14-118 C.M.R. Chapter 11, Rules Governing the Controlled Substances Prescription Monitoring Program and Prescription of Opioid Medications

Disclaimer
This document is intended to summarize and provide answers to frequently asked questions (FAQs) pertaining to 14-118 C.M.R. Chapter 11, Rules Governing the Controlled Substances Prescription Monitoring Program and Prescription of Opioid Medications. The information contained in this document should not be relied upon as setting forth all the requirements. As is always the case, pharmacies and dispensers are responsible for complying with the actual text of the rule and statute which can be found on the Maine Prescription Monitoring Program’s website at http://www.maine.gov/dhhs/samhs/osa/data/pmp/index.htm. This document was created in collaboration between the Maine Board of Pharmacy (MBOP) and Department of Health and Human Services (DHHS) to assist dispensers in understanding and complying with the specific requirements and expectations and dispensing opioid medications. Should dispensers have additional questions or concerns they should contact DHHS at:

Substance Abuse and Mental Health Services (“SAMHS”)
Phone: (207) 287-2595 - Email: SAMHS.PMP@maine.gov - Fax: 207-287-4334
Johanna Buzzell, Prescription Monitoring Program Coordinator

Your role in the proper dispensing of opioid medication is critical to the health of patients and the prevention of drug abuse, diversion and unintended deaths. As dispensers, compliance with the regulation, combined, with its objectives and compliance from prescribers will assure patient safety while maintaining the dignity of the patient and ensuring access and continuation of care to those patients in medical need of controlled substances.

Key Definitions
Dispenser. "Dispenser" means a pharmacist who is licensed or registered under Title 32 PMP. “PMP” means Prescription Monitoring Program
MME. “MME” means Morphine Milligram Equivalents
DHHS. “DHHS” means the Maine Department of Health and Human Services

Frequently Asked Questions
1. Q: As a dispenser, do I need to register for the Maine PMP?
   Ans: Yes, all dispensers are required to register as a data requestor with the Maine PMP. Here is the web link for PMP Information for Dispensers, http://www.maine.gov/dhhs/samhs/osa/data/pmp/dispenser.htm

2. Q: As a dispenser, when do I need to check PMP?
   Ans: On or after January 1, 2017, a dispenser shall check prescription monitoring information prior to dispensing a benzodiazepine or an opioid medication to a person under any of the following circumstances:
   A. The person is not a resident of this state;
   B. The prescription is from a prescriber with an address outside of this State;

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C. The person is paying cash when the person has prescription insurance on file; or
D. According to the pharmacy prescription record, the person has not had a
   prescription for a benzodiazepine or an opioid medication in the previous 12-month
   period.

A dispenser shall withhold a prescription until the dispenser is able to contact the prescriber
of that prescription if the dispenser has reason to believe that the prescription is fraudulent
or duplicative.

3. Q: As a dispenser, are there penalties and sanctions for not complying with the PMP laws
   and rules?
   Ans: Yes. A dispenser who knowingly fails to submit prescription monitoring information or
   who fails to check the prescription monitoring information system in accordance with laws
   and rules commits a civil violation for which a fine of $250 per incident, not to exceed
   $5,000 per calendar year, may be adjudged. Additionally, a dispenser who knowingly fails to
   submit prescription monitoring information to PMP as required by this rule or by statutes is
   subject to discipline by the Maine Board of Pharmacy.

4. Q: As a dispenser, what do I do when the prescriber writes for a second opioid prescription
   to replace the previous opioid prescription?
   Ans: Regarding Exemption code H circumstances, when an individual is prescribed a 2nd
   opioid after proving unable to tolerate a first opioid; the individual is not required to return
   the initial prescription drug dispensed to a pharmacy for collection prior to dispensation of
   the 2nd prescription. In these instances and when aware, dispensers must provide patients
   with guidance on proper disposal of the first opioid prescription.

5. Q: As a dispenser, how do I handle early refills of a prescription? Examples include 7 or 30
   days acute and chronic prescriptions.
   Ans: Dispensers can provide an early refill of a prescription before the refill date if, in the
   judgment of the dispenser, the early refill does not represent a pattern of early refill requests
   by the individual.

6. Q: What information can be added to a prescription by a dispenser?
   Ans: Dispensers are allowed to contact prescribers by telephone to verify and document
   information about prescriptions. A dispenser may add any information outside of the DEA
   requirements. You must adhere to DEA limitations on modifications. Examples of a
   modification include: adding acute or chronic, ICD-10 codes, or Exemption codes as a
   requirement to the regulation on the prescription.

7. Q: As a dispenser, how do I handle opioid prescriptions that are written by out-of-state
   prescribers that do not comply with department [DHHS] rules?
   Ans: The dispenser may fill the prescription if the dispenser records an oral confirmation
   with the out-of-state prescriber on validity of the prescription and documents any missing
information, such as; diagnosis code, Exemption code, and acute or chronic pain notation. The dispenser must make a reasonable effort to determine that the oral confirmation came from the prescriber or prescriber's agent, and records information, such as; the date and time of a telephone call to the prescriber and the telephone number.

8. **Q:** Is there a delay for the requirement of pharmacies and dispensers to provide the transmission of data to PMP for Exemption codes and ICD-10 codes?
   **Ans:** Yes. The Department of Health and Human Services has delayed the implementation date until July 1, 2018, thereafter, DHHS may grant a waiver to a dispenser, for good cause.

