

SENATE
STATE OF MINNESOTA
NINETIETH SESSION

S.F. No. 1773

(SENATE AUTHORS: HOFFMAN)

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OFFICIAL STATUS
Introduction and first reading
Referred to Health and Human Services Finance and Policy

1.1 A bill for an act
 1.2 relating to health; exempting certain facilities that deliver home renal products
 1.3 from pharmacy licensure requirements; amending Minnesota Statutes 2016, sections
 1.4 151.19, subdivision 1, by adding a subdivision; 151.46.

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

1.6 Section 1. Minnesota Statutes 2016, section 151.19, subdivision 1, is amended to read:

1.7 Subdivision 1. **Pharmacy licensure requirements.** (a) No person shall operate a
 1.8 pharmacy without first obtaining a license from the board and paying any applicable fee
 1.9 specified in section 151.065. The license shall be displayed in a conspicuous place in the
 1.10 pharmacy for which it is issued and expires on June 30 following the date of issue. It is
 1.11 unlawful for any person to operate a pharmacy unless the license has been issued to the
 1.12 person by the board.

1.13 (b) Application for a pharmacy license under this section shall be made in a manner
 1.14 specified by the board.

1.15 (c) No license shall be issued or renewed for a pharmacy located within the state unless
 1.16 the applicant agrees to operate the pharmacy in a manner prescribed by federal and state
 1.17 law and according to rules adopted by the board. No license shall be issued for a pharmacy
 1.18 located outside of the state unless the applicant agrees to operate the pharmacy in a manner
 1.19 prescribed by federal law and, when dispensing medications for residents of this state, the
 1.20 laws of this state, and Minnesota Rules.

1.21 (d) No license shall be issued or renewed for a pharmacy that is required to be licensed
 1.22 or registered by the state in which it is physically located unless the applicant supplies the
 1.23 board with proof of such licensure or registration.

2.1 (e) The board shall require a separate license for each pharmacy located within the state
2.2 and for each pharmacy located outside of the state at which any portion of the dispensing
2.3 process occurs for drugs dispensed to residents of this state.

2.4 (f) ~~The board shall not issue~~ Before issuing an initial or renewed license for a pharmacy
2.5 ~~unless, the board may require~~ the pharmacy ~~passes to pass~~ an inspection conducted by an
2.6 authorized representative of the board. In the case of a pharmacy located outside of the state,
2.7 the board may require the applicant to pay the cost of the inspection, in addition to the
2.8 license fee in section 151.065, unless the applicant furnishes the board with a report, issued
2.9 by the appropriate regulatory agency of the state in which the facility is located, of an
2.10 inspection that has occurred within the 24 months immediately preceding receipt of the
2.11 license application by the board. The board may deny licensure unless the applicant submits
2.12 documentation satisfactory to the board that any deficiencies noted in an inspection report
2.13 have been corrected.

2.14 (g) The board shall not issue an initial or renewed license for a pharmacy located outside
2.15 of the state unless the applicant discloses and certifies:

2.16 (1) the location, names, and titles of all principal corporate officers and all pharmacists
2.17 who are involved in dispensing drugs to residents of this state;

2.18 (2) that it maintains its records of drugs dispensed to residents of this state so that the
2.19 records are readily retrievable from the records of other drugs dispensed;

2.20 (3) that it agrees to cooperate with, and provide information to, the board concerning
2.21 matters related to dispensing drugs to residents of this state;

2.22 (4) that, during its regular hours of operation, but no less than six days per week, for a
2.23 minimum of 40 hours per week, a toll-free telephone service is provided to facilitate
2.24 communication between patients in this state and a pharmacist at the pharmacy who has
2.25 access to the patients' records; the toll-free number must be disclosed on the label affixed
2.26 to each container of drugs dispensed to residents of this state; and

2.27 (5) that, upon request of a resident of a long-term care facility located in this state, the
2.28 resident's authorized representative, or a contract pharmacy or licensed health care facility
2.29 acting on behalf of the resident, the pharmacy will dispense medications prescribed for the
2.30 resident in unit-dose packaging or, alternatively, comply with section 151.415, subdivision
2.31 5.

3.1 Sec. 2. Minnesota Statutes 2016, section 151.19, is amended by adding a subdivision to
3.2 read:

3.3 Subd. 1a. **Home renal products.** A facility licensed as a manufacturer under section
3.4 151.252, subdivision 1, or as a wholesaler or third party logistics provider under section
3.5 151.47 that delivers dialysate necessary to perform home renal dialysis to a patient in this
3.6 state is exempt from subdivision 1 if:

3.7 (1) the manufacturer of the dialysate is licensed by the board as a manufacturer and the
3.8 manufacturer or its agent leases or owns the licensed manufacturing or wholesaling facility
3.9 from which the dialysate will be delivered;

3.10 (2) the dialysate has been approved by the United States Food and Drug Administration;

3.11 (3) the dialysate is stored and delivered in its original sealed and unopened manufacturer's
3.12 packaging;

3.13 (4) the dialysate is delivered only upon receipt of a prescription drug order issued by a
3.14 licensed practitioner;

3.15 (5) the dialysate is delivered by the manufacturer or licensed manufacturer's agent, except
3.16 that the manufacturer may use a common carrier to deliver the dialysate;

3.17 (6) prescriptions and record of delivery are maintained by the manufacturer for a
3.18 minimum of three years and are made available to the board upon request; and

3.19 (7) the manufacturer or its agent delivers the dialysate directly to the patient for whom
3.20 the dialysate was prescribed, or to a designee of the patient, for self-administration of dialysis
3.21 therapy.

3.22 Sec. 3. Minnesota Statutes 2016, section 151.46, is amended to read:

3.23 **151.46 PROHIBITED DRUG PURCHASES OR RECEIPT.**

3.24 It is unlawful for any person to knowingly purchase or receive a prescription drug from
3.25 a source other than a person or entity licensed under the laws of the state, except where
3.26 otherwise provided. Licensed wholesale drug distributors other than pharmacies shall not
3.27 dispense or distribute prescription drugs directly to patients except for licensed facilities
3.28 that dispense or distribute home renal products directly to patients pursuant to section 151.19,
3.29 subdivision 1a. A person violating the provisions of this section is guilty of a misdemeanor.