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S.F. No. 3727 - Opiate manufacturer reporting requirements amendments and opiate product registration fee determination process amendments (as amended by the A-1 Amendment)

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Section Summaries

Section 1 (amends Minn. Stat. § 151.066, subd. 1) This section excludes exclusive medical gas manufacturers from the definition of manufacturer, inserts a definition of “third-party logistics provider,” and excludes exclusive medical gas distributors from the definition of wholesaler for purposes of section 151.066.

Section 2 (amends Minn. Stat. § 151.066, subd. 2) Existing law requires manufacturers and wholesalers to annually report to the Board of Pharmacy every sale, delivery, or other distribution of an opiate into Minnesota to a practitioner, pharmacy, hospital, veterinary hospital, or certain other permitted persons. This section provides that, even if no reportable distributions occurred for a given year, notification by a manufacturer or wholesaler must still be provided to the board. This section further requires each third-party logistics provider to report any delivery or distribution into Minnesota of any opiate, for the prior year, to the extent the delivery or distribution was not reported by a manufacturer or wholesaler.

Section 3 (amends Minn. Stat. § 151.066, subd. 3) This section clarifies that, for the purposes of this subdivision (which relates to registration fees which must be paid to the Board of Pharmacy by manufacturers), an opiate’s units of sold product will be assigned to the manufacturer holding the New Drug Application or Abbreviated New Drug Application, as listed by the FDA.