Questions & Answers on Chapter 488, An Act to Prevent Opiate Abuse by Strengthening the Controlled Substances Prescription Monitoring Program

1. **Given the effective date of the 100 mg MME (morphine milligram equivalent) limit on July 29, 2016, what are the options for patients who are currently receiving a daily dose of opioid medication which exceeds the daily limit?**

   In addition to the various statutory exceptions for cancer pain, palliative care, end-of-life and hospice care, a patient who had an active prescription for such medication in excess of 100 morphine milligram equivalents per day as of July 29, 2016, may be prescribed up to 300 milligrams until July 1, 2017. The rule published by HHS added some additional exceptions to address specific circumstances as follows:

   a. A pregnant individual with a pre-existing condition for opioids in excess of the 100 Morphine Milligram Equivalent aggregate daily limit. This exemption applies only during the duration of the pregnancy. (Code E)
   b. Acute pain for an individual with an existing opioid prescription for chronic pain. In such situations, the acute pain must be postoperative or new onset. The seven-day prescription limit applies. (Code F)
   c. Individuals pursuing an active taper of opioid medications, with a maximum taper period of six months, after which time the opioid limitations will apply, unless one of the additional exceptions in this subsection apply. (Code G)
   d. Individuals who are prescribed a second opioid after being unable to tolerate the first. Neither prescription may by itself exceed the 100 MME limit.

2. **Does the law impact the prescribing of opioid medication for treatment of substance use disorders, such as suboxone?**

   Unfortunately it does by requiring the use of Code D on the script and e-prescribing as of July 1, 2017 (unless a waiver is applied for and granted). The law limits prescribing of opioid medication for the management of pain and is not intended to impact opioid medication prescribed for treatment of addiction/substance use disorder. Some pharmacists are requiring that “chronic” be written on the script but that is not required by the law or rule.

3. **Does the law apply to physicians or other prescribers employed by the Veterans Administration (VA) or to medication picked up at the VA pharmacy?**

   Because of the supremacy clause of the United State Constitution, federal law takes priority over state law and the VA cannot be regulated by this type of legislation. But the Department of Veterans Affairs has indicated its intent to comply with the objective of the law. VA Providers and those providers whose prescriptions are filled by the VA pharmacy should consult the VA Office of General Counsel if they have any specific questions regarding the applicability of the law to their practice. Prescribers with a Maine license must adhere to the law, even if employed by the federal government.

4. **If a patient lives in Maine but is seen by a prescriber in New Hampshire and any prescription issued by said physician is filled in NH, does any of the Maine law apply?**

   No. Maine law does not regulate the NH prescriber. An issue may be raised if the NH prescriber also had a Maine license, but that would have to be resolved at the licensing board level. Under a standard conflict of laws analysis, it is unlikely the prescriber seeing the patient in New Hampshire could be disciplined or fined in Maine, even if he or she had a Maine license.

5. **Could a patient in Maine see a Maine physician and then take a script in excess of the limits to New Hampshire to be filled?**

   The patient might be able to get such a script filled in NH but the physician in Maine would be subject to a penalty for violating the law. The law regulates the conduct of the prescriber and the pharmacist, not the patient.

6. **When can a prescriber be fined or referred to the licensing boards for violating the law?**

   Penalties can now be assessed, although we are not aware of anyone being fined for violating the law.

7. **Now that the mandate to check the Prescription Monitoring Program (PMP) has taken effect (on Jan. 1, 2017), must the prescriber check the PMP or can that still be done by a delegate registered under the license of the prescriber?**

   Delegates can still check on behalf of the prescriber. There was no intent to change that practice in this law. The prescriber is required to review three specific elements of the report, however:

   1. The dosage
   2. The number of prescibers
   3. The number of pharmacies

8. **How far in advance of writing the script may the PMP check take place?**

   The law as written does not specify the answer to this question. In responding to comments filed on the rule, DHHS staff did not sanction doing the check a day or two prior to the time the script is written.

9. **Who will determine whether the education a prescriber takes will qualify for the three hours of CME required as of Dec. 31, 2017 and every two years thereafter?**

   The licensing boards governing each category of prescriber have been given this responsibility and each board is expected to amend its rules on education to specify the process for determining whether a course will meet the requirement which simply states that the education must be on the subject of prescribing of opioid medication. We believe that related topics such as how to taper a patient and how to communicate with patients effectively about their pain and treatment options will be included. The Board rules proposed do not go into detail regarding what content is acceptable, but have expanded the applicability of the CME provision by including all licensees whether they prescribe opioid medication or not (this may be changed prior to the end of the year).

10. **Can a physician be a delegate of another physician for purposes of the PMP check? How about a pharmacist?**

    The law does not address those questions. We would argue that it is appropriate for one physician, for example a surgeon, to be the delegate of an anesthesiologist. On the other hand, because of the difference between the prescriber role and the dispensing role that a pharmacist exercises, it would make sense that a pharmacist could not be a delegate of a prescribing physician. We believe the redundancy of checks by the prescriber and pharmacist is intentional and positive.

