STATE OF MAINE
DEPARTMENT OF PROFESSIONAL
AND FINANCIAL REGULATION
OFFICE OF PROFESSIONAL AND OCCUPATIONAL REGULATION
BOARD OF PHARMACY
35 STATE HOUSE STATION
AUGUSTA, MAINE
04333-0035

Janet T. Mills
Governor

Anne L. Head, Esq.
Commissioner

Geraldine L. Betts
Administrator

RE: New Law – Insulin Product Registration Fee

The purpose of this communication is to remind manufacturers of their obligations under M.R.S. Title 32, section 13800-D, concerning insulin product registration fees. This law took effect on October 18, 2021.

Pursuant to M.R.S. Title 32, section 13800-D(1), a manufacturer that produces insulin that is sold, delivered or distributed in Maine is required to pay an annual insulin product registration fee of $75,000 to the Board, unless the manufacturer qualifies for an exception pursuant to M.R.S. Title 32, section 13800-D(2), as discussed further below. A manufacturer that produces insulin is a person engaged in the manufacture of insulin. See 32 M.R.S. § 13702-A(18) (defining "manufacture"). The annual insulin product registration fee is due on December 31st of each year. This fee is in addition to the prescription drug manufacturer license renewal fee, which is currently $200.

A manufacturer whose aggregate total of insulin sold, delivered or distributed in Maine does not exceed 500,000 units in the year in which the annual insulin product registration fee is due is not required to pay the fee. A "unit of insulin" means the lowest identifiable quantity of insulin that is dispensed. To qualify for this exception, a manufacturer must demonstrate to the Board, by January 31st of the year following the year in which the fee is due, that the aggregate total of insulin produced by the manufacturer that was sold, delivered or distributed in Maine did not exceed 500,000 units. Prescription drug manufacturers may request an exception for the period ending December 31, 2022, as detailed below. The Board must receive the completed exception request by January 31, 2023.

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76 NORTHERN AVENUE, GARDINER, MAINE

Below are answers to potential questions concerning this process. This guidance is being provided to help manufacturers comply with the law. It is not legal advice, and nothing herein is binding on the Board. Manufacturers are encouraged to seek independent legal counsel as they deem necessary.

1. Must a manufacturer pay the $75,000 annual insulin product registration fee even if its insulin is sold, delivered or distributed in Maine by an intermediary that may not be present in Maine?

***Answer**:* Yes, if the amount of the manufacturer's insulin sold, delivered or distributed in Maine exceeds 500,000 units, the manufacturer must pay the $75,000 insulin product registration fee, regardless of whether an intermediary sells, delivers or distributes the insulin, where that intermediary may be located and whether the intermediary may be a so-called "third-party logistic provider." In addition, pursuant to Title 32, section 13758, all manufacturers whose products are distributed in Maine in any manner must be licensed by the Board.

2. When submitting an application online, how do I obtain the Company ID and Payment ID for purposes of payment?

***Answer**:* We do not provide the Company ID or Payment ID. These are your entity's internal accounting numbers that will need to be provided to the State's bank when submitting your ACH payment. It is critical that you be sure that the numbers entered in the online application are identical to the numbers that are submitted in your ACH transaction, which allows us to match your online application to your ACH payment.

3. If a manufacturer's aggregate total of insulin sold, delivered or distributed in Maine does not exceed 500,000 units, how does the manufacturer request an exception from paying the $75,000 annual insulin product registration fee?

***Answer**:* Any manufacturer seeking relief from this fee because it did not exceed the 500,000-unit threshold must submit to the Board sales, deliveries and distributions of insulin as described further below.

4. If insulin was not produced, sold, delivered or distributed to Maine in the reporting year, does the manufacturer need to report this to the Board?

***Answer**:* Yes, by attestation that insulin was not produced.

5. Will a submission acknowledgment report be provided?

***Answer**:* Yes. Your annual report or an annual exception request must be completed using our online filing portal, which will provide you with a transaction receipt upon completion.

6. What form of report is acceptable and what data must be reported by a manufacturer that requests an exception from paying the $75,000 annual insulin product registration fee?

***Answer**:* Any manufacturer seeking an exception must submit detailed and clear information to substantiate the request. The submission must include the following data and follow this naming convention:

- Name of licensed entity and assigned Maine license number.
- Only .docx, .bmp, .png, .jpg, .pdf extensions will be accepted.
- Report shall include all sales, delivery or distributions in Maine of insulin in the format suggested as follows:

  The report shall be in a table .docx file extension
  − Reporting Period (January 1, 2021, through December 31, 2021)
  − NDC − Drug Product Family
  − Drug Product Description
  − Units
  − 2021 Total units of insulin for each product description
  − 2021 Aggregate total units of insulin