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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, VEREB, CIVERA, J. EVANS, RAPP, MILLER, QUINN, GERGELY, PRESTON, KOTIK, MAHONEY, CHRISTIANA, McGEEHAN, GODSHALL, MAJOR, DAY, BOYLE, BRIGGS, MOUL, BEAR, BRADFORD, PETRI, OBERLANDER, TALLMAN, STURLA, HARHART AND CRUZ, FEBRUARY 26, 2009

AS AMENDED ON SECOND CONSIDERATION, HOUSE OF REPRESENTATIVES, AUGUST 4, 2009

AN ACT

Providing a standard of care for the treatment of persons 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 Standards of Care Act.

Section 2. Declaration of policy.

The General Assembly finds and declares as follows:

(1) Hemophilia is a rare, hereditary bleeding disorder affecting at least 1,700 individuals in this Commonwealth. It is a chronic, lifelong, incurable disease.

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

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

(4) 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.

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

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

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. § 256b).

"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 Food and Drug Administration and which is used for the treatment and prevention of symptoms associated with bleeding disorders. The term includes, but is not limited to:

(1) Factor VIIa, Factor VIII and Factor IX products.

(2) Von Willebrand Factor products.

(3) Prothrombin complex concentrates.

(4) Activated prothrombin complex concentrates.

(5) Other products approved by the FDA for the treatment of bleeding disorders and associated inhibitors.

"Clinical coagulation laboratory." A laboratory affiliated with a ~~State-recognized~~ STATE-FUNDED hemophilia program which is ← able to diagnose bleeding disorders and perform specialized coagulation studies of human blood for patients with bleeding disorders.

"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 or preferred therapeutic agents, 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 ~~pharmacy~~ PROVIDER." A vendor ~~or~~ 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 ~~that does the following:~~

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

~~(2) Supplies 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.~~

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

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

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

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

~~(7) Provides appropriate and necessary recordkeeping and documentation.~~

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

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

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

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

~~(12) Is certified by the Department of Health.~~, AS DESCRIBED FULLY IN SECTION 5. ←

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

"Health insurance policy."

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

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

(ii) The act of December 29, 1972 (P.L.1701, No.

364), known as the Health Maintenance Organization Act.

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

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

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

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

(i) Hospital indemnity.

(ii) Accident only policies.

(iii) Specified disease policies.

(iv) Disability income policies.

(v) Dental plans.

(vi) Vision plans.

(vii) CHAMPUS supplement.

(viii) Long-term care policies.

(ix) Other limited benefit plans.

"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 or menstrual bleeding.

"Participating ~~pharmacy." An~~ PHARMACY" OR "PARTICIPATING PROVIDER." A PHARMACY OR OTHER entity which enters into an agreement with a health care insurer to dispense blood clotting products, ancillary infusion equipment and supplies to individuals with bleeding disorders.

~~"Pharmacy." A full-service home care pharmacy, a mail-order pharmacy, 340B program 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 pharmacies, home nursing services.~~

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

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

~~"State-recognized~~ "STATE-FUNDED hemophilia program." A facility and program 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. Coverage.

(a) Products.--A health care insurer shall contract with pharmacies that will provide blood clotting products as prescribed by the covered person's treating physician. The pharmacies shall not make any substitutions of blood clotting

products without the prior approval of the treating physician.

(b) Payments.--

(1) 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.

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

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

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

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

Section 5. ~~Pharmacies~~ PROVIDERS OF PRODUCTS AND SERVICES. ←

(a) Choice of ~~pharmacies~~ PROVIDERS.--A health care insurer ←

shall provide to a covered person a choice of at least three full-service home care ~~pharmacies which demonstrate full compliance with this act~~ PROVIDERS, EACH OF WHICH MUST DO THE FOLLOWING:

(1) SUPPLIES BLOOD CLOTTING PRODUCTS AND HOME NURSING SERVICES AS PRESCRIBED BY THE COVERED PERSON'S TREATING PHYSICIAN AND DOES NOT MAKE ANY SUBSTITUTIONS OF BLOOD CLOTTING PRODUCTS WITHOUT THE PRIOR APPROVAL OF THE TREATING PHYSICIAN.

(2) SUPPLIES 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.

(3) SUPPLIES ALL NEEDED ANCILLARY INFUSION EQUIPMENT AND SUPPLIES.

(4) PROVIDES DIRECTLY OR THROUGH A RELIABLE THIRD-PARTY AGENCY HOME NURSING SERVICES, WHENEVER THE SERVICES ARE PRESCRIBED AND DEEMED NECESSARY BY THE TREATING PHYSICIAN.

(5) UPON RECEIVING A PRESCRIPTION, SENDS IN A SINGLE SHIPMENT THE PRESCRIBED BLOOD CLOTTING PRODUCTS AND ANCILLARY INFUSION EQUIPMENT TO THE COVERED PERSON WITHIN THREE BUSINESS DAYS.

(6) PROVIDES A PHARMACIST ON CALL, AVAILABLE AT ALL TIMES TO FILL PRESCRIPTIONS FOR BLOOD CLOTTING PRODUCTS.