11. Different MME calculators give different answers. Which is the appropriate one to use?

The PMP now performs MME conversions. Unfortunately, there is not a calculator that would allow a prescriber to determine what dosage of an intended prescription would stay under the maximum limits. The PMP Coordinator advises using the US CDC calculator for that purpose.

12. Is the Maine Medical Association planning to provide opioid education that meets the statutory requirements?

Yes, we have such courses and they meet the requirements of the statute. We have a one-hour program on the opioid law that you can have us present to your practice, and our MICIS (Maine Independent Clinical Information Service) program has several half-hour modules on various aspects of opioid prescribing, tapering, and naloxone available. MMA is dedicated to providing opioid education at no cost to the attendees. Many of our educational presentations are financially supported by the state. Upcoming courses can be found on the Association's website at www.mainemed.com.

13. Do I have to do a PMP check for a short term benzodiazepine prescription? Even for one day's worth?

Yes. The PMP check requirement applies to all opioid and benzodiazepine prescriptions and refills, at the outset and every 90 days thereafter. So for the initial prescription, regardless of whether it is for one day or 90 days, a check is required.

14. Is there an exemption from the limits for chronic pain treatment?

No, there are only the exemptions listed in the statute and the HHS rule. For chronic pain to be exempted it must fall within one of these exemptions.

15. Some patients are upset that they will not be able to get the pills they once were getting at the strength they once did. What feedback could you give us about why this part of the law was included? What are doctors saying about it?

When the law was passed, there were over 16,000 patients in Maine who were over 100 morphine milligram equivalents, which the CDC in Atlanta considers a dangerously high dose. Many of these patients can and should be tapered down to a more appropriate dose. There is a lot of medical literature now demonstrating that these mega doses of opioid medication do not even help the patient in the long term and these high doses are impacting the rate of overdose death. In other words, there is more risk than benefit. Based on CDC data, prescribers in Maine prescribed, on a per capita basis, the most extended release opioid medication in the country in 2012. But there has been a 21.5% decrease in the number of opioid scripts from 2013 through 2016.

16. I have a patient with Limb Girdle Muscular Dystrophy. He is wheelchair bound and has been on chronic pain meds for about 10 years that I have been caring for him. He is well above the 100 mg morphine equivalent. How to I find out more about an exception for him or will I be forced to wean him down? I don't think he is palliative at this stage but has significantly severe illness. If there isn't a decision on patients like this yet when will they be made? How do I navigate this issue?

Here are some thoughts on that issue. Until July 1, 2017, you can prescribe up to 300 MME. After that time, we recommend examining the language in the palliative care exemption. The legal definition of palliative care does NOT require a terminal condition or illness.

17. **If we have a hospice patient or cancer patient on opioids (thus there is an exemption), are we supposed to simply write HOSPICE or CANCER on the actual prescription or how exactly do we get this exception? Is there a form? After we check the PMP on a particular patient, is there a record of that? How does the pharmacist who is dispensing the med know that we have checked the PMP?**

    The pharmacists will not know whether you checked the PMP and they are not given enforcement authority under the statute. It is the responsibility of the prescriber, or his or her delegate to check it. If it is not done, the prescriber can be fined or referred to the applicable licensing board. You may wish to print out a copy of the report and include it in the patient's record so that you have proof of the fact that you did check if you are challenged. The new rule lists eight exemption codes, one of which you should include on the prescription if an exemption is being claimed.

18. **I know that nursing home patients are officially excluded. However, my assisted living patients who lives in the same building (just on a different floor) may also be on opiates, however the RN administers their medications. Thus there is an exemption for this. Again, how can these patients officially qualify for the exclusion?**

    If we understand your question, the patient in the assisted living facility is exempt from the limits under the exception for medication directly ordered or administered to a person in a long-term care facility or a residential care facility.

19. **Does the law require that patients being prescribed opioid medication over the 100 MME limit be seen by the prescriber every thirty (30) days?**

    No. But the new MaineCare rule requires a progress note evidencing progress toward treatment goals every thirty days. In addition, “prescribers must assess and document functions and pain in a face to face visit every time opioids are prescribed or at least every thirty days.” These requirements would obviously apply only to MaineCare patients.

20. **Is it true that an ICD-10 code must be included on a prescription exceeding 100 MME (daily) if the palliative care exemption is being used, in addition to including Exemption Code B?**

    Yes. The final HHS rule, which took effect March 31, 2017, removed the ICD-10 code requirement for the other statutory exemptions but retained it for palliative care. The reasoning is that the palliative care definition is very broad and it is hoped that at some point research can be done to see what diagnoses are underlying the palliative care exemptions being claimed.