SF1227 REVISOR EM S1227-1 1st Engrossment

SENATE STATE OF MINNESOTA NINETY-SECOND SESSION

S.F. No. 1227

(SENATE AUTHORS: KORAN, Nelson and Draheim)

960 Author added Draheim

See HF2128, Art. 4, Sec. 1-6 See First Special Session 2021, HF33, Art. 4, Sec. 6; Art. 11, Sec. 14, 48

1.1 A bill for an act

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relating to health care; establishing a separate licensure for medical gas distributors; 1 2 creating exemptions for certain opiate manufacturers from the opiate registration 1.3 fee; clarifying the opiate epidemic response advisory council's role in reporting to 1.4 the legislature and determining grant awards and amounts; specifying the term 1.5 limits for the initial advisory council members; reducing the license fee for 1.6 manufacturers and wholesalers of medical gases; amending Minnesota Statutes 1.7 2020, sections 16A.151, subdivision 2; 151.01, subdivision 29, by adding 1.8 subdivisions; 151.065, subdivisions 1, 3, 7; 151.066, subdivision 3; 256.042, 1.9 subdivision 4; 256.043, subdivision 4; proposing coding for new law in Minnesota 1.10 Statutes, chapter 151; repealing Minnesota Statutes 2020, section 151.19, 1.11 subdivision 3. 1.12

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

- Section 1. Minnesota Statutes 2020, section 16A.151, subdivision 2, is amended to read:
- Subd. 2. **Exceptions.** (a) If a state official litigates or settles a matter on behalf of specific injured persons or entities, this section does not prohibit distribution of money to the specific injured persons or entities on whose behalf the litigation or settlement efforts were initiated. If money recovered on behalf of injured persons or entities cannot reasonably be distributed to those persons or entities because they cannot readily be located or identified or because the cost of distributing the money would outweigh the benefit to the persons or entities, the money must be paid into the general fund.
- (b) Money recovered on behalf of a fund in the state treasury other than the general fund may be deposited in that fund.
- 1.24 (c) This section does not prohibit a state official from distributing money to a person or 1.25 entity other than the state in litigation or potential litigation in which the state is a defendant 1.26 or potential defendant.

Section 1.

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(d) State agencies may accept funds as directed by a federal court for any restitution or monetary penalty under United States Code, title 18, section 3663(a)(3), or United States Code, title 18, section 3663A(a)(3). Funds received must be deposited in a special revenue account and are appropriated to the commissioner of the agency for the purpose as directed by the federal court.

- (e) Tobacco settlement revenues as defined in section 16A.98, subdivision 1, paragraph (t), may be deposited as provided in section 16A.98, subdivision 12.
- (f) Any money received by the state resulting from a settlement agreement or an assurance of discontinuance entered into by the attorney general of the state, or a court order in litigation brought by the attorney general of the state, on behalf of the state or a state agency, against one or more opioid manufacturers or opioid wholesale drug distributors or consulting firms working for an opioid manufacturer or opioid wholesale drug distributor related to alleged violations of consumer fraud laws in the marketing, sale, or distribution of opioids in this state or other alleged illegal actions that contributed to the excessive use of opioids, must be deposited in a separate account in the state treasury and the commissioner shall notify the chairs and ranking minority members of the Finance Committee in the senate and the Ways and Means Committee in the house of representatives that an account has been created. Notwithstanding section 11A.20, all investment income and all investment losses attributable to the investment of this account shall be credited to the account. This paragraph does not apply to attorney fees and costs awarded to the state or the Attorney General's Office, to contract attorneys hired by the state or Attorney General's Office, or to other state agency attorneys. If the licensing fees under section 151.065, subdivision 1, clause (16), and subdivision 3, clause (14), are reduced and the registration fee under section 151.066, subdivision 3, is repealed in accordance with section 256.043, subdivision 4, then the commissioner shall transfer from the separate account created in this paragraph to the opiate epidemic response fund under section 256.043 an amount that ensures that \$20,940,000 each fiscal year is available for distribution in accordance with section 256.043, subdivisions 2 and subdivision 3.
- (g) Notwithstanding paragraph (f), if money is received from a settlement agreement or an assurance of discontinuance entered into by the attorney general of the state or a court order in litigation brought by the attorney general of the state on behalf of the state or a state agency against a consulting firm working for an opioid manufacturer or opioid wholesale drug distributor and deposited into the separate account created under paragraph (f), the commissioner shall annually transfer from the separate account to the opiate epidemic response fund under section 256.043 an amount equal to the estimated amount submitted

