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HOUSE . . . . . No. 4590

The Commonwealth of Massachusetts

In the Year Two Thousand Ten

An Act relative to coverage and standards of treatment of persons with bleeding disorders..

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

SECTION 1. Chapter 111 of the general laws is hereby amended by inserting after the Section 6C the following section:—

Section 6C 1/2. This act shall be known as the Bleeding Disorders Treatment Standards Act

(a) Declaration of policy and purposes.

The General Court finds and declares as follows:

(1) Hemophilia and von Willebrand disease are bleeding disorders affecting hundreds of individuals in the Commonwealth. They are chronic, lifelong, incurable diseases.

(2) Without proper management, bleeding disorders like hemophilia and von Willebrand disease can be crippling, life-constraining, and even fatal. In younger and older sufferers alike, uncontrolled bleeding causes pain, destroys joints, and damages muscles and organs.

(3) Today, however, promptly administered therapies – clotting factors dispensed through specialty pharmacies and given intravenously in the patient's home – enable most persons with bleeding disorders to avoid lifelong impairments and to lead normal, productive lives free of pain and crippling arthritis.

(4) Access to and qualified administration of clotting therapies can be costly, but they save lives, prevent disabilities, and produce cost-effective health outcomes. It is critical that the care available to sufferers of bleeding disorders meet medically-endorsed treatment standards and not be delayed or curtailed by short-sighted cost-reduction measures.

(5) The purpose of this act is to establish qualifications and standards for specialty pharmacies from whom persons with bleeding disorders receive care, institute measures to detect undiagnosed cases of von Willebrand disease, ensure access to comprehensive hemophilia treatment facilities and specialized diagnostic labs, and guarantee coverage of needed services by third party payors.

(b) 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 which is 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 in order 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 that is approved for distribution by the Food and Drug Administration and which is used for the treatment and prevention of hemorrhagic episodes 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 federally-funded hemophilia treatment center which is able to diagnose bleeding disorders and perform specialized coagulation studies of human blood for patients with bleeding disorders.

“Comprehensive hemophilia care center.” A federally funded hemophilia treatment center or any clinic formally affiliated with a federally funded hemophilia treatment center; or a hospital-based clinic determined by the Department to (1) provide regular multidisciplinary team care in the treatment and management of hemophilia and other bleeding disorders, and (2) satisfy such other criteria as the Department may by regulation establish.

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

"Department." The Massachusetts Department of Public Health.

"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.

“Federally funded hemophilia treatment center.” A hospital or hospital-based clinic that receives funding support from the Centers for Disease Control of the U.S. Department of Health and Human Services as part of a network of centers promoting the management, treatment, and prevention of complications experienced by persons with hemophilia and other bleeding disorders.

"Health care insurer." An entity that issues an individual or a group health insurance policy or the state program of medical assistance administered by the Commonwealth pursuant to the requirements of Title XIX of the Social Security Act, 42 U.S.C. §§ 1396, et seq.

"Health insurance policy."

(1) An individual or group health insurance policy, subscriber contract, certificate or plan which covers medical or health care services by a health care facility or licensed health care provider.

(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 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." A pharmacy which enters into an agreement with a health care insurer to dispense blood clotting products and ancillary infusion equipment and supplies to individuals with bleeding disorders.

"Pharmacy." A mail-order pharmacy, 340B program, or other dispensing pharmacy that is licensed by the Commonwealth to dispense blood clotting products and ancillary infusion equipment and supplies.

"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 the Commonwealth.

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

(c) Coverage.

(1) Pharmacy services.---A health care insurer shall contract with any pharmacy that provides blood clotting factors and that satisfies the pertinent standards of service set forth in Section 5 of this act.

(2) Hemophilia treatment centers.—A health care insurer shall contract with any 340B program affiliated with a federally funded hemophilia treatment center that furnishes blood clotting products and that satisfies the standards of service set forth in Section 5 of this act for a pharmacy. A health care insurer shall provide payment for (1) physician services at a hospital with a comprehensive hemophilia care center and (2) clinical laboratory services at a hospital with a comprehensive hemophilia care center 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.

(3) Blood clotting products.—

(i) 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.

(ii) 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.

(iii) A health care insurer shall provide payment for ancillary infusion equipment and supplies as prescribed by the treating physician in connection with prescriptions of blood clotting products for a covered person.

(iv) 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.

(v) No health care insurer shall require a participating pharmacy to make any substitution for blood clotting products prescribed by a covered person's treating physician without the prior approval of such physician.

(vi) 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 waived upon the request of the treating physician.

(d) von Willebrand disease screening.—A health care insurer shall provide payment for the screening services required under Section 6 of this act, including, but not limited to, related physician's fees and diagnostic laboratory services.

(e) Standards of services by participating pharmacies.

(1) Pharmacies shall be open and staffed at a minimum from 9 a.m. until 8 p.m., Eastern Time, Monday through Friday, not including holidays. At all such times a pharmacist shall be present and available to fill prescriptions for blood clotting products. At any time that the

pharmacy is not open, on-call arrangements shall be in place to secure the prompt services of a pharmacist and delivery service in response to emergency demands for blood clotting products.

(2) Pharmacy staff shall have 24-hour access to multilingual interpreters.

(3) When dispensing blood clotting products to a covered person, pharmacies shall furnish ancillary infusion equipment and supplies as prescribed by the treating physician.

(4) In addition to the foregoing, pharmacies shall:

(i) Supply blood clotting products as prescribed by the covered person's treating physician and shall make no substitutions of blood clotting products without prior approval by the treating physician.

(ii) Be able to supply any 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.

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

(iv) Upon receiving a prescription, correctly fill and deliver the prescribed blood clotting products and ancillary infusion equipment and supplies to the covered person within 48 hours from the time the order is placed for established patients.

(v) Upon consultation with the treating physician, have a plan in place to ensure that, in case of emergent need, the patient shall have access to factor concentrate, equipment, and supplies within 12 hours of expressed need, with a goal of three hours where logistically

possible. If the pharmacy is contacted about an emergency situation, the treating physician should be notified.

(vi) Provide appropriate and necessary recordkeeping and documentation.

(vii) Provide administrative assistance for covered persons to obtain payment for blood clotting products, ancillary infusion equipment and supplies, and home nursing services.

(viii) Explain patient deductibles, coinsurance payment responsibilities, and lifetime cap limits clearly at the time the first order is placed, upon request, and annually when updating insurance information or sooner if there has been a change in insurance.

(ix) Participate in the National Patient Notification System and provide patient notification of recalls and withdrawals of blood clotting products and ancillary infusion equipment and supplies as soon as practical.

(x) Provide sharps containers or the equivalent for the removal and disposal of medical waste.

(xi) Be certified bi-annually by the Department to meet the standards established by this section.

(f) List of pharmacies.--The Department shall compile and distribute, upon request, a list of pharmacies that comply with this section.

(g) Medical screening.

(1) 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.

(2) Place of screening.--The medical screening referenced in subsection (a) shall be performed at a clinical coagulation laboratory associated with a comprehensive hemophilia care center.

(h) Regulations.

The department shall promulgate all rules and regulations necessary to effectuate the purposes of this section

Section 2. Effective date.

This act shall take effect upon its passage.