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State of Minnesota

HOUSE OF REPRESENTATIVES

NINETY-SECOND SESSION

H. F. No. 2023

03/08/2021 Authored by Huot
The bill was read for the first time and referred to the Committee on Health Finance and Policy

1.1 A bill for an act
1.2 relating to health; clarifying requirements for the licensure of facilities that handle
1.3 medical gases; amending Minnesota Statutes 2020, section 151.01, subdivision
1.4 29, by adding subdivisions; proposing coding for new law in Minnesota Statutes,
1.5 chapter 151; repealing Minnesota Statutes 2020, section 151.19, subdivision 3.

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

1.7 Section 1. Minnesota Statutes 2020, section 151.01, subdivision 29, is amended to read:

1.8 Subd. 29. Legend Medical gas. "Legend Medical gas" means a liquid or gaseous
1.9 substance used for medical purposes and that is required by federal law to be dispensed
1.10 only pursuant to the prescription of a licensed practitioner any gas or liquid manufactured
1.11 or stored in a liquefied, nonliquefied, or cryogenic state that:

1.12 (1) has a chemical or physical action in or on the human body or animals or is used in
1.13 conjunction with medical gas equipment; and

1.14 (2) is intended to be used for the diagnosis, cure, mitigation, treatment, or prevention of
1.15 disease.

1.16 Sec. 2. Minnesota Statutes 2020, section 151.01, is amended by adding a subdivision to
1.17 read:

1.18 Subd. 29a. Medical gas manufacturer. "Medical gas manufacturer" means any person:

1.19 (1) originally manufacturing a medical gas by chemical reaction, physical separation,
1.20 compression of atmospheric air, purification, or other means;

1.21 (2) filling a medical gas into a dispensing container via gas to gas, liquid to gas, or liquid
1.22 to liquid processes;

2.1 (3) combining two or more medical gases into a container to form a medically appropriate
2.2 mixture; or

2.3 (4) filling a medical gas via liquid to liquid into a final use container at the point of use.

2.4 Sec. 3. Minnesota Statutes 2020, section 151.01, is amended by adding a subdivision to
2.5 read:

2.6 Subd. 29b. **Medical gas wholesaler.** "Medical gas wholesaler" means any person who
2.7 sells a medical gas to another business or entity for the purpose of reselling or providing
2.8 that medical gas to the ultimate consumer or patient.

2.9 Sec. 4. Minnesota Statutes 2020, section 151.01, is amended by adding a subdivision to
2.10 read:

2.11 Subd. 29c. **Medical gas dispenser.** "Medical gas dispenser" means any person, other
2.12 than a licensed practitioner or pharmacy, who sells or provides a medical gas directly to the
2.13 ultimate consumer or patient via a valid prescription.

2.14 Sec. 5. **[151.191] LICENSING MEDICAL GAS FACILITIES; FEES;**
2.15 **PROHIBITIONS.**

2.16 Subdivision 1. **Medical gas manufacturers; requirements.** (a) No person shall act as
2.17 a medical gas manufacturer without first obtaining a license from the board and paying any
2.18 applicable fee specified in section 151.065.

2.19 (b) Application for a medical gas manufacturer license under this subdivision must be
2.20 made in a manner specified by the board.

2.21 (c) A license must not be issued or renewed for a medical gas manufacturer unless the
2.22 applicant agrees to operate in a manner prescribed by federal and state law.

2.23 (d) A license must not be issued or renewed for a medical gas manufacturer that is
2.24 required to be licensed or registered by the state in which it is physically located unless the
2.25 applicant supplies the board with proof of licensure or registration. The board may establish
2.26 standards for the licensure of a medical gas manufacturer that is not required to be licensed
2.27 or registered by the state in which it is physically located.

2.28 (e) The board must require a separate license for each facility located within the state at
2.29 which medical gas manufacturing occurs and for each facility located outside of the state
2.30 at which medical gases that are shipped into the state are manufactured.