Section 1. 2

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

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

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Sec. 4. Minnesota Statutes 2020, section 151.01, is amended by adding a subdivision to 4.1 read: 4.2 Subd. 29b. Medical gas wholesaler. "Medical gas wholesaler" means any person who 4.3 sells a medical gas to another business or entity for the purpose of reselling or providing 4.4 4.5 that medical gas to the ultimate consumer or patient. Sec. 5. Minnesota Statutes 2020, section 151.01, is amended by adding a subdivision to 4.6 read: 4.7 Subd. 29c. Medical gas dispenser. "Medical gas dispenser" means any person, other 4.8 than a licensed practitioner or pharmacy, who sells or provides a medical gas directly to the 4.9 ultimate consumer or patient via a valid prescription. 4.10 Sec. 6. Minnesota Statutes 2020, section 151.065, subdivision 1, is amended to read: 4.11 Subdivision 1. Application fees. Application fees for licensure and registration are as 4.12 follows: 4.13 (1) pharmacist licensed by examination, \$175; 4.14 (2) pharmacist licensed by reciprocity, \$275; 4.15 (3) pharmacy intern, \$50; 4.16 (4) pharmacy technician, \$50; 4.17 (5) pharmacy, \$260; 4.18 (6) drug wholesaler, legend drugs only, \$5,260; 4.19 (7) drug wholesaler, legend and nonlegend drugs, \$5,260; 4.20 (8) drug wholesaler, nonlegend drugs, veterinary legend drugs, or both, \$5,260; 4.21 (9) drug wholesaler, medical gases, \$5,260 for the first facility and \$260 for each 4.22 additional facility; 4.23 (10) third-party logistics provider, \$260; 4.24 (11) drug manufacturer, nonopiate legend drugs only, \$5,260; 4.25 (12) drug manufacturer, nonopiate legend and nonlegend drugs, \$5,260; 4.26 (13) drug manufacturer, nonlegend or veterinary legend drugs, \$5,260; 4.27

(14) drug manufacturer, medical gases, \$5,260 for the first facility and \$260 for each

Sec. 6. 4

additional facility;

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Sec. 7. 5

(15) medical gas dispenser, \$260;

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6.1 (16) controlled substance researcher, \$75; and

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(17) pharmacy professional corporation, \$100.

EFFECTIVE DATE. This section is effective the day following final enactment.

- Sec. 8. Minnesota Statutes 2020, section 151.065, subdivision 7, is amended to read:
- 6.5 Subd. 7. **Deposit of fees.** (a) The license fees collected under this section, with the exception of the fees identified in paragraphs (b) and (c), shall be deposited in the state government special revenue fund.
 - (b) \$5,000 of each fee collected under subdivision 1, clauses (6) to (9) (8), and (11) to (13), and (15), and subdivision 3, clauses (4) to (7) (6), and (9) to (11), and (13), and \$55,000 of each fee collected under subdivision 1, clause (16), and subdivision 3, clause (14), shall be deposited in the opiate epidemic response fund established in section 256.043.
 - (c) If the fees collected under subdivision 1, clause (16), or subdivision 3, clause (14), are reduced under section 256.043, \$5,000 of the reduced fee shall be deposited in the opiate epidemic response fund in section 256.043.
 - Sec. 9. Minnesota Statutes 2020, section 151.066, subdivision 3, is amended to read:
 - Subd. 3. **Determination of an opiate product registration fee.** (a) The board shall annually assess an opiate product registration fee on any manufacturer of an opiate that annually sells, delivers, or distributes an opiate within or into the state 2,000,000 or more units as reported to the board under subdivision 2.
 - (b) For purposes of assessing the annual registration fee under this section and determining the number of opiate units a manufacturer sold, delivered, or distributed within or into the state, the board shall not consider any opiate that is used for medication assisted therapy for substance use disorders. If there is money deposited into the separate account as described in section 16A.151, subdivision 2, paragraph (g), the board shall submit to the commissioner of management and budget an estimate of the difference in the annual fee revenue collected under this section due to this exception.
 - (c) The annual registration fee for each manufacturer meeting the requirement under paragraph (a) is \$250,000.
- 6.29 (e) (d) In conjunction with the data reported under this section, and notwithstanding section 152.126, subdivision 6, the board may use the data reported under section 152.126,

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subdivision 4, to determine which manufacturers meet the requirement under paragraph (a) and are required to pay the registration fees under this subdivision.