(7) PROVIDES APPROPRIATE AND NECESSARY RECORDKEEPING AND DOCUMENTATION.

(8) PROVIDES ADMINISTRATIVE ASSISTANCE FOR COVERED PERSONS TO OBTAIN PAYMENT FOR BLOOD CLOTTING PRODUCTS, ANCILLARY INFUSION EQUIPMENT AND HOME NURSING SERVICES.

(9) PROVIDES COVERED PERSONS, UPON REQUEST, WITH INFORMATION ABOUT THE ANTICIPATED OUT-OF-POCKET COSTS FOR BLOOD CLOTTING PRODUCTS, ANCILLARY INFUSION EQUIPMENT AND SERVICES THAT ARE NOT OTHERWISE PAID FOR BY THE HEALTH CARE INSURER.

(10) PROVIDES PATIENT NOTIFICATION OF RECALLS AND WITHDRAWALS OF BLOOD CLOTTING PRODUCTS AND ANCILLARY INFUSION EQUIPMENT AS SOON AS PRACTICAL.

(11) PROVIDES SHARPS CONTAINERS OR THE EQUIVALENT FOR THE REMOVAL AND DISPOSAL OF MEDICAL WASTE.

(b) Using other ~~pharmacies~~ PROVIDERS.--A patient with hemophilia may obtain blood clotting products and ancillary infusion equipment from any other participating pharmacy OR PROVIDER and from the 340B program affiliated with the patient's ~~State-recognized~~ STATE-FUNDED hemophilia program.

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

Section 6. ~~State-recognized~~ STATE-FUNDED hemophilia programs.

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

(1) Physician services.

(2) Blood clotting products, if available, from a 340B program or similar program associated with a ~~State-recognized~~ STATE-FUNDED hemophilia program.

(3) Clinical laboratory services at a hospital with a ~~State-recognized~~ STATE-FUNDED hemophilia program when a covered person's treating physician determines that the use of the hospital's clinical coagulation laboratory is

medically necessary for the screening, diagnosis, provisional diagnosis and treatment of bleeding disorders or suspected bleeding disorders. The term medically necessary includes, but is not limited to, circumstances deemed urgent by the treating physician.

Section 7. Medical screening.

(a) Required screening.--A physician licensed in this Commonwealth to provide obstetrical and gynecological services shall request 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 coagulation laboratory associated with a ~~State-recognized~~ STATE-FUNDED hemophilia program.

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

Section 8. Applicability.

THIS ACT SHALL APPLY TO NEW CONTRACTS AND CONTRACT RENEWALS OCCURRING 90 DAYS AFTER THE EFFECTIVE DATE OF THIS ACT. All health care insurers shall comply with the provisions of this act.

~~Section 9. Regulations.~~

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

~~Section 10. Effective date.~~

~~This act shall take effect in 60 days.~~

SECTION 9. ENFORCEMENT.

(A) DUTIES OF DEPARTMENT.--THE DEPARTMENT SHALL ENSURE COMPLIANCE WITH THIS ACT. THE DEPARTMENT MAY REQUIRE HEALTH CARE INSURERS OR PROVIDERS UNDER THIS ACT TO PROVIDE IT WITH RECORDS, DOCUMENTS AND OTHER INFORMATION, INCLUDING CREDENTIALING PLANS, PROVIDER CONTRACTS AND NETWORK ADEQUACY DATA, NECESSARY FOR IT TO INVESTIGATE THE HEALTH CARE INSURER'S OR PROVIDER'S COMPLIANCE WITH THIS ACT.

(B) POTENTIAL VIOLATIONS.--THE DEPARTMENT SHALL INVESTIGATE POTENTIAL VIOLATIONS OF THE ACT BASED UPON INFORMATION PROVIDED TO IT BY COVERED PERSONS, PROVIDERS AND OTHER SOURCES IN ORDER TO ENSURE COMPLIANCE WITH THIS ACT.

(C) CIVIL PENALTY.--THE DEPARTMENT MAY IMPOSE A CIVIL PENALTY OF UP TO $5,000 FOR A VIOLATION OF THIS ACT.

(D) INJUNCTIONS.--THE DEPARTMENT MAY MAINTAIN AN ACTION IN THE NAME OF THE COMMONWEALTH FOR AN INJUNCTION TO PROHIBIT ANY ACTIVITY WHICH VIOLATES THE PROVISIONS OF THIS ACT.

(E) PLAN OF CORRECTION.--THE DEPARTMENT MAY REQUIRE A HEALTH CARE INSURER OR PROVIDER TO DEVELOP AND ADHERE TO A PLAN OF CORRECTION APPROVED BY THE DEPARTMENT. THE DEPARTMENT SHALL MONITOR COMPLIANCE WITH THE PLAN OF CORRECTION.

(F) REGULATIONS.--THE DEPARTMENT MAY ADOPT REGULATIONS TO CARRY OUT THE PROVISIONS OF THIS ACT.

SECTION 10. EFFECTIVE DATE.

THIS ACT SHALL TAKE EFFECT IN 90 DAYS.