary.--If a health care insurer has a drug formulary, all FDA-approved blood clotting products shall be included in the formulary.

(e) Ancillary infusion equipment.--When dispensing blood clotting products to individuals with bleeding disorders in this Commonwealth, all providers shall supply ancillary infusion equipment sufficient to prepare and infuse the quantity of blood clotting product being dispensed.

Section 5. Full-service home care providers and other providers.

(a) Choice to providers.--A health care insurer shall provide to a covered person a choice of at least three full-service home care providers who demonstrate full compliance with this act.

(b) Participating provider.--Each full-service home care provider in subsection (a) shall be a participating provider in the health care insurer's network.

(c) Payments.--All payment requests for blood clotting products, ancillary infusion equipment and home nursing services submitted by full-service home health care providers who comply with this act shall be accepted for payment by a health care insurer.

(d) Requirements.--Each full-service home care provider shall:

(1) Supply blood clotting products and home nursing services as prescribed by the covered person's treating physician and not make any substitutions of blood clotting products without the prior approval of the treating physician.

(2) Supply all FDA-approved brands of blood clotting products in mulitiple assay ranges (low, medium and high, as applicable), including products manufactured from human plasma and those manufactured with recombinant biotechnology techniques.

(3) Supply all needed ancillary infusion equipment and supplies.

(4) Provide directly or through a reliable third-party agency home nursing services, whenever such services are prescribed by the treating physician.

(5) Upon receiving a prescription, ship the prescribed blood clotting products and ancillary infusion equipment to the covered person within three business days or less.

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

(7) Provide appropriate and necessary recordkeeping and documentation.

(8) Provide assistance for covered persons in obtaining third-party reimbursement.

(9) Provide expedited patient notification of recalls and withdrawals of blood clotting products and ancillary infusion equipment.

(10) Provide sharps containers for the removal and disposal of medical waste.

(11) Provide covered persons with a written copy of the health care insurer's policy for the discontinuation of services related to a loss of coverage.

(12) Provide covered persons, upon request, with information about the expected costs for medications and services that are not otherwise paid for by the health care

insurer.

(e) Optional coverage.--In addition to the full-service home care providers required in subsection (b), a health care insurer may offer to a covered person a choice of additional providers:

(1) Providers of blood clotting products authorized by health care insurers pursuant to this subsection may, but are not required to, comply with subsection (d)(1) through (12).

(2) All payment requests for blood clotting products, ancillary infusion equipment and home nursing services submitted by providers and authorized by health care insurers pursuant to this subsection shall be accepted for payment by a health care insurer.

(f) List of providers.--The department shall compile and distribute to health care insurers and covered persons, upon request, a list of full-service home care providers who comply with this act.

Section 6. State-recognized hemophilia programs.

(a) Payment for services.--A health care insurer that issues a health insurance policy or contract or offers a managed care plan shall provide payment for all patient services, including physician's fees, provided to a covered person at a State-recognized hemophilia program.

(b) Clinical laboratory.--A health care insurer shall provide payment for services provided by the clinical laboratory at a hospital with a State-recognized hemophilia program when a covered person's treating physician determines that the use of the hospital's clinical laboratory is necessary for the screening, diagnosis, provisional diagnosis and treatment of bleeding disorders or suspected bleeding disorders or when:

(1) the results of laboratory tests are medically

necessary immediately or earlier than the normal return time of results from the health care insurer's participating laboratories;

(2) accurate test results must be determined by closely supervised venipuncture procedures and laboratory techniques in a controlled environment which cannot be achieved by the health care insurer's participating laboratories; or

(3) accurate, consistent or timely results cannot be achieved by the health care insurer's participating laboratories, in the opinion of the patient's treating physician.

(c) Rate of payment.--A health care insurer shall provide payment for services provided by the clinical laboratory according to the usual and customary fee schedule, but no less than the rate of payment provided to the laboratory by the Centers for Medicare and Medicaid Services for similar procedures.

(d) Right of review.--A health care insurer, or its designee, shall retain the right to review all services provided to a covered person pursuant to this section for medical necessity, except that a covered person's treating physician shall be the final arbiter for determining medical necessity in situations where the treating physician deems the circumstances to be urgent.

Section 7. Medical screening for von Willebrand Disease and other bleeding disorders.

(a) Required screening.--Any physician licensed in this Commonwealth to provide obstetrical and gynecological services shall order a medical screening for von Willebrand Disease and other bleeding disorders prior to advising an individual that an

invasive uterine surgical procedure is the most appropriate treatment for menorrhagia.

(b) Place of screening.--The medical screening referenced in subsection (a) shall be performed at a clinical laboratory associated with a State-recognized hemophilia program.

(c) Coverage for screening.--All health care insurers shall provide full coverage for the medical screening required under subsection (a).

Section 8. Regulations.

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

Section 9. Contingency.

This act shall not be contingent upon the enactment of any other law or regulation.

Section 10. Applicability.

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

Section 11. Effective date.

This act shall take effect in 60 days.