

1.1 A bill for an act

1.2 relating to health; requiring the Board of Pharmacy to adopt rules to govern
1.3 pharmaceutical services for individuals needing plasma protein therapies;
1.4 proposing coding for new law in Minnesota Statutes, chapter 151.

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

1.6 Section 1. **[151.58] PHARMACIES PROVIDING PLASMA PROTEIN**
1.7 **THERAPIES.**

1.8 Subdivision 1. **Definitions.** (a) For purposes of this section, the terms defined in
1.9 this subdivision have the meanings given.

1.10 (b) "Assay" means the amount of a particular constituent of a mixture or of the
1.11 biological or pharmacological potency of a drug.

1.12 (c) "Ancillary infusion equipment and supplies" means the equipment and supplies
1.13 required to infuse a plasma protein therapy into a human vein including, but not limited
1.14 to, syringes, needles, sterile gauze, field pads, gloves, alcohol swabs, numbing creams,
1.15 tourniquets, medical tape, sharps or equivalent biohazard waste containers, and cold
1.16 compression packs.

1.17 (d) "Plasma protein therapy" means a medicine manufactured from human plasma
1.18 or recombinant biotechnology techniques, approved for distribution by the federal Food
1.19 and Drug Administration, that is used for the treatment and prevention of symptoms
1.20 associated with alpha₁-antitrypsin deficiency, primary immunodeficiency diseases, and
1.21 von Willebrand disease.

1.22 (e) "Home nursing services" means specialized nursing care provided in the home
1.23 setting to assist a patient in the reconstitution and administration of plasma protein
1.24 therapies.

2.1 (f) "Home use" means infusion or other use of a plasma protein therapy in a place
2.2 other than a hemophilia treatment center, hospital, emergency room, physician's office,
2.3 outpatient infusion facility, or clinic.

2.4 (g) "Pharmacy" means a pharmacy that provides patients with plasma protein
2.5 therapies and ancillary infusion equipment and supplies.

2.6 Subd. 2. Rules for standards of care. The Board of Pharmacy shall promulgate
2.7 rules that govern standards of pharmaceutical services for individuals needing plasma
2.8 protein therapies. The rules shall include when feasible the standards established by the
2.9 medical advisory committees of the patient groups and professional societies representing
2.10 individuals with primary immunodeficiency diseases, alpha₁-antitrypsin deficiency, and
2.11 von Willebrand disease. The rules shall include safeguards to ensure the pharmacy
2.12 provides:

2.13 (1) all brands of plasma protein therapies needed by the patients served that are
2.14 approved by the federal Food and Drug Administration in all available assays and vial
2.15 sizes;

2.16 (2) the shipment of prescribed plasma protein therapies to the patient within:

2.17 (i) two business days or less, for established patients once coverage is verified;

2.18 (ii) three business days or less for new patients in nonemergency situations; and

2.19 (iii) in cases of emergency, within the time necessary to meet the patient's need;

2.20 (3) all necessary ancillary infusion equipment and supplies for administration of
2.21 plasma protein therapies;

2.22 (4) coordination of pharmacy services with home nursing services when home
2.23 nursing services are deemed necessary by the treating physician; and

2.24 (5) patients who have received plasma protein therapies with a designated contact
2.25 telephone number for emergency refills and for reporting problems with a delivery or
2.26 product.