Janet T. Mills
Governor

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To: Licensed Manufacturers

From: Maine Board of Pharmacy

Date: May 12, 2021

RE: Registration Fee and Report 2020 Opiate Distributions for Exception Requests

This communication is being sent by the Maine Board of Pharmacy (Board) to all Maine-licensed manufacturers and pending manufacturer applicants, with an email address on file with the Board. The purpose of this communication is to remind manufacturers of their obligations under M.R.S. Title 32, sections 13724 and 13800-C, concerning opioid medication. This document supplements the prior related guidance provided by the Board on October 6, 2020.

Pursuant to M.R.S. Title 32, section 13724(2), a manufacturer of an opioid medication is required to pay an annual fee to the Board of $55,000, unless all of the manufacturer's opioid medications are approved by the United States Food and Drug Administration for use only in veterinary medicine. A manufacturer of an opioid medication is a person engaged in the manufacture of a controlled substance containing an opioid. *See* 32 M.R.S. § 13702-A(19), (20-A); *see also* 32 M.R.S. § 13702-A(18) (defining "manufacture"). Any manufacturer that has not yet paid the required fee is requested to pay it by May 26, 2021.

In addition, pursuant to M.R.S. Title 32, section 13800-C(1)-(2), a manufacturer that sells, delivers or distributes 2,000,000 or more units of an opioid medication in Maine is required to pay an annual product registration fee to the Board of $250,000. In calculating the units of an opioid medication, the law directs that a unit is the lowest identifiable quantity of the opioid medication that is dispensed. *See 32* M.R.S. § 13800-C. Units of an opioid medication prescribed for the purpose of medication-assisted treatment of substance use disorder may be excluded from this calculation. 32 M.R.S. § 13800-C(3). The 2020 fee was due on December 31, 2020. Any manufacturer seeking relief from this fee because it did not sell, deliver, or distribute 2,000,000 or more units of an opioid medication in Maine must submit to the Board distributions of DEA Schedules II-IV, Opiates only. The 2020 report was due on January 31, 2021. The Board decided to accept reports through May 26, 2021.

A manufacturer that has already complied with the above requirements need not take any further action at this time.

Below are answers to frequently asked 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. **Who is subject to the $55,000 fee assessment?**
   Any manufacturer of opioid medications that are distributed in Maine in any manner. A manufacturer is not subject to this fee if all of the manufacturer's opioid medications are approved by the United States Food and Drug Administration for use only in veterinary medicine. If your entity has not done this yet, please visit this website link to apply.

2. **If a manufacturer does not manufacture an opioid medication, does it apply only for a prescription drug manufacturer license and pay only the license fee of $200.00?**
   Yes, a manufacturer that does not manufacture an opioid medication should apply for a prescription drug manufacturer license in this circumstance if it is otherwise required to be licensed under the law.

3. **What is the statutory definition for "unit of an opioid medication?"**
   Pursuant to Title 32, section 13800-C, a unit of an opioid medication means the lowest identifiable quantity of the opioid medication that is dispensed. For purposes of reporting a unit, an example may include the individual dosage form of the particular drug product that is prescribed to the patient. One unit equals one tablet, capsule, patch, syringe, milliliter, or mg.

4. **Is a manufacturer of an opioid medication required to pay the $55,000 fee assessment even if less than 2,000,000 units of its opioid medications are sold, delivered or distributed in Maine?**
   Yes, the $55,000 licensing fee is assessed against a manufacturer of an opioid medication. This fee need not be paid if all of the manufacturer's opioid medications are approved by the United States Food and Drug Administration for use only in veterinary medicine. Separately, if 2,000,000 or more units of the manufacturer's opioid medications are sold, delivered or distributed in Maine, subject to certain exceptions, the manufacturer must also pay a product registration fee of $250,000.

5. **Is a manufacturer of an opioid medication that is not located in Maine subject to the $55,000 fee assessment?**
   Pursuant to M.R.S. Title 32, section 13758, any manufacturer, regardless of where it is located, whose products are distributed in Maine in any manner must be licensed by the Board. Any such manufacturer that is a manufacturer of an opioid medication is required to pay an annual fee to the Board of $55,000, unless all of the manufacturer's opioid medications are approved by the United States Food and Drug Administration for use only in veterinary medicine.

6. **Can an extension be requested to comply with the requirement to register and pay the $55,000 fee assessment?**
   The requirement to register and pay the $55,000 fee assessment took effect on June 16, 2020. On October 6, 2020, the Board provided guidance concerning the law, announced registration would be available the next day and requested that manufacturers comply by October 31, 2020. Due to COVID-19 pandemic-related delays in implementing the law, the Board has decided to accept registrations and fees through May 26, 2021. There will be no further extensions.

7. **For purposes of determining whether an opioid manufacturer must pay the $250,000 registration fee, what will count as a unit of an opioid medication?**
   Pursuant to M.R.S. Title 32, section 13800-C, a unit is the lowest identifiable quantity of the opioid medication that is dispensed. Units of an opioid medication prescribed for the purpose of medication-assisted treatment of substance use disorder may be excluded from this calculation. *See* 32 M.R.S. § 13800-C(3).

