SENATE
STATE OF MINNESOTA
NINETY-THIRD SESSION

S.F. No. 2142

(SENATE AUTHORS: MANN, Port and Fateh)

DATE	D-PG	OFFICIAL STATUS
02/27/2023	1134	Introduction and first reading Referred to Health and Human Services See SF2995

A bill for an act

relating to health; increasing application and renewal fees for opiate drug wholesalers; establishing an opiate product fee for certain opiate drug wholesalers; eliminating the sunset for opioid fees; amending Minnesota Statutes 2022, sections 151.065, subdivisions 1, 3, 7; 151.066, subdivisions 3, 4; 151.47, subdivision 1a; 256.043, subdivision 1; repealing Minnesota Statutes 2022, section 256.043, subdivision 4.

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

Section 1. Minnesota Statutes 2022, section 151.065, subdivision 1, is amended to read:

Subdivision 1. **Application fees.** Application fees for licensure and registration are as follows:

(1) pharmacist licensed by examination, $175;

(2) pharmacist licensed by reciprocity, $275;

(3) pharmacy intern, $50;

(4) pharmacy technician, $50;

(5) pharmacy, $260;

(6) drug wholesaler, nonopiate legend drugs only, $5,260;

(7) drug wholesaler, nonopiate legend and nonlegend drugs, $5,260;

(8) drug wholesaler, nonlegend drugs, veterinary legend drugs, or both, $5,260;

(9) drug wholesaler, medical gases, $5,260 for the first facility and $260 for each additional facility;

(10) third-party logistics provider, $260;

(11) drug manufacturer, nonopiate legend drugs only, $5,260;

(12) drug manufacturer, nonopiate legend and nonlegend drugs, $5,260;

(13) drug manufacturer, nonlegend or veterinary legend drugs, $5,260;

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

(15) drug manufacturer, also licensed as a pharmacy in Minnesota, $5,260;

(16) drug manufacturer of opiate-containing controlled substances listed in section 152.02, subdivisions 3 to 5, $55,260;

(17) medical gas dispenser, $260;

(18) controlled substance researcher, $75; ~~and~~

(19) pharmacy professional corporation, $150~~.~~; and

(20) drug wholesaler of opiate-containing controlled substances listed in section 152.02, subdivisions 3 to 5, $55,260.

EFFECTIVE DATE. This section is effective July 1, 2023, and applies to any license issued on or after that date.

Sec. 2. Minnesota Statutes 2022, section 151.065, subdivision 3, is amended to read:

Subd. 3. **Annual renewal fees.** Annual licensure and registration renewal fees are as follows:

(1) pharmacist, $175;

(2) pharmacy technician, $50;

(3) pharmacy, $260;

(4) drug wholesaler, nonopiate legend drugs only, $5,260;

(5) drug wholesaler, nonopiate legend and nonlegend drugs, $5,260;

(6) drug wholesaler, nonlegend drugs, veterinary legend drugs, or both, $5,260;

(7) drug wholesaler, medical gases, $5,260 for the first facility and $260 for each additional facility;

(8) third-party logistics provider, $260;

(9) drug manufacturer, nonopiate legend drugs only, $5,260;

(10) drug manufacturer, nonopiate legend and nonlegend drugs, $5,260;

(11) drug manufacturer, nonlegend, veterinary legend drugs, or both, $5,260;

(12) drug manufacturer, medical gases, $5,260 for the first facility and $260 for each additional facility;

(13) drug manufacturer, also licensed as a pharmacy in Minnesota, $5,260;

(14) drug manufacturer of opiate-containing controlled substances listed in section 152.02, subdivisions 3 to 5, $55,260;

(15) medical gas dispenser, $260;

(16) controlled substance researcher, $75; ~~and~~

(17) pharmacy professional corporation, $100~~.~~; and

(18) drug wholesaler of opiate-containing controlled substances listed in section 152.02, subdivisions 3 to 5, $55,260.

EFFECTIVE DATE. This section is effective July 1, 2023, and applies to any license renewed on or after that date.

Sec. 3. Minnesota Statutes 2022, section 151.065, subdivision 7, is amended to read:

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), and (11) to (15), and subdivision 3, clauses (4) to (7), and (9) to (13), and $55,000 of each fee collected under subdivision 1, ~~clause~~ clauses (16) and (20), and subdivision 3, ~~clause~~ clauses (14) and (18), ~~shall~~ must 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.~~

EFFECTIVE DATE. This section is effective July 1, 2023.

Sec. 4. Minnesota Statutes 2022, section 151.066, subdivision 3, is amended to read:

Subd. 3. **Determination of an opiate product registration fee.** (a) The board ~~shall~~ must annually assess an opiate product registration fee on any manufacturer or wholesaler 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 or wholesaler sold, delivered, or distributed within or into the state, the board shall not consider any opiate that is used for substance use disorder treatment with medications for opioid use disorder.