3.1 (f) Before issuing an initial or renewed license for a medical gas manufacturing facility,
3.2 the board may require that the facility pass an inspection conducted by an authorized
3.3 representative of the board. In the case of a medical gas manufacturing facility located
3.4 outside of the state, the board may require that the applicant pay the cost of the inspection,
3.5 in addition to the license fee in section 151.065, unless the applicant provides the board a
3.6 report issued by the appropriate regulatory agency of the state in which the facility is located
3.7 of an inspection that has occurred within the 24 months immediately preceding receipt of
3.8 the license application by the board. The board may deny licensure unless the applicant
3.9 submits documentation satisfactory to the board that any deficiencies noted in an inspection
3.10 report have been corrected.

3.11 (g) A duly licensed medical gas manufacturing facility may also wholesale or dispense
3.12 any medical gas that is manufactured by the licensed facility or manufactured or wholesaled
3.13 by another properly licensed medical gas facility without also obtaining a medical gas
3.14 wholesaler license or medical gas dispenser registration.

3.15 (h) The filling of a medical gas into a final use container at the point of use and by liquid
3.16 to liquid transfer is permitted if the facility used as the base of operations is duly licensed
3.17 as a medical gas manufacturer.

3.18 Subd. 2. **Medical gas wholesalers; requirements.** (a) No person shall act as a medical
3.19 gas wholesaler without first obtaining a license from the board and paying any applicable
3.20 fee specified in section 151.065.

3.21 (b) Application for a medical gas wholesaler license under this subdivision must be
3.22 made in a manner specified by the board.

3.23 (c) A license must not be issued or renewed for a medical gas wholesaler unless the
3.24 applicant agrees to operate in a manner prescribed by federal and state law.

3.25 (d) A license must not be issued or renewed for a medical gas wholesaler that is required
3.26 to be licensed or registered by the state in which it is physically located unless the applicant
3.27 supplies the board with proof of licensure or registration. The board may establish standards
3.28 for the licensure of a medical gas wholesaler that is not required to be licensed or registered
3.29 by the state in which it is physically located.

3.30 (e) The board must require a separate license for each facility located within the state at
3.31 which medical gas wholesaling occurs and for each facility located outside of the state from
3.32 which medical gases that are shipped into the state are wholesaled.

4.1 (f) Before issuing an initial or renewed license for a medical gas wholesaling facility,
4.2 the board may require that the facility pass an inspection conducted by an authorized
4.3 representative of the board. In the case of a medical gas wholesaling facility located outside
4.4 of the state, the board may require that the applicant pay the cost of the inspection, in addition
4.5 to the license fee in section 151.065, unless the applicant provides the board a report issued
4.6 by the appropriate regulatory agency of the state in which the facility is located of an
4.7 inspection that has occurred within the 24 months immediately preceding receipt of the
4.8 license application by the board. The board may deny licensure unless the applicant submits
4.9 documentation satisfactory to the board that any deficiencies noted in an inspection report
4.10 have been corrected.

4.11 (g) A duly licensed medical gas wholesaling facility may also dispense any medical gas
4.12 that is manufactured or wholesaled by another properly licensed medical gas facility.

4.13 **Subd. 3. Medical gas dispensers; requirements.** (a) A person or establishment not
4.14 licensed as a pharmacy, practitioner, medical gas manufacturer, or medical gas wholesaler
4.15 must not engage in the dispensing of medical gases without first obtaining a registration
4.16 from the board and paying the applicable fee in section 151.065. The registration must be
4.17 displayed in a conspicuous place in the business for which it is issued and expires on the
4.18 date set by the board.

4.19 (b) Application for a medical gas dispenser registration under this subdivision must be
4.20 made in a manner specified by the board.

4.21 (c) A registration must not be issued or renewed for a medical gas dispenser located
4.22 within the state unless the applicant agrees to operate in a manner prescribed by federal and
4.23 state law. A registration must not be issued for a medical gas dispenser located outside of
4.24 the state unless the applicant agrees to operate in a manner prescribed by federal law and,
4.25 when dispensing medical gases for residents of this state, the laws of this state.