8. **Is there a list of opioid medication prescribed for the purpose of medication-assisted treatment of substance use disorder that may be excluded from the calculation of whether 2,000,000 or more units of a manufacturer's opioid medication are sold, delivered or distributed within Maine?**
   The Board's October 6, 2020 guidance includes a MAT list.

9. **Must a manufacturer pay the $250,000 product registration fee even if its opioid medication is distributed in Maine by an intermediary that may not be present in Maine?**
   Yes, if the amount of the manufacturer's opioid medications distributed in Maine equals or exceeds 2,000,000 units, the manufacturer must pay the $250,000 product registration fee, regardless of whether an intermediary distributes the opioid medication, 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.

10. **When submitting an application online, how do I obtain the Company ID and Payment ID for purposes of payment?**
    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. Here is an example of the ACH payment information online:

11. **If a manufacturer stops manufacturing any qualifying opioid medication prior to paying the $55,000 fee assessment, must it still report to the Board the number of units of its opioid medication sold, delivered or distributed within Maine?**
    Absent an extension by the Board, on January 31st of each year a manufacturer must submit to the Board distributions of DEA Schedules II-IV, Opiates only, for the prior year.

    For 2020 reporting, due to COVID-19 pandemic-related delays in implementing the law, Board Staff will be contacting manufacturers concerning their reporting obligations. If Board Staff does not hear from a registered opioid manufacturer by May 26, 2021, we will contact the manufacturer to obtain an affirmation that the entity did not produce 2,000,000 or more units of opioid medications. Also, to ensure that all licensed manufacturers are in compliance with the law on opioid manufacturing registration and opioid product registration, each licensed manufacturer will be contacted to ensure compliance where necessary. This will occur in early June 2021.

12. **If the total number of a manufacturer's opioid medication units distributed in Maine is less than 2,000,000, how does the manufacturer request an exception from paying the $250,000 product registration fee?**
    Any manufacturer seeking relief from this fee because it did not reach the 2,000,000 unit threshold must submit to the Board distributions of DEA Schedules II-IV, Opiates only. The 2020 report was due on January 31, 2021. The Board decided to accept reports through May 26, 2021. There will be no further extensions.

13. Does an opioid manufacturer that has obtained an exception from paying the $250,000 product registration fee have to seek an exception each year?

Yes, any manufacturer seeking relief from this fee must submit its distributions of DEA Schedules II-IV, Opiates only, annually and no later than January 31st of the year following the year in which the registration fee is due, absent an extension by the Board. For example, reports of distributions for calendar year 2021 will be due by January 31, 2022.

14. What form of report is acceptable and what data must be reported by an opioid manufacturer that requests an exception from paying the $250,000 product registration fee?

Any opioid manufacturer seeking relief from this fee must submit detailed and clear information to substantiate the request for exception. The report must include the following data and follow this naming convention:

- Name of licensed entity and assigned Maine license number.
- DEA number of reporting entity.
- Reporting shall be in a similar format to the DEA's Automation of Reports and Consolidated Orders System (ARCOS) format and must contain only DEA Schedules II-IV, Opiates only, distribution data. An ARCOS report is acceptable.
- Only .DOCX or.XLSX file extensions will be accepted.
- Report shall include all sales, delivery, or distributions of an opioid medication in the format suggested as follows: *The report shall be in a table .docx file extension or an excel spreadsheet .xlsx file extension:*
  - Reporting Period (January 1 through December 31, 2020)
  - NDC
  - Drug Product Family
  - Drug Product Description
  - Drug Schedule Description
  - Units
  - 2020 Total units for each product description
  - 2020 Total units