(c) The annual registration fee for each manufacturer or wholesaler meeting the requirement under paragraph (a) is $250,000.

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

(e) By April 1 of each year, beginning April 1, 2020, the board ~~shall~~ must notify a manufacturer or wholesaler that the manufacturer or wholesaler 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), or section 151.47, subdivision 1a, paragraph (q), as applicable.

(f) A manufacturer or wholesaler may dispute the board's determination that the manufacturer or wholesaler must pay the registration fee no later than 30 days after the date of notification. However, the manufacturer or wholesaler must still remit the fee as required by section 151.252, subdivision 1, paragraph (b), or section 151.47, subdivision 1a, paragraph (q), as applicable. The dispute must be filed with the board in the manner and using the forms specified by the board. A manufacturer or wholesaler 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 or wholesaler has satisfactorily demonstrated that the fee was incorrectly assessed, the board must refund the amount paid in error.

(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 July 1, 2023.

Sec. 5. Minnesota Statutes 2022, section 151.066, subdivision 4, is amended to read:

Subd. 4. **Report.** (a) The Board of Pharmacy ~~shall~~ must evaluate the registration fee on drug manufacturers and wholesalers established under this section, and whether the registration fee and the increased licensure fees have impacted the prescribing practices of opiates by reducing the number of opiate prescriptions issued during calendar years 2021, 2022, and 2023, or creating any unintended consequences in the availability of opiates for the treatment of chronic or intractable pain to the extent the board has the ability to effectively identify a correlation. Notwithstanding section 152.126, subdivision 6, the board may access the data reported under section 152.126, subdivision 4, to conduct this evaluation.

(b) The board ~~shall~~ must submit the results of its evaluation to the chairs and ranking minority members of the legislative committees with jurisdiction over health and human services policy and finance by March 1, 2024.

EFFECTIVE DATE. This section is effective July 1, 2023.

Sec. 6. Minnesota Statutes 2022, section 151.47, subdivision 1a, is amended to read:

Subd. 1a. **Licensing.** (a) The board ~~shall~~ must license wholesale distributors in a manner that is consistent with United States Code, title 21, section 360eee-2, and the regulations promulgated thereunder. In the event that the provisions of this section, or of the rules of the board, conflict with the provisions of United States Code, title 21, section 360eee-2, or the rules promulgated thereunder, the federal provisions ~~shall~~ must prevail. The board shall not license a person as a wholesale distributor unless the person is engaged in wholesale distribution.

(b) ~~No~~ A person ~~shall~~ must not act as a wholesale distributor without first obtaining a license from the board and paying any applicable fee specified in section 151.065.

(c) Application for a wholesale distributor license under this section shall be made in a manner specified by the board.

(d) ~~No~~ A license ~~shall~~ must not be issued or renewed for a wholesale distributor unless the applicant agrees to operate in a manner prescribed by federal and state law and according to the rules adopted by the board.

(e) ~~No~~ A license ~~may~~ must not be issued or renewed for a wholesale distributor facility that is located in another state unless the applicant supplies the board with proof of licensure

or registration by the state in which the wholesale distributor is physically located or by the United States Food and Drug Administration.

(f) The board ~~shall~~ must require a separate license for each drug wholesale distributor facility located within the state and for each drug wholesale distributor facility located outside of the state from which drugs are shipped into the state or to which drugs are reverse distributed, except that a wholesaler of opiate-containing controlled substances must not be required to pay the fee under section 151.065, subdivision 1, clause (20), or 3, clause (18), for more than one facility.

(g) The board ~~shall~~ must not issue an initial or renewed license for a drug wholesale distributor facility unless the facility passes an inspection conducted by an authorized representative of the board or is inspected and accredited by an accreditation program approved by the board. In the case of a drug wholesale distributor 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, or furnishes the board with proof of current accreditation. 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.

(h) As a condition for receiving and retaining a wholesale drug distributor license issued under this section, an applicant ~~shall~~ must satisfy the board that it:

(1) has adequate storage conditions and facilities to allow for the safe receipt, storage, handling, and sale of drugs;

(2) has minimum liability and other insurance as may be required under any applicable federal or state law;

(3) has a functioning security system that includes an after-hours central alarm or comparable entry detection capability, and security policies and procedures that include provisions for restricted access to the premises, comprehensive employee applicant screening, and safeguards against all forms of employee theft;

(4) will maintain appropriate records of the distribution of drugs, which ~~shall~~ must be kept for a minimum of two years and be made available to the board upon request;

(5) employs principals and other persons, including officers, directors, primary shareholders, and key management executives, who will at all times demonstrate and maintain

their capability of conducting business in conformity with state and federal law, at least one of whom will serve as the primary designated representative for each licensed facility and who will be responsible for ensuring that the facility operates in a manner consistent with state and federal law;

(6) will ensure that all personnel have sufficient education, training, and experience, in any combination, so that they may perform assigned duties in a manner that maintains the quality, safety, and security of drugs;

