A bill for an act

relating to health; requiring coverage for plasma protein therapies and home nursing services; requiring medical assistance coverage of plasma protein therapies; amending Minnesota Statutes 2008, section 256B.0625, by adding a subdivision; proposing coding for new law in Minnesota Statutes, chapters 62Q; 151.

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

Section 1. **[62Q.82] COVERAGE OF PLASMA PROTEIN THERAPIES AND HOME NURSING SERVICES.**

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

(b) "Home nursing services" has the meaning given in section 151.58, subdivision 1.

(c) "Plasma protein therapy" has the meaning given in section 151.58, subdivision 1.

Subd. 2. **Home treatment.** Any health plan offered by a health plan company must provide coverage for home nursing services associated with primary immunodeficiency diseases, alpha$_1$-antitrypsin deficiency, and von Willebrand disease.

Subd. 3. **Drug formulary.** If a health plan company maintains a drug formulary, including a formulary relating to specialty pharmaceutical therapies, all FDA-approved plasma protein therapies shall be included in the formulary.

Subd. 4. **Preauthorization.** If a health plan company requires preauthorization or preapproval of a plasma protein therapy before the product can be dispensed, preapproval or preauthorization shall be completed within 24 hours or one business day, whichever is later. If the circumstances are deemed urgent by the treating physician, preapproval or preauthorization shall be administered upon the request of the treating physician.

Subd. 5. **Multiple pharmacies.** A health plan company shall provide an enrollee who has been diagnosed with a primary immunodeficiency disease, an alpha$_1$-antitrypsin deficiency, or von Willebrand disease with the option of receiving covered services at more than one pharmacy that meets the requirements in section 151.58 and the rules adopted by the board under section 151.58.

Subd. 6. **Medical screening for von Willebrand disease.** (a) A health plan company may require a physician to perform a medical screening for von Willebrand disease and other bleeding disorders before providing coverage for an invasive uterine surgical procedure for menorrhagia. This requirement must meet the guidelines established by the National Heart, Lung, and Blood Institute of the National Institutes of Health.

(b) A health plan company shall provide coverage for the medical screening required in paragraph (a), including physician's fees and clinical laboratory services.

Sec. 2. **[151.58] PHARMACIES PROVIDING PLASMA PROTEIN THERAPIES.**

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

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

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

(d) "Plasma protein therapy" means a medicine manufactured from human plasma or recombinant biotechnology techniques, approved for distribution by the federal Food and Drug Administration, that is used for the treatment and prevention of symptoms associated with alpha$_1$-antitrypsin deficiency, primary immunodeficiency diseases, and von Willebrand disease.

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

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

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

Subd. 2. **Rules for standards of care.** The Board of Pharmacy shall promulgate rules that govern standards of pharmaceutical services for individuals needing plasma protein therapies. The rules shall include when feasible the standards established by the medical advisory committees of the patient groups and professional societies representing individuals with primary immunodeficiency diseases, alpha$_1$-antitrypsin deficiency, and von Willebrand disease. The rules shall include safeguards to ensure the pharmacy provides:

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

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

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

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

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

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

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

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

(6) patients with notification of recalls and withdrawals of plasma protein therapies and ancillary infusion equipment within 24 hours of receipt of the notification.

Subd. 3. **Standards for processing prescription orders.** Notwithstanding section 151.21, a pharmacy shall dispense all prescriptions of plasma protein therapies as written by the prescribing physician. No changes or substitutions shall be made without prior approval of the prescribing physician. If the prescription does not indicate a specific brand name of product, the provider must contact the prescribing physician to determine the product that should be dispensed.

Subd. 4. **Consent.** The plasma protein therapy and infusion technique may not be changed without the consent of the treating physician and the patient.

Sec. 3. Minnesota Statutes 2008, section 256B.0625, is amended by adding a subdivision to read:

Subd. 53. **Plasma protein therapies.** (a) For patients diagnosed with conditions reliant on plasma protein therapies, medical assistance covers:

(1) home delivery of plasma protein therapies and ancillary infusion equipment and supplies, including emergency deliveries of the therapy when medically necessary;

(2) medically necessary ancillary infusion equipment and supplies required to administer the plasma protein therapies; and

(3) in-home assessments conducted by a pharmacist, nurse, or local home health care agency trained in plasma protein therapies when deemed necessary by the patient's treating physician.

(b) For purposes of this section, "plasma protein therapy" has the meaning given in section 151.58.