

HOUSE No. 915

The Commonwealth of Massachusetts

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In the Year Two Thousand Nine
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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:

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

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

5 (a) Declaration of policy and purposes.

6 The General Court finds and declares as follows:

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

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

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

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

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

25 (b) Definitions.

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

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

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

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

40 "Blood clotting product." An intravenously administered medicine manufactured from
41 human plasma or recombinant biotechnology techniques that is approved for distribution by the
42 Food and Drug Administration and which is used for the treatment and prevention of
43 hemorrhagic episodes associated with bleeding disorders. The term includes, but is not limited
44 to:

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

46 (2) von Willebrand Factor products.

47 (3) Prothrombin complex concentrates.

48 (4) Activated prothrombin complex concentrates.

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

51 "Clinical coagulation laboratory." A laboratory affiliated with a federally-funded
52 hemophilia treatment center which is able to diagnose bleeding disorders and perform
53 specialized coagulation studies of human blood for patients with bleeding disorders.

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

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

60 "Department." The Massachusetts Department of Public Health.

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

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

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

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

73 "Health insurance policy."

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

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

79 (i) Hospital indemnity.

80 (ii) Accident-only policies.

81 (iii) Specified disease policies.

82 (iv) Disability income policies.

83 (v) Dental plans.

84 (vi) Vision plans.

85 (vii) CHAMPUS supplement.

86 (viii) Long-term care policies.

87 (ix) Other limited benefit plans.

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

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

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

95 "Menorrhagia." Excessive uterine or menstrual bleeding.

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

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

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

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

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

108 (c) Coverage.

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

112 (b) Hemophilia treatment centers.—A health care insurer shall contract with any 340B
113 program affiliated with a federally funded hemophilia treatment center that furnishes blood
114 clotting products and that satisfies the standards of service set forth in Section 5 of this act for a
115 pharmacy. A health care insurer shall provide payment for (1) physician services at a hospital
116 with a comprehensive hemophilia care center and (2) clinical laboratory services at a hospital
117 with a comprehensive hemophilia care center when a covered person's treating physician
118 determines that the use of the hospital's clinical coagulation laboratory is medically necessary for
119 the screening, diagnosis, provisional diagnosis and treatment of bleeding disorders or suspected
120 bleeding disorders. The term medically necessary includes, but is not limited to, circumstances
121 deemed urgent by the treating physician.

122 (c) Blood clotting products.—

123 (1) A health care insurer shall provide payment for all FDA-approved brands of blood
124 clotting products in multiple assay ranges, low, medium and high, as applicable, including
125 products manufactured from human plasma and those manufactured with recombinant
126 biotechnology techniques.

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

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

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

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

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

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

147 (d) Standards of services by participating pharmacies.

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

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

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

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

156 (d) In addition to the foregoing, pharmacies shall:

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

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

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

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

168 (5) Upon consultation with the treating physician, have a plan in place to ensure that, in
169 case of emergency need, the patient shall have access to the prescribed products, equipment, and
170 supplies within three hours of expressed need. If the pharmacy is contacted about an emergency
171 situation, the treating physician should be notified.

- 172 (6) Provide appropriate and necessary recordkeeping and documentation.
- 173 (7) Provide administrative assistance for covered persons to obtain payment for blood
174 clotting products, ancillary infusion equipment and supplies, and home nursing services.
- 175 (8) Explain patient deductibles, coinsurance payment responsibilities, and lifetime cap
176 limits clearly at the time the first order is placed, upon request, and annually when updating
177 insurance information or sooner if there has been a change in insurance.
- 178 (9) Participate in the National Patient Notification System and provide patient
179 notification of recalls and withdrawals of blood clotting products and ancillary infusion
180 equipment and supplies as soon as practical.
- 181 (10) Provide sharps containers or the equivalent for the removal and disposal of medical
182 waste.
- 183 (11) Be certified bi-annually by the Department to meet the standards established by this
184 section.
- 185 (e) List of pharmacies.--The department shall compile and distribute, upon request, a list
186 of pharmacies that comply with this section.
- 187 (e) Medical screening.
- 188 (a) Required screening.--A physician licensed in this Commonwealth to provide
189 obstetrical and gynecological services shall request a medical screening for von Willebrand
190 disease and other bleeding disorders prior to advising an individual that an invasive uterine
191 surgical procedure is the most appropriate treatment for menorrhagia.

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

195 (f) Regulations.

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

198 Section 2. Effective date.

199 This act shall take effect upon its passage.