MN HOUSE RESEARCH

Bill Summary

H.F. 4098

As introduced

Subject	Opiate Product Registration Fee Reporting
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Overview

Minnesota requires opiate manufacturers that sell, deliver, or distribute opiates in a quantity of 2,000,000 or more units a year to pay to the Board of Pharmacy an annual opiate product registration fee of $250,000, and requires manufacturers, wholesalers, and pharmacies to report opiate sales, deliveries, and distributions to the board. This bill modifies these reporting requirements, by requiring reporting by third-party logistics providers, requiring manufacturers and wholesalers to notify the board if no reportable opiate distributions are made, clarifying how opiate units are assigned to a manufacturer, and making other related changes.

Summary

Section	Description
1	**Definitions.** Amends § 151.066, subd. 1. Modifies the definition of "manufacturer" by removing the qualifier that the manufacturer be "engaged in the manufacturing of an opiate" and providing an exclusion for manufacturers that exclusively manufacture medical gas. Modifies the definition of "wholesaler" by removing the qualifier that the wholesaler be "engaged in the wholesale distribution of an opiate" and provides an exclusion for wholesalers that exclusively distribute medical gas. Also adds a definition of "third-party logistics provider."
2	**Reporting requirements.** Amends § 151.066, subd. 2. The amendment to paragraph (a) requires manufacturers and wholesalers with no reportable distributions of opiates during the previous calendar year to notify the Board of Pharmacy, in the manner specified by the board.

Section	Description

A new paragraph (c) requires third-party logistics providers to report to the board the delivery or distribution into the state of any opiate, to the extent the delivery or distribution is not reported by a licensed wholesaler or manufacturer.

3 **Determination of an opiate product registration fee.**

Amends § 151.066, subd. 3. The amendment to paragraph (a) requires the board to assess an opiate product registration fee on manufacturers whose opiate product is sold, delivered, or distributed in a specific quantity (without specifying the entity that does this; current law refers to the sale, delivery, or distribution by the manufacturer).

A new paragraph (h) specifies that an opiate's units will be assigned to the manufacturer holding the New Drug Application or Abbreviated New Drug Application, as listed by the U.S. Food and Drug Administration.