Example of an accepted report -

NDC	Product Description	01/2020	02/2020	03/2020	04/2020	05/2020	06/2020	07/2020	08/2020	09/2020	10/2020	11/2020	12/2020	2020 TOTAL	Multiplier (Package Size)	Adjusted Units 2020
00054-0243-24	Codeine Sulf Tab USP NDA 15mg 2x5x10				1 EA		1 EA				5 EA		4 EA	11 EA	100	1,100
00054-0244-25	Codeine Sulf Tab USP NDA 30mg 100s	30 EA	37 EA	13 EA		16 EA	20 EA	19 EA	13 EA	11 EA	22 EA	10 EA	19 EA	210 EA	100	21,000
00641-6019-10	DURAMORPH 10MG/10ML AMPUL X 10	11 PCK	14 PCK	16 PCK	7 PCK	7 PCK	13 PCK	15 PCK	5 PCK	15 PCK	9 PCK	7 PCK	12 PCK	131 EA	10	1,310
00641-6020-10	DURAMORPH 5MG/10ML AMPUL X 10	1 PCK	4 PCK	1 PCK	1 PCK	2 PCK	2 PCK		6 PCK	9 PCK	3 PCK	5 PCK	6 PCK	40 EA	10	400
00641-6029-25	FENTANYL 1000MCG/20 ML VIAL X 25		3 PCK	12 PCK										15 EA	25	375
00641-6027-25	FENTANYL 100MCG/2ML VIAL X 25	465 PCK	284 PCK	1,301 PCK	124 PCK	25 PCK	54 PCK	108 PCK	139 PCK	60 PCK	87 PCK	52 PCK	53 PCK	2,752 EA	25	68,800
00641-2341-41	HYDROMORPHONE 40MG/20ML VIAL X 1										2 PCK	1 PCK	2 PCK	5 EA	1	5
00054-0264-25	Hydromorphone HCl Tab USP 4mg 100s	7 EA		10 EA	4 EA	4 EA	6 EA	6 EA	6 EA	6 EA	8 EA	8 EA	8 EA	73 EA	100	7,300
00641-6151-25	HYDROMORPHONE USP 2mg/mL, 1mL/2mL Vial	18 PCK	26 PCK	20 PCK	36 PCK	10 PCK	9 PCK	4 PCK	47 PCK	7 PCK	31 PCK	52 PCK	26 PCK	286 EA	25	7,150
00641-6039-01	INFUMORPH 200 200MG/20ML AMPUL X 1												2 PCK	2 EA	1	2
00641-6040-01	INFUMORPH 500 500MG/20ML AMPUL X 1			2 PCK	5 PCK	12 PCK	4 PCK							23 EA	1	23
00641-6052-25	MEPERIDINE 25MG/ML VIAL X 25	1 PCK	3 PCK	1 PCK		1 PCK	3 PCK	1 PCK	5 PCK	1 PCK		2 PCK	3 PCK	21 EA	25	525
00641-6053-25	MEPERIDINE 50MG/ML VIAL X 25			1 PCK			3 PCK	1 PCK	2 PCK	2 PCK	2 PCK	5 PCK	2 PCK	18 EA	25	450
00054-3545-63	Meperidine HCl OS USP 50mg/5mL 500mL	2 EA	2 EA	3 EA	2 EA			1 EA			2 EA	2 EA	1 EA	15 EA	1	15
00641-6127-25	MORPHINE 10MG/ML 1ML/2ML VIAL	80 PCK	53 PCK	78 PCK	51 PCK	73 PCK	40 PCK	63 PCK	33 PCK	41 PCK	31 PCK	25 PCK	81 PCK	649 EA	25	16,225
00641-6125-25	MORPHINE 4MG/ML 1ML/2ML VIAL	34 PCK	46 PCK	23 PCK	19 PCK	17 PCK	21 PCK	18 PCK	18 PCK	16 PCK	15 PCK	19 PCK	20 PCK	266 EA	25	6,650
00054-0517-50	Morphine Sulf OS 100mg/5mL Col 120mL	2 EA	5 EA	5 EA	2 EA	1 EA		1 EA		1 EA	1 EA	2 EA		20 EA	1	20
00054-0238-49	Morphine Sulf OS NDA 20mg/5mL 100mL	7 EA	8 EA	5 EA	7 EA	1 EA	1 EA	6 EA	6 EA	14 EA	9 EA	9 EA	19 EA	92 EA	1	92
00054-0404-50	Morphine Sulfate Osol 100mg/5mL 120mL		1 EA						2 EA		1 EA			4 EA	1	4
00054-0404-44	Morphine Sulfate Osol 100mg/5mL 30 mL	7 EA	11 EA	46 EA	19 EA	11 EA	19 EA	5 EA	13 EA	6 EA	8 EA	6 EA	2 EA	153 EA	1	153
00054-0236-24	Morphine Sulfate Tab NDA 30mg 2x5x10										3 EA	2 EA	1 EA	6 EA	100	600
00054-0390-41	Oxycodone HCl OS USP 5mg/5mL 15mL	3 EA			2 EA	2 EA		3 EA		4 EA	9 EA		10 EA	33 EA	1	33
00054-0390-63	Oxycodone HCl OS USP 5mg/5mL 500mL	12 EA	1 EA	6 EA	9 EA	9 EA	11 EA	2 EA	5 EA	5 EA	22 EA	10 EA	10 EA	102 EA	1	102
00054-0284-25	Oxymorphone HCl Tab USP 10mg 100s	7 EA	6 EA	4 EA	14 EA	3 EA	3 EA	10 EA	5 EA	6 EA	12 EA	6 EA	4 EA	80 EA	100	8,000
00054-0283-25	Oxymorphone HCl Tab USP 5mg 100s	13 EA	13 EA	19 EA	7 EA	2 EA	2 EA	2 EA		14 EA		3 EA	2 EA	77 EA	100	7,700
														TOTAL UNITS		651,540

15. **If no opioid medication units of a manufacturer were sold, delivered or distributed in Maine, does the opioid manufacturer need to report this to the Board?**
    Yes. A zero report is required to confirm that no opioid medication units of the manufacturer were sold, delivered or distributed in Maine. When submitting a zero report, the report header should identify the reporting entity and a single transaction record with a code '7' (per DEA ARCOS coding) which indicates there were no transactions to report during the previous calendar year.

16. **Will a submission acknowledgment report be provided?**
    Yes. Your annual report or an annual exemption request must be completed using our online filing portal which will provide you with a transaction receipt upon completion.