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

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

Section 1. [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; and

(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.