ARTICLE 8
BOARD OF PHARMACY

Section 1. Minnesota Statutes 2022, section 151.01, subdivision 23, is amended to read:

Subd. 23.
Practitioner. "Practitioner" means a licensed doctor of medicine, licensed doctor of osteopathic medicine duly licensed to practice medicine, licensed doctor of dentistry, licensed doctor of optometry, licensed podiatrist, licensed veterinarian, licensed advanced practice registered nurse, licensed certified midwife, or licensed physician assistant. For purposes of sections 151.15, subdivision 4; 151.211, subdivision 3; 151.252, subdivision 3, subdivision 2, paragraph (b); and 151.461, "practitioner" also means a dental therapist authorized to dispense and administer under chapter 150A. For purposes of sections 151.252, subdivision 3, and 151.461, "practitioner" also means a pharmacist authorized to prescribe self-administered hormonal contraceptives, nicotine replacement medications, or opiate antagonists under section 151.37, subdivision 14, 15, or 16.

EFFECTIVE DATE. This section is effective July 1, 2025.

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

Subd. 4a. Application and fee; relocation. A person who is registered with or licensed by the board must submit a new application to the board before relocating the physical location of the person's business. An application must be submitted for each affected license. The application must set forth the proposed change of location on a form established by the board. If the licensee or registrant remitted payment for the full amount during the state's fiscal year, the relocation application fee is the same as the application fee in subdivision 1, except that the fees in clauses (6) to (9) and (13) to (16) are reduced by $5,000 and the fee in clause (16) is reduced by $55,000. If the application is made within 60 days before the date of the original license or registration expiration, the applicant must pay the full application fee provided in subdivision 1. Upon approval of an application for a relocation, the board shall issue a new license or registration.

Sec. 2. Minnesota Statutes 2022, section 151.065, is amended by adding a subdivision to read:

Subd. 4b. Application and fee; change of ownership. A person who is registered with or licensed by the board must submit a new application to the board before changing the ownership of the licensee or registrant. An application must be submitted for each affected license. The application must set forth the proposed change of ownership on a form established by the board. If the licensee or registrant remitted payment for the full amount during the state's fiscal year, the application fee is the same as the application fee in subdivision 1, except that the fees in clauses (6) to (9) and (13) to (16) are reduced by $5,000 and the fee in clause (16) is reduced by $55,000. If the application is made within 60 days before the date of the original license or registration expiration, the applicant must pay the
full application fee provided in subdivision 1. Upon approval of an application for a change of ownership, the board shall issue a new license or registration.

Sec. 3. Minnesota Statutes 2022, section 151.065, is amended by adding a subdivision to read:

Subd. 8. Transfer of licenses. Licenses and registrations granted by the board are not transferable.

Sec. 4. Minnesota Statutes 2022, section 151.066, subdivision 1, is amended to read:

Subdivision 1. Definitions. (a) For purposes of this section, the following terms have the meanings given to them in this subdivision.

(b) "Manufacturer" means a manufacturer licensed under section 151.252 that is engaged in the manufacturing of an opiate, excluding those exclusively licensed to manufacture medical gas.

(c) "Opiate" means any opiate-containing controlled substance listed in section 152.02 subdivisions 3 to 5, that is distributed, delivered, sold, or dispensed into or within this state.

(d) "Third-party logistics provider" means a third-party logistics provider licensed under section 151.471.

(e) "Wholesaler" means a wholesale drug distributor licensed under section 151.47 that is engaged in the wholesale drug distribution of an opiate, excluding those exclusively licensed to distribute medical gas.

Sec. 5. Minnesota Statutes 2022, section 151.066, subdivision 2, is amended to read:

Subd. 2. Reporting requirements. (a) By March 1 of each year, beginning March 1, 2020, each manufacturer and each wholesaler must report to the board every sale, delivery, or other distribution within or into this state of any opiate that is made to any practitioner, pharmacy, hospital, veterinary hospital, or other person who is permitted by section 151.37 to possess controlled substances for administration or dispensing to patients that occurred during the previous calendar year. Reporting must be in the automation of reports and consolidated orders system format unless otherwise specified by the board. If no reportable distributions occurred for a given year, notification must be provided to the board in a manner and format specified by the board for deliveries and distributions that occurred required under this paragraph on a timely basis; the board may assess an administrative penalty of $500 per day. This penalty shall not be considered a form of disciplinary action.

(b) By March 1 of each year, beginning March 1, 2020, each owner of a pharmacy with at least one location within this state must report to the board any intracompany delivery or distribution into this state, of any opiate, to the extent that those deliveries and distributions are not reported to the board by a licensed wholesaler owned by, under contract to, or otherwise operating on behalf of the owner of the pharmacy. Reporting must be in the manner and format specified by the board for deliveries and distributions that occurred.
during the previous calendar year. The report must include the name of the manufacturer or wholesaler from which the owner of the pharmacy ultimately purchased the opiate, and the amount and date that the purchase occurred.

(c) By March 1 of each year, beginning March 1, 2025, each third-party logistics provider must report to the board any delivery or distribution into this state of any opiate, to the extent that those deliveries and distributions are not reported to the board by a licensed wholesaler or manufacturer. Reporting must be in the manner and format specified by the board for deliveries and distributions that occurred during the previous calendar year.

Sec. 6. 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 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 in a quantity of 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 substance use disorder treatment with medications for opioid use disorder.

(c) The annual registration fee for each manufacturer 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 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 notify all manufacturers required to report under subdivision 2 whether the manufacturer meets the requirement in paragraph (a) and whether the manufacturer is required to pay the annual registration fee in accordance with section 151.252, subdivision 1, paragraph (b).

(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.
(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.

(h) For the purposes of this subdivision, an opiate's units will be assigned to the manufacturer holding the New Drug Application (NDA) or Abbreviated New Drug Application (ANDA), as listed by the United States Food and Drug Administration.