

06/15/2018

FACT SHEET

Implementation of Enacted Prescribing Limits and Requirements and Relevant Opioid Prescribing Laws and Rules

Background:

The 2016 law (Chapter 488) makes five major changes to opioid prescribing:

1. It mandates use of the State's Prescription Monitoring Program and expands those who use it;
2. Enacts strict limits on opioid prescribing for acute and chronic pain (ALL opioids, not just Schedule II);
3. Mandates education for opioid prescribers;
4. Mandates electronic prescribing of opioids;
5. Provides for a "Partial Fill" at a pharmacy, at the direction of the patient

The Chapter 21 rules from the prescriber licensing boards require additional actions in connection with opioid prescribing, such as:

1. Universal precautions for opioid prescribing;
2. Opioid CME for all licensees of the Board of Licensure in Medicine (the MD Board);
3. Mandated urine drug screens.

Prescription Monitoring Program (PMP)

Requires prescribers to check the PMP upon initial prescription of a benzodiazepine or an opioid, and every 90 days thereafter for as long as the prescription is renewed.

This provision does not apply when a benzodiazepine or an opioid is ordered or administered in an emergency room, an inpatient hospital, a long-term care facility or a residential care facility, or in connection with a surgical procedure. Note that the foregoing exceptions apply only to ordering opioids for administration by a health care professional, not to prescribing opioids for later self administration. Also, does not apply if patient is in hospice care or is receiving end-of-life treatment.

Requires dispensers (normally pharmacists) to check the PMP prior to dispensing a benzodiazepine or opioid under the following circumstances:

- A. The person is not a resident of the State;
- B. The prescription is from a prescriber with an address outside of this State;
- C. The person is paying cash when the person has a prescription insurance on file;
- D. According to the pharmacy record, the person has not had a prescription for a benzodiazepine or an opioid medication in the previous 12 months.

- Requires that dispensers withhold a prescription until the dispenser is able to contact the prescriber if the dispenser has reason to believe that the prescription is fraudulent or duplicative.
- Adds veterinarians to definition of prescriber.
- Allows staff authorized by the Chief Medical Officer of a hospital to access the PMP for patients of the hospital or emergency department and allows the CMO to access prescription reports of prescribers he/she employs.
- Allows on-duty pharmacists to authorize staff to access the PMP for customers filling prescriptions.
- Requires the Department of Health and Human Services to include enhancements to the PMP, including a calculator to convert dosages to and from MMEs and increased access for staff members of prescribers to access the program with authorization.

Limits on Prescribing

Limits new opioid prescriptions, or an aggregate of multiple opioid prescriptions, to no more than 100 MMEs per day.

Exceptions by Statute:

- Pain for active and aftercare cancer treatment (Exception Code A)
- Palliative care in conjunction with a serious illness or injury (Code B)
- End of life and hospice care (Code C)
- Medication-assisted treatment for Substance Abuse Disorder (Code D); or
- Opioid directly ordered or administered in an emergency room, an inpatient hospital setting or a long-term care or residential treatment facility.

Exceptions by Rule:

- A pregnant individual with a pre-existing prescription for opioids in excess of the 100 Morphine Milligram Equivalent aggregate daily limit which is being tapered. This exemption applies only during the duration of the pregnancy. (Code E)
- 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)
- 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)
- Individuals who are prescribed a second opioid after being unable to tolerate the first. Neither prescription may by itself exceed the 100 MME limit. (Code H)

Opioid prescriptions for acute pain limited to 7-day supply within a 7-day period (renewable).
 Opioid prescriptions for chronic pain limited to a 30-day supply within a 30-day period (renewable). "Acute Pain" or "Chronic pain" must be written on the script.

Education

12/31/17 – As a condition of prescribing opioid medications, all prescribers must complete 3 hours of Continuing Medical Education (CME) on the prescription of opioid medication every 2 years. Medical Doctors and Physician Assistants licensed by the BOLIM must complete the education by 12/31/18 regardless of whether they prescribe opioid medication.