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- (d) (e) By April 1 of each year, beginning April 1, 2020, the board shall notify a manufacturer that the manufacturer meets the requirement in paragraph (a) and is required to pay the annual registration fee in accordance with section 151.252, subdivision 1, paragraph (b).
- (e) (f) A manufacturer may dispute the board's determination that the manufacturer must pay the registration fee no later than 30 days after the date of notification. However, the manufacturer must still remit the fee as required by section 151.252, subdivision 1, paragraph (b). The dispute must be filed with the board in the manner and using the forms specified by the board. A manufacturer must submit, with the required forms, data satisfactory to the board that demonstrates that the assessment of the registration fee was incorrect. The board must make a decision concerning a dispute no later than 60 days after receiving the required dispute forms. If the board determines that the manufacturer has satisfactorily demonstrated that the fee was incorrectly assessed, the board must refund the amount paid in error.
- (f) (g) For purposes of this subdivision, a unit means the individual dosage form of the particular drug product that is prescribed to the patient. One unit equals one tablet, capsule, patch, syringe, milliliter, or gram.
 - **EFFECTIVE DATE.** This section is effective the day following final enactment.

Sec. 10. [151.191] LICENSING MEDICAL GAS FACILITIES; FEES;

PROHIBITIONS.

- Subdivision 1. Medical gas manufacturers; requirements. (a) No person shall act as 7.22 a medical gas manufacturer without first obtaining a license from the board and paying any 7.23 applicable fee specified in section 151.065. 7.24
- (b) Application for a medical gas manufacturer license under this section must be made 7.25 in a manner specified by the board. 7.26
- (c) A license must not be issued or renewed for a medical gas manufacturer unless the 7.27 applicant agrees to operate in a manner prescribed by federal and state law and according 7.28 7.29 to Minnesota Rules.
- (d) A license must not be issued or renewed for a medical gas manufacturer that is 7.30 required to be licensed or registered by the state in which it is physically located unless the 7.31 applicant supplies the board with proof of licensure or registration. The board may establish 7.32

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standards for the licensure of a medical gas manufacturer that is not required to be licensed or registered by the state in which it is physically located.

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- (e) The board must require a separate license for each facility located within the state at which medical gas manufacturing occurs and for each facility located outside of the state at which medical gases that are shipped into the state are manufactured.
- (f) Prior to the issuance of an initial or renewed license for a medical gas manufacturing facility, the board may require the facility to pass an inspection conducted by an authorized representative of the board. In the case of a medical gas manufacturing facility 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.
- (g) A duly licensed medical gas manufacturing facility may also wholesale or dispense any medical gas that is manufactured by the licensed facility, or manufactured or wholesaled by another properly licensed medical gas facility, without also obtaining a medical gas wholesaler license or medical gas dispenser registration.
- (h) The filling of a medical gas into a final use container, at the point of use and by liquid to liquid transfer, is permitted as long as the facility used as the base of operations is duly licensed as a medical gas manufacturer.
- Subd. 2. Medical gas wholesalers; requirements. (a) No person shall act as a medical gas wholesaler without first obtaining a license from the board and paying any applicable fee specified in section 151.065.
- (b) Application for a medical gas wholesaler license under this section must be made in a manner specified by the board.
- (c) A license must not be issued or renewed for a medical gas wholesaler unless the applicant agrees to operate in a manner prescribed by federal and state law and according to Minnesota Rules.
 - (d) A license must not be issued or renewed for a medical gas wholesaler 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 licensure or registration. The board may establish standards

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for the licensure of a medical gas wholesaler that is not required to be licensed or registered by the state in which it is physically located.

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- (e) The board must require a separate license for each facility located within the state at which medical gas wholesaling occurs and for each facility located outside of the state from which medical gases that are shipped into the state are wholesaled.
- (f) Prior to the issuance of an initial or renewed license for a medical gas wholesaling facility, the board may require the facility to pass an inspection conducted by an authorized representative of the board. In the case of a medical gas wholesaling facility 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.
- (g) A duly licensed medical gas wholesaling facility may also dispense any medical gas that is manufactured or wholesaled by another properly licensed medical gas facility.
- Subd. 3. Medical gas dispensers; requirements. (a) A person or establishment not licensed as a pharmacy, practitioner, medical gas manufacturer, or medical gas dispenser must not engage in the dispensing of 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.
- (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

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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.

