

1.1 A bill for an act

1.2 relating to health; requiring coverage of plasma protein treatments; amending  
1.3 Minnesota Statutes 2006, section 256B.0625, by adding a subdivision; proposing  
1.4 coding for new law in Minnesota Statutes, chapter 144A.

1.5 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

1.6 Section 1. [144A.435] PLASMA PROTEIN THERAPIES COVERAGE.

1.7 Subdivision 1. Definitions. For purposes of this section, the following terms have  
1.8 the meanings given them.

1.9 (a) "Plasma protein therapies" includes, but is not limited to, the following: all  
1.10 plasma derived blood clotting products; recombinant Factor VII, Factor VIII, and  
1.11 Factor IX products; von Willebrand Factor; bypass products for patients with inhibitors;  
1.12 recombinant-activated Factor VIIa; activated prothrombin complex concentrates,  
1.13 intravenous intramuscular or subcutaneous immune globulins, and alpha-1 proteinase  
1.14 inhibitors.

1.15 (b) "Ancillary infusion equipment" includes, but is not limited to, syringes, needles,  
1.16 and sterile gauze.

1.17 (c) "Home care provider" means an individual, organization, association,  
1.18 corporation, unit of government, or other entity that is regularly engaged in the  
1.19 delivery, directly or by contractual arrangement, of home care services for a fee for  
1.20 management of bleeding disorders, such as hemophilia or von Willebrand's disease,  
1.21 primary immunodeficiency diseases and other conditions reliant on immune globulin  
1.22 treatment, and alpha-1 anti-trypsin deficiency. At least one home care service must be  
1.23 provided directly, although additional home care services may be provided by contractual  
1.24 arrangements. Home care services must be provided in a patient's home setting as

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2.1 described in subdivision 2. Every home care provider must comply with the minimum  
2.2 criteria specified in subdivision 2, paragraph (d).

2.3 Subd. 2. **Home treatment; required coverage.** (a) Health plan companies must  
2.4 cover health care services for the home treatment of bleeding episodes associated with  
2.5 chronic bleeding disorders such as hemophilia or von Willebrand's disease, and for  
2.6 the home treatment of primary immunodeficiency diseases, other conditions reliant on  
2.7 immune globulin treatment, and alpha-1 anti-trypsin disorder.

2.8 (b) Health plan companies shall contract with home care providers that provide  
2.9 treatment services for bleeding disorders that meet the minimum standards set out in  
2.10 paragraph (d) and offer those services to covered persons.

2.11 (c) Health plan companies shall accept for payment all claims for plasma protein  
2.12 therapies, ancillary infusion equipment, and home nursing services submitted by home  
2.13 care providers for preventive care and treatment of bleeding disorders required under  
2.14 paragraph (a).

2.15 (d) At a minimum, home care providers, in connection with care specified in this  
2.16 section, must do the following:

2.17 (1) supply products and services under a prescription from the covered person's  
2.18 treating physician and not make any substitutions of plasma protein therapies without  
2.19 prior approval of the treating physician;

2.20 (2) supply all needed drugs and ancillary supplies for the administration of plasma  
2.21 protein therapies, including, but not limited to, needles, syringes, and cold compression  
2.22 packs;

2.23 (3) provide directly, or through a third party agency, supportive home nursing  
2.24 services to assist in the reconstitution and administration of plasma protein therapies,  
2.25 when such services are prescribed by the treating physician;

2.26 (4) provide record keeping and documentation and assist covered persons in  
2.27 obtaining third party reimbursement;

2.28 (5) provide expedited notification to patients of plasma protein therapy recalls or  
2.29 withdrawals;

2.30 (6) provide for proper removal and disposal of hazardous medical waste in  
2.31 compliance with applicable state and federal law; and

2.32 (7) provide covered persons, upon request, information about the expected costs for  
2.33 medication and services that are not otherwise reimbursed by the covered person's health  
2.34 plan company.

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3.1 (e) The commissioner of health shall compile a list of home care providers who meet  
3.2 the minimum standards set out in paragraph (d) and make the list available to health plan  
3.3 companies and, upon request, to covered persons.

3.4 Subd. 3. **Clinical laboratory services; coverage required.** (a) Health plan  
3.5 companies shall provide payment for services to a clinical laboratory at a hospital that  
3.6 has a hemophilia program, regardless of whether that hospital's clinical laboratory is  
3.7 a participating provider in the health plan company, if the covered person's treating  
3.8 physician determines that use of the clinical laboratory is necessary for either of the  
3.9 following reasons:

3.10 (1) the results of laboratory tests are medically necessary sooner than the normal  
3.11 return time for results from the health plan company's participating clinical laboratory; or

3.12 (2) accurate test results must be determined by closely supervised venipuncture  
3.13 procedures and laboratory techniques in a controlled environment, which cannot be  
3.14 provided by the health plan company's participating clinical laboratory.

3.15 (b) Health plan companies shall pay the clinical laboratory for all laboratory services  
3.16 according to the usual and customary fee schedule for such services, but the hospital may  
3.17 not be reimbursed at a rate less than that provided by the medical assistance fee schedule.

3.18 Subd. 4. **Medical screening for von Willebrand's disease.** Health plan companies  
3.19 shall require that, prior to covering a complex uterine surgical procedure for menorrhagia, a  
3.20 medical screening for von Willebrand's disease and other bleeding disorders be performed.  
3.21 The health plan company shall provide coverage for such required medical screenings.

3.22 Subd. 5. **Application to medical assistance.** The coverage requirements in this  
3.23 section apply to medical assistance coverage under the same terms and conditions required  
3.24 of health plan companies.

3.25 Sec. 2. Minnesota Statutes 2006, section 256B.0625, is amended by adding a  
3.26 subdivision to read:

3.27 Subd. 49. **Plasma protein therapies.** Medical assistance covers plasma protein  
3.28 therapies under the same terms and conditions required of health plans under section  
3.29 144A.435.

3.30 Sec. 3. **EFFECTIVE DATE.**

3.31 Sections 1 and 2 are effective August 1, 2007, and apply to coverage issued or  
3.32 renewed on or after that date.