Minnesota Board of Pharmacy Opiate Product Registration

This communication is being sent to all Minnesota licensed wholesalers and manufacturers as well as all previously registered reporters of opiate data. It encompasses a reminder to report, provides information regarding the section of §151.066 that was affected by the 2021 Special Session, provides an exemption request form for applicable licensees, as well as additional clarification regarding the reporting requirements.

The MN Board of Pharmacy reporting website opens for calendar year 2021 on January 12, 2022. Submissions received after March 1, 2022 will be considered late and subject to an administrative penalty of $500 per day. Please review the User Guide if you are needing to create a data submitter account. Of note, an error message will display on the reporting website if you try to access it prior to January 12, 2022.

NOTE: It is critical that the Board of Pharmacy maintain a record of the facility’s DEA number. Please take a moment to submit the facility’s DEA number to the Board on the forms page to ensure it is on file by December 31, 2021. If the facility does NOT have a DEA number, see the Exemption Request Form after reviewing the information to follow.

Minnesota Statute §151.066 went into effect on July 1, 2019 and establishes the Opiate Product Registration Fee along with reporting requirements for manufacturers and wholesalers.

- 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 (ARCOS format) unless otherwise specified by the board. If a manufacturer or wholesaler fails to provide information 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.

In the 2021 1st Special Session, 151.066 subd. 3 was amended as follows:

- 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.

In short, sales, deliveries, or distributions of opiates used for medication-assisted therapy for substance use disorder must still be reported to the Board of Pharmacy; however, these units are not taken into consideration when determining a manufacturer’s opiate product registration fee.
Additional important information:

- **If your facility does NOT have a DEA number and does not sell, deliver, or distribute any opiate within or into the State of Minnesota** 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, an [exemption from reporting request form](#) can be submitted to the Board of Pharmacy for review. If this scenario applies to your facility, filing an exemption with the Board prevents unnecessary, and oftentimes time-consuming inquiries for both parties, due to the absence of data.

- **If your facility has a DEA number but does not sell, deliver, or distribute any opiate within or into the State of Minnesota** 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, a **ZERO REPORT must be submitted for the previous calendar year in ARCOS format, by March 1st of each year, as applicable.** Additional information regarding submitting a zero report can be found in the [Data Submission Guide](#).

- **If your facility utilizes a Third-Party Logistics Provider (3PL):**
  - Minnesota Statute §151.066 requires manufacturers and wholesalers to report opiate distributions, not 3PLs. However, the Board recognizes that there may be virtual manufacturers or wholesalers, which have opiates distributed through a 3PL. Due to this or similar practices, it is acceptable for a 3PL to report opiate distributions to the Board – if directed to do so by the manufacturer or wholesaler.
  - If a 3PL is reporting opiate distributions to the Board, it is critical that the manufacturer or wholesaler, as well as the Board, be notified of the reporting. This is to prevent duplicative reporting to the Board by both the 3PL and manufacturer or wholesaler.
    - If this situation applies to your facility, review and submit the [3PL Reporting form](#) to the Board of Pharmacy via email to opiateproductregistrationfee@state.mn.us

- **If your facility is registered with the FDA as an outsourcing facility,** the facility must report opiate distributions to the Board as defined in Minnesota Statute §151.066.
  - To assist in validating the facility’s opiates, please supply to the Board an excel spreadsheet of opiates that the outsourcing facility produces. In the excel, include the following:
    - Unique identifier for product, unique identifier product name – including strength and dosage form, and package description
    - Ensure the active ingredient and active ingredient information is captured in the excel to the Board
    - This information can be sent via email to opiateproductregistrationfee@state.mn.us
  - **Note:** It is the outsourcing facility’s responsibility to ensure the Board is in receipt of the facility's current list of compounded opiates.

- **Which opiates must be reported?** "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. Please note, this includes codeine-containing preparations that are schedule III-controlled substances in MN as well as butorphanol and pentazocine.

Questions regarding this communication can be directed to Board staff at opiateproductregistrationfee@state.mn.us