9. **Q:** As a dispenser, what do I do if I receive a prescription from a veterinarian without an Exemption or ICD-10 code?
   **Ans:** Exemption and ICD-10 codes are not required on veterinary prescriptions. This should not preclude you from filling the prescription.

10. **Q:** Do prescribers have exemptions to limits on opioid medication prescribing?
    **Ans:** Yes, by rule prescribers are exempted from the limits on opioid medication prescribing when specific criteria thresholds are present. The exemptions are the responsibility of the prescriber and not the dispenser.

11. **Q:** How do I contact Maine PMP or DHHS?
    **Ans:** Substance Abuse and Mental Health Services (“SAMHS”), Phone: (207) 287-2595 - Email: SAMHS.PMP@maine.gov - Fax: 207-287-4334, Johanna Buzzell, Prescription Monitoring Program Coordinator

12. **Q:** What State of Maine department is authorized to enforce the regulation?
    **Ans:** Maine Department of Health and Human Services

13. **Q:** As a dispenser, what is considered an opioid medication?
    **Ans:** DHHS SAMHS Chapter 11 Rules Governing the Controlled Substances Prescription Monitoring Program and Prescription of Opioid Medications defines Opioid medication as “A controlled substance containing an opioid and included in 21 United States Code, Section 812 or 21 Code of Federal Regulations, Part 1308.” (14-118, Chapter 11, Sec. 3, 22) Please see the following link for additional information.

14. **Q:** Can a controlled substance such as Tramadol have refills under this regulation?
    **Ans:** Tramadol is not considered an opioid medication and as such, refills are permitted as with other controlled substances in Schedules 3 through 5.

15. **Q:** Methadone and Buprenorphine conversions to MME differ pending upon the conversion table that is used. As a dispenser, which resource table should I be using?
Ans: CDC Opioid Prescribing Guideline from the U.S. Department of Health and Human Services Centers for Disease Control and Prevention. However, Appriss, the vendor for PMPAware is working to harmonize the two tables together (Appriss and CDC). The CDC App can be downloaded on your smartphone or tablet and is available through the Apple store or Google Play. https://www.cdc.gov/drugoverdose/pdf/app_opioid_prescribing_guideline-a.pdf.

16. Q: If an opioid is written for something other than pain, does it need to have acute or chronic on it? Examples include: Morphine written for an indication of shortness of breath, Tylenol #3 or Robitussin with Codeine being prescribed for cough, or Buprenorphine for treatment of addiction.

Ans: Yes, the prescription would need to include acute or chronic with the goal of understanding the duration of treatment, unless an exemption code is listed then the designation of acute or chronic is not required, or as otherwise required by DHHS rules. For more information please see the Opioid Prescription Requirements document here: http://www.maine.gov/dhhs/samhs/documents/Opioid-Prescription-Requirements-UserGuide.pdf.

17. Q: Can prescribers receive a waiver from having to electronically prescribe opioid medications?

Ans: Yes, beginning in April 2017, prescribers can request a waiver from DHHS. A pharmacist is NOT required to verify that a practitioner has a waiver from the requirement to electronically prescribe or properly falls under one of the other exceptions from the requirement to electronically prescribe. It is the responsibility of the practitioner to ensure their compliance with the electronic prescribing mandate. Pharmacists may continue to dispense medications from otherwise valid written, oral or fax prescriptions that are consistent with current laws and regulations.

The Department will be conducting periodic audits and if a prescriber is identified as repeatedly submitting written prescriptions to a pharmacy, that provider may be at risk for professional discipline.

For information on Electronic Prescribing Clarifications go to: http://www.maine.gov/dhhs/samhs/osa/data/pmp/index.htm

18. Q: On and after July 1, 2017 as a dispenser what do I do if the opioid prescription is not under 100 MME?

Ans: Prescribers have an Exemption code for this situation which allows for another 6 months to taper the patient's prescription. An opioid prescription written for greater than 100 MME should not preclude you from dispensing the medication as long as the prescription includes the appropriate Exemption code or the dispenser contacts the prescriber or prescriber's agent and documents the missing information.
19. **Q:** As a dispenser, do I have immunity from liability within this regulation?

**Ans:** No, except for the following conditions:

A. A dispenser or prescriber is immune from liability for disclosure of information if the disclosure was made pursuant to and in accordance with these rules.

B. A pharmacist who dispenses opioid medication in good faith is immune from any civil liability that might otherwise result from dispensing medication in excess of the limit established in this regulation, if the prescription was dispensed in accordance with a prescription issued by a practitioner.

C. In a proceeding regarding immunity from liability, there is a rebuttable presumption of good faith.

**Statutory Reference.** 32 MRS §13786-C. Dispensing of prescription of opioid medication; immunity. A pharmacist who dispenses opioid medication in good faith is immune from any civil liability that might otherwise result from dispensing medication in excess of the limit established in section 2210, subsection 1, paragraphs A and B; section 2600-C, subsection 1, paragraphs A and B; section 3300-F, subsection 1, paragraphs A and B; section 3657, subsection 1, paragraphs A and B; or section 18308, subsection 1, paragraphs A and B, if the medication was dispensed in accordance with a prescription issued by a practitioner. In a proceeding regarding immunity from liability, there is a rebuttable presumption of good faith.

20. **Q:** How can I obtain a copy of Opioid Dispensing Clarifications?

**Ans:** Visit [http://www.maine.gov/dhhs/samhs/osa/data/pmp/indes.htm](http://www.maine.gov/dhhs/samhs/osa/data/pmp/indes.htm)