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

Janet T. Mills
Governor

Anne L. Head, Esq.
Commissioner

Geraldine L. Betts
Administrator

To: Licensed Manufacturers

From: Maine Board of Pharmacy

Date: October 6, 2020

RE: **URGENT AND IMPORTANT MESSAGE**
Manufacturer of Opioid Medication and Opioid Product Registration
Public Law 2020 Chapter 536 (LD 793) Eff. June 16, 2020
http://www.mainelegislature.org/legis/bills/getPDF.asp?paper=SP0237&item=5&snum=129

Public Law 2020 Chapter 536 establishes a Prevention and Treatment Fund to be funded by fees collected annually by the Board of Pharmacy from manufacturers that manufacture opioid medication and opioid medication product registration. Unfortunately, the unexpected COVID-19 pandemic has slowed progress on implementing this new law; however, the Board has actively been working on computer modifications to begin collecting the required fees associated with opioid manufacturing and opioid product registration.

OPENING DATE FOR ONLINE REGISTRATION FOR A MANUFACTURER OF OPIOID (MFO) IS: OCTOBER 7, 2020

https://licensing.web.maine.gov/cgi-bin/online/licensing/begin.pl?board_number=4380

Applications are available online only at the link listed directly above. Paper applications will not be available. You may only apply and make payments online.

1. A manufacturer licensed in Maine (MF) that manufactures opioid medication must complete the Opioid Prescription Drug Manufacturer (MFO) application online. You will need your MF license number (or if you have a pending application you may use the pending license number) and access code for this process. The total fee is $55,000. Payments must be made through ACH only. Please have your Company ID and Payment ID information available before applying online. The State of Maine bank routing and account number will be provided during the transaction process. **For a manufacturer that holds a current Maine manufacturer (MF) license and manufactures opioids, the entity must apply for an MFO by October 31, 2020**.

If the manufacturer does not hold an active Maine manufacturer's license, the entity must apply for a Manufacturer (MF) license before submitting an MFO application. At this time, you must download a paper Manufacturer (MF) application from the board's website for an initial application. The online application for MF is currently under construction but not yet available. Once we have received your application for the MF license, a pending license number will be assigned and be available for you to obtain using this link https://www.pfr.maine.gov/almsonline/almsquery/SearchCompany.aspx You may then apply online for the MFO registration.

2. A Manufacturer of opioid medication (MFO) will be assessed for a total fee of $55,000. IF the entity only manufactures an opioid medication(s) that is approved by the United States Food and Drug Administration for use only in veterinary medicine, the $55,000 assessment does not apply, but the MFO registration is still required.

3. A Manufacturer of opioid medication (MFO) that sells, delivers, or distributes an opioid medication within Maine shall pay an annual product registration fee of $250,000 to the board at the time of renewal (December 31 annually). **Exception:** A manufacturer that does not sell, deliver or distribute 2,000,000 or more units of an opioid medication within Maine in the year in which a registration fee is due the manufacturer is exempt from the product registration fee. To qualify for the exception, the manufacturer must demonstrate proof to the board, by January 31st of the following year in which the registration fee is due. Example: Registration due December 31, 2020, request for an exception must be submitted by January 31, 2021, and so on.)

"UNIT" OF AN OPIOID MEDICATION

"Unit" of an opioid medication means the lowest identifiable quantity of the opioid medication that is dispensed.

CALCULATION OF UNITS OF AN OPIOID MEDICATION PRODUCT SOLD, DELIVERED OR DISTRIBUTED WITHIN MAINE

When calculating the number of units of an opioid medication product sold, delivered, or distributed by a manufacturer, the following is a list of opioid medications identified by the board as medication-assisted treatment (MAT) for substance use disorders that may be excluded for calculating purposes.

(APPLICABLE TO ALL CURRENT OR FUTURE GENERIC EQUIVALENTS)

FDA-approved buprenorphine products approved for the treatment of opioid dependence include:

- Bunavail (buprenorphine and naloxone) buccal film
- Cassipa (buprenorphine and naloxone) sublingual film
- Probuphine (buprenorphine) implant for subdermal administration
- Sublocade (buprenorphine extended-release) injection for subcutaneous use
- Suboxone (buprenorphine and naloxone) sublingual film for sublingual or buccal use, or sublingual tablet
- Subutex (buprenorphine) sublingual tablet
- Zubsolv (buprenorphine and naloxone) sublingual tablets

FDA-approved methadone products approved for the treatment of opioid dependence include:

- Dolophine (methadone hydrochloride) tablets
- Methadose (methadone hydrochloride) oral concentrate
- Levo-alpha-acetylmethadol (LAAM or Orlaam)

FDA-approved naltrexone products approved for the treatment of opioid dependence include:

- Vivitrol (naltrexone for extended-release injectable suspension intramuscular)

Thank you. If you have questions, please contact:

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Jessica Gowell at 207-624-8651 Jessica.Gowell@maine.gov.

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