Update on Maine Laws and Associated Rules on Prescribing Opioid Medication

Gordon H. Smith, Esq.
Executive Vice President
Maine Medical Association
2018
Disclosure

There are no significant or relevant financial relationships to disclose, nor do we have any financial relationships with the manufacturers of any commercial product(s) and/or provider of commercial services discussed in this activity.
This presentation is funded in part by a contract with:

Department of Health and Human Services
Maine People Living Safe, Healthy and Productive Lives

Paul R. LePage, Governor  Ricker Hamilton, Commissioner
Opioids: the difficult truth

“We know of no other medication routinely used for a nonfatal condition that kills patients so frequently.”

NEJM: 374;16 4-21-16

Dosage >200 MME: Number Needed to Kill = 32
More than One Death per Day in Maine

- Maine led nation in rate of long-acting opioid prescriptions at 21.8 Rx/100 people (2012)
- 60 to 65 pills prescribed for every man, woman and child in Maine annually
- Overdose death rate in Maine increased 38% from 2015-2016 and 11% from 2016-2017
- 376 overdose deaths in 2016 (313 involving opioids)
- 418 overdose deaths in 2017 (31 per 100,000)
- 180 deaths in the first 6 months of 2018
A Lethal Dose

[Image of three clear glass vials labeled 'HEROIN', 'FENTANYL', and 'CARFENTANIL']
Naloxone Administrations

- 1,565 in 2015
- 2,380 in 2016

Indications: Emergency treatment of respiratory & CNS depression due to known or suspected opioid overdose
Maine Death Rates

- Overdose
- Traffic Deaths
- Homicides

Yearly Counts:
- 2014: Overdose 208, Traffic Deaths 131, Homicides 30
- 2015: Overdose 272, Traffic Deaths 156, Homicides 23
- 2016: Overdose 376, Traffic Deaths 160, Homicides 19
- 2017: Overdose 418, Traffic Deaths 171, Homicides 20
Maine Babies Born Drug Affected

• Maine’s 2016 infant mortality rate (6.6/1000) exceeds the national average (5.9/1000) (source: America’s Health Rankings)

• 1 out of every 12 babies in Maine was born drug-affected in 2016

• A reduction in 2017 but still more than 3 drug affected babies born each day
The Opioid Epidemic By the Numbers
Drug-Affected Babies


Source: State Inpatient Databases, Healthcare Cost and Utilization Project.

* NAS cases per 1,000 hospital births.
National Public Health Emergency

- Drug overdose deaths surpassed 72,000 in 2017, an increase of 9.5% from 2016. Nearly 30,000 deaths involved fentanyl.
- More than 42,000 of those deaths caused by opioids*
- 200 drug overdose deaths every day or one every eight minutes
- The increase from 2016 to 2017 was primarily driven by a surge in deaths involving synthetic opioids, including fentanyl
- Drug overdoses killed 630