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- (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.
- (g) A facility holding a medical gas dispenser registration must not engage in the manufacturing or wholesaling of medical gases, except that a medical gas dispenser may transfer medical gases from one of its duly registered facilities to other duly registered medical gas manufacturing, wholesaling, or dispensing facilities owned or operated by that same company, without requiring a medical gas wholesaler license.
- Sec. 11. Minnesota Statutes 2020, section 256.042, subdivision 4, is amended to read: 10.21
 - Subd. 4. Grants. (a) The commissioner of human services shall submit a report of the grants proposed by the advisory council to be awarded for the upcoming fiscal year to the chairs and ranking minority members of the legislative committees with jurisdiction over health and human services policy and finance, by March 1 of each year, beginning March 1, 2020, describing the priorities and specific activities the advisory council intends to address for the upcoming fiscal year based on the projected funds available for grant distribution.
 - (b) The commissioner of human services shall award grants from the opiate epidemic response fund under section 256.043. The grants shall be awarded to proposals selected by the advisory council that address the priorities in subdivision 1, paragraph (a), clauses (1) to (4), unless otherwise appropriated by the legislature. The advisory council shall determine grant awards and funding amounts based on the funds appropriated to the commissioner under section 256.043, subdivision 3, paragraph (e). The commissioner shall award the

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grants from the opiate epidemic response fund and administer the grants in compliance with section 16B.97. No more than three percent of the grant amount may be used by a grantee for administration.

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- Sec. 12. Minnesota Statutes 2020, section 256.043, subdivision 4, is amended to read:
- Subd. 4. **Settlement; sunset.** (a) If the state receives a total sum of \$250,000,000 either as a result of a settlement agreement or an assurance of discontinuance entered into by the attorney general of the state, or resulting from a court order in litigation brought by the attorney general of the state on behalf of the state or a state agency, against one or more opioid manufacturers or opioid wholesale drug distributors or consulting firms working for an opioid manufacturer or opioid wholesale drug distributor related to alleged violations of consumer fraud laws in the marketing, sale, or distribution of opioids in this state, or other alleged illegal actions that contributed to the excessive use of opioids, or from the fees collected under sections 151.065, subdivisions 1 and 3, and 151.066, that are deposited into the opiate epidemic response fund established in this section, or from a combination of both, the fees specified in section 151.065, subdivisions 1, clause (16), and 3, clause (14), shall be reduced to \$5,260, and the opiate registration fee in section 151.066, subdivision 3, shall be repealed.
- (b) The commissioner of management and budget shall inform the Board of Pharmacy, the governor, and the legislature when the amount specified in paragraph (a) has been reached. The board shall apply the reduced license fee for the next licensure period.
- (c) Notwithstanding paragraph (a), the reduction of the license fee in section 151.065, subdivisions 1 and 3, and the repeal of the registration fee in section 151.066 shall not occur before July 1, 2024.
- 11.24 **EFFECTIVE DATE.** This section is effective the day following final enactment.

Sec. 13. <u>OPIATE EPIDEMIC RESPONSE ADVISORY COUNCIL; INITIAL</u> MEMBERSHIP TERMS.

Notwithstanding Minnesota Statutes, section 256.042, subdivision 2, paragraph (c), the initial term for members of the opiate epidemic response advisory council established under Minnesota Statutes, section 256.042, identified in Minnesota Statutes, section 256.042, subdivision 2, paragraph (a), clauses (1), (3), (5), (7), (9), (11), (13), (15), and (17), ends September 30, 2022. The initial term for members identified under Minnesota Statutes, section 256.042, subdivision 2, paragraph (a), clauses (2), (4), (6), (8), (10), (12), (14), and (16), ends September 30, 2023.

Sec. 13.

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12.2	(a) For purposes of assessing the opiate registration fee under Minnesota Statutes, section
12.3	151.066, subdivision 3, that is required to be paid on June 1, 2021, in accordance with
12.4	Minnesota Statutes, section 151.252, subdivision 1, paragraph (b), the Board of Pharmacy
12.5	shall not consider any injectable opiate product distributed to a hospital or hospital pharmacy.
12.6	If there is money deposited into the separate account as described in Minnesota Statutes,
12.7	section 16A.151, subdivision 2, paragraph (g), the board shall submit to the commissioner
12.8	of management and budget an estimate of the difference in the annual opiate registration
12.9	fee revenue collected under Minnesota Statutes, section 151.066, due to the exception
12.10	described in this paragraph.
12.11	(b) Any estimated loss to the opiate registration fee revenue attributable to paragraph
12.12	(a) must be included in any transfer that occurs under Minnesota Statutes, section 16A.151,
12.13	subdivision 2, paragraph (g), in calendar year 2021.

(c) If a manufacturer has already paid the opiate registration fee due on June 1, 2021, the Board of Pharmacy shall return the amount of the fee to the manufacturer if the manufacturer would not have been required to pay the fee after the calculations described in paragraph (a) were made.

12.18 Sec. 15. **REPEALER.**

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

Sec. 15. 12

APPENDIX Repealed Minnesota Statutes: S1227-1

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.