Opioid Use Disorder Prevention and Treatment Fund

Public Law 2020 Chapter 536 (LD 793) Effective June 16, 2020

Report on Manufacturer of Opioids Fee Assessments and Product Registration Fees Collected

Report Period Covered: January 1, 2023 through December 31, 2023

The Board of Pharmacy is required pursuant to Public Law 2020 Chapter 536 to collect a $55,000.00 fee from each opioid medication manufacturer, less $325.00 which may be retained by the Board of Pharmacy and $250,000.00 product registration fee assessment from manufacturers that sell, deliver, or distribute 2,000,000 or more units of an opioid medication within Maine. This fee does not apply to a manufacturer of an opioid medication if all of that manufacturer's opioid medications are approved by the United States Food andDrug Administration for use only in veterinary medicine.

History: At the initial stage of enactment of the law notices were sent to all licensed Manufacturers and posted to the Board of Pharmacy webpage

- Initial notice to Licensed Manufacturers Opening Date for Online Registration: October 6, 2020
  https://www.maine.gov/pfr/professionallicensing/sites/maine.gov.pfr.professionallicensing/files/inline-files/notice_manufacturers_of_opioid_medication_and_opioid_product_registration_0.pdf

*This report is for **the period of January 1, 2023 through December 31, 2023.** The following represents initial and renewal licenses for Manufacturer of Opioids (MFO).*

- 4 Original/Initial Manufacturer of Opioid application filings
- 29 Renewal Manufacturer of Opioid application filings

*Fees collected during the period of **January 1, 2023 through December 31, 2023***

➢ 4 Manufacturer of Opioids (MFO) *original/initial* licenses at the Fee Assessment of $55,000 each	**$ 220,000**
➢ 29 Manufacturer of Opioids (MFO) *renewal* licenses at the Fee Assessment rate of $55,000 each	**$1,595,000**
➢ 3 Manufacturer of Opioids (MFO) Product registration fee at $250,000 each	**$ 750,000**
➢ Less @ $325 for 33 Original/Initial and Renewal licenses retained by the Board of Pharmacy for administration and collection pursuant to Title 5 § 20010, Section 1(B)	**($ 10,725)**
➢ Total amount transferred to the Opioid Treatment Fund	**$2,554,275**

License Renewal: All pharmacy licenses, including Manufacturer of Opioids (MFO) licenses expire December 31st annually. The window for license renewal opens November 1 annually. Throughout the year new manufacturers (initial licensure) apply for licensure and are subject to the $55,000 fee assessment upon initial application for licensure. At the time of renewal a Manufacturer of Opioids (MFO) having manufactured 2 million or more opioids is subject to the $250,000 product registration fee.

To reiterate, the DPFR, Board of Pharmacy only acts as a collection agency for purposes of collecting the fee assessments for the fund. It has no authority or role with the Opioid Use Disorder Prevention and Treatment Fund under the Department of Health and Human Services (DHHS).