4.26 (d) A registration must not be issued or renewed for a medical gas dispenser that is
4.27 required to be licensed or registered by the state in which it is physically located unless the
4.28 applicant supplies the board with proof of the licensure or registration. The board may
4.29 establish standards for the registration of a medical gas dispenser that is not required to be
4.30 licensed or registered by the state in which it is physically located.

4.31 (e) The board must require a separate registration for each medical gas dispenser located
4.32 within the state and for each facility located outside of the state from which medical gases
4.33 are dispensed to residents of this state.

5.1 (f) Before issuing an initial or renewed registration for a medical gas dispenser, the board
5.2 may require that the medical gas dispenser pass an inspection conducted by an authorized
5.3 representative of the board. In the case of a medical gas dispenser located outside of the
5.4 state, the board may require that the applicant pay the cost of the inspection, in addition to
5.5 the applicable fee in section 151.065, unless the applicant provides the board a report issued
5.6 by the appropriate regulatory agency of the state in which the facility is located of an
5.7 inspection that has occurred within the 24 months immediately preceding receipt of the
5.8 registration application by the board. The board may deny registration unless the applicant
5.9 submits documentation satisfactory to the board that any deficiencies noted in an inspection
5.10 report have been corrected.

5.11 (g) A facility holding a medical gas dispenser registration must not engage in the
5.12 manufacturing or wholesaling of medical gases, except that a medical gas dispenser may
5.13 transfer medical gases from one of its duly registered facilities to other duly licensed or
5.14 registered medical gas manufacturing, wholesaling, or dispensing facilities owned or operated
5.15 by that same company without requiring a medical gas wholesaler license.

5.16 Sec. 6. **REPEALER.**

5.17 Minnesota Statutes 2020, section 151.19, subdivision 3, is repealed.

151.19 REGISTRATION; FEES.

Subd. 3. **Sale of federally restricted medical gases.** (a) A person or establishment not licensed as a pharmacy or a practitioner must not engage in the retail sale or dispensing of federally restricted medical gases without first obtaining a registration from the board and paying the applicable fee specified in section 151.065. The registration must be displayed in a conspicuous place in the business for which it is issued and expires on the date set by the board. It is unlawful for a person to sell or dispense federally restricted medical gases unless a certificate has been issued to that person by the board.

(b) Application for a medical gas dispenser registration under this section must be made in a manner specified by the board.

(c) A registration must not be issued or renewed for a medical gas dispenser located within the state unless the applicant agrees to operate in a manner prescribed by federal and state law and according to the rules adopted by the board. A license must not be issued for a medical gas dispenser located outside of the state unless the applicant agrees to operate in a manner prescribed by federal law and, when dispensing medical gases for residents of this state, the laws of this state and Minnesota Rules.

(d) A registration must not be issued or renewed for a medical gas dispenser that is required to be licensed or registered by the state in which it is physically located unless the applicant supplies the board with proof of the licensure or registration. The board may, by rule, establish standards for the registration of a medical gas dispenser that is not required to be licensed or registered by the state in which it is physically located.

(e) The board must require a separate registration for each medical gas dispenser located within the state and for each facility located outside of the state from which medical gases are dispensed to residents of this state.

(f) Prior to the issuance of an initial or renewed registration for a medical gas dispenser, the board may require the medical gas dispenser to pass an inspection conducted by an authorized representative of the board. In the case of a medical gas dispenser located outside of the state, the board may require the applicant to pay the cost of the inspection, in addition to the license fee in section 151.065, unless the applicant furnishes the board with a report, issued by the appropriate regulatory agency of the state in which the facility is located, of an inspection that has occurred within the 24 months immediately preceding receipt of the license application by the board. The board may deny licensure unless the applicant submits documentation satisfactory to the board that any deficiencies noted in an inspection report have been corrected.