Electronic Prescribing

All prescribers “with the capability” must prescribe opioids electronically. A waiver from DHHS must be requested in writing if compliance cannot be met.

Penalties

Individuals who violate this law may be subject to civil penalties of \$250 per violation, not to exceed \$5,000 per calendar year. Violations may be reported to licensing boards.

Chapter 21 Opioid Prescribing Rules

The Board of Licensure in Medicine, the Board of Osteopathic Licensure, and the Board of Nursing have established very specific joint rules under “Chapter 21” that apply to all prescribers licensed by those boards. Those rules require the following:

Universal Precautions

- 1) Patient evaluation:
 - a) Medical history & physical (specific items to be included are listed in rule);
 - b) Risk assessment (specific items to be included are listed in rule).

Treatment Plan

Requirements for initiating or continuing prior opioid therapy:

- 1) Start with lowest possible dose and titrate to effect based on documented functional assessment;
- 2) Immediate release rather than extended release when initiating;
- 3) Begin as trial for no more than 30 days, evaluate harms and benefits within 28 days;
- 4) Dosage limits;
- 5) Dosage limit exemptions (as in statute and DHHS rules);
- 6) Electronic prescriptions, time limits, and rules for palliative care exemption;
- 7) Naloxone for high risk patients;
- 8) Avoid concurrent opioid and benzodiazepine prescription whenever possible.
- 9) Periodic review of treatment efficacy, with frequency based on risk level (specified requirements for review).
- 10) Consult or refer for additional evaluation or treatment as necessary.

- 11) Coordination of care with other clinicians who have narcotic contract with patient.
- 12) Tapering and/or managed withdrawal or treatment if opioid therapy is discontinued.

Informed Consent and Risk Assessment

- 1) Written and signed
- 2) Minimum contents
 - a) Benefits: pain reduction, improved physical and psychological function.
 - b) Risks:
 - i) Side effects;
 - ii) Effect on vehicle operation;
 - iii) Allergic reactions;
 - iv) Medication interaction;
 - v) Likelihood of tolerance or dependence;
 - vi) Risks of misuse, addiction and potentially fatal overdose;
 - vii) Potential for withdrawal symptoms;
 - viii) Risk of fatal overdose due to accidental exposure, especially to children;
 - ix) Risk of use during pregnancy.

Use of PMP

Treatment Agreement

- 1) List of required provisions, including:
 - a) Disclose all medical conditions and medications;
 - b) Responsibility to be discreet about possessing narcotics;
 - c) Take only as prescribed;
 - d) Prescribing policies and expectations, including use of single pharmacy and policy on early and after-hour refills;
 - e) Disclose any other opioids received from other clinicians;
 - f) Keep scheduled appointments, comply with random pill counts and urine/blood testing;
 - g) Statement that clinician may notify authorities if concerned re: illegal activity;
 - h) Statement that violation of agreement may result in decrease or termination of opioid prescriptions.
- 2) Clinician must document all violations and response to violation, along with rationale for any changes in treatment plan.

Toxicological Drug Screens

If prescription for 90+ days, documented screen prior to treatment initiation and randomly thereafter, at least annually.

Pill Counts

“An additional tool”, not mandated but encouraged. Must be documented if ordered.

Medical Records

Specific list of what records must contain.

CDC Guidelines

Prescribers “must be aware of and follow” US CDC guidelines on opioids and chronic pain prescribing.

Continuing Education

All prescribers licensed by Board of Licensure in Medicine must take 3 hours of Category 1 CME on opioid prescribing, regardless of whether they prescribe opioids.

All prescribers licensed by Board of Osteopathic Licensure or Board of Nursing must take 3 hours of Category 1 CME on opioid prescribing as a condition of prescribing opioids.

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More resources available at <https://mainequalitycounts.org/initiatives-resources/opioid-epidemic-caring-for-me-2/> or <https://www.micismaine.org>