(7) will provide the board with updated information about each wholesale distributor facility to be licensed, as requested by the board;

(8) will develop and, as necessary, update written policies and procedures that ~~assure~~ ensure reasonable wholesale drug distributor preparation for, protection against, and handling of any facility security or operation problems, including but not limited to those caused by natural disaster or government emergency, inventory inaccuracies or drug shipping and receiving, outdated drugs, appropriate handling of returned goods, and drug recalls;

(9) will have sufficient policies and procedures in place for the inspection of all incoming and outgoing drug shipments;

(10) will operate in compliance with all state and federal requirements applicable to wholesale drug distribution; and

(11) will meet the requirements for inspections found in this subdivision.

(i) An agent or employee of any licensed wholesale drug distributor need not seek licensure under this section. Paragraphs (i) to (p) apply to wholesaler personnel.

(j) The board is authorized to and ~~shall~~ must require fingerprint-based criminal background checks of facility managers or designated representatives, as required under United States Code, title 21, section 360eee-2. The criminal background checks ~~shall~~ must be conducted as provided in section 214.075. The board ~~shall~~ must use the criminal background check data received to evaluate the qualifications of persons for ownership of or employment by a licensed wholesaler and ~~shall~~ must not disseminate this data except as allowed by law.

(k) A licensed wholesaler ~~shall~~ must not be owned by, or employ, a person who has:

(1) been convicted of any felony for conduct relating to wholesale distribution, any felony violation of United States Code, title 21, section 331, subsection (i) or (k), or any felony violation of United States Code, title 18, section 1365, relating to product tampering; or

(2) engaged in a pattern of violating the requirements of United States Code, title 21, section 360eee-2, or the regulations promulgated thereunder, or state requirements for licensure, that presents a threat of serious adverse health consequences or death to humans.

(l) An applicant for the issuance or renewal of a wholesale distributor license ~~shall~~ must execute and file with the board a surety bond.

(m) Prior to issuing or renewing a wholesale distributor license, the board ~~shall~~ must require an applicant that is not a government owned and operated wholesale distributor to submit a surety bond of $100,000, except that if the annual gross receipts of the applicant for the previous tax year is $10,000,000 or less, a surety bond of $25,000 ~~shall~~ must be required.

(n) If a wholesale distributor can provide evidence satisfactory to the board that it possesses the required bond in another state, the requirement for a bond ~~shall~~ must be waived.

(o) The purpose of the surety bond required under this subdivision is to secure payment of any civil penalty imposed by the board pursuant to section 151.071, subdivision 1. The board may make a claim against the bond if the licensee fails to pay a civil penalty within 30 days after the order imposing the fine or costs become final.

(p) A single surety bond ~~shall~~ must satisfy the requirement for the submission of a bond for all licensed wholesale distributor facilities under common ownership.

(q) In addition to the license required under paragraph (b), each wholesaler required to pay the registration fee under section 151.066 must pay the fee by June 1 of each year, beginning June 1, 2024. In the event of a change of ownership of the wholesaler, the new owner must pay the registration fee specified under section 151.066, subdivision 3, that the original owner would have been assessed had the original owner retained ownership. The registration fee collected under this paragraph must be deposited in the opiate epidemic response fund established under section 256.043.

EFFECTIVE DATE. This section is effective July 1, 2023.

Sec. 7. Minnesota Statutes 2022, section 256.043, subdivision 1, is amended to read:

Subdivision 1. **Establishment.** (a) The opiate epidemic response fund is established in the state treasury. The commissioner of management and budget shall establish within the opiate epidemic response fund two accounts: (1) a registration and license fee account; and (2) a settlement account. Beginning in fiscal year 2021, for each fiscal year, the fund shall be administered according to this section.

(b) The commissioner of management and budget shall deposit into the registration and license fee account the registration fee assessed by the Board of Pharmacy under section 151.066 and the license fees identified in section 151.065, subdivision 7, ~~paragraphs~~ paragraph (b) ~~and (c)~~.

(c) The commissioner of management and budget shall deposit into the settlement account 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, 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, pursuant to section 16A.151, subdivision 2, paragraph (f).

EFFECTIVE DATE. This section is effective July 1, 2023.

Sec. 8. **REPEALER; OPIOID FEE SUNSET.**

Minnesota Statutes 2022, section 256.043, subdivision 4, is repealed, effective July 1, 2023.

256.043 OPIATE EPIDEMIC RESPONSE FUND.

Subd. 4. **Settlement; sunset.** (a) If the state receives a total sum of $250,000,000: (1) 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, 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; (2) 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 (3) 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. For purposes of this paragraph, any money received as a result of a settlement agreement specified in this paragraph and directly allocated or distributed and received by either the state or a municipality as defined in section 466.01, subdivision 1, shall be counted toward determining when the $250,000,000 is reached.

(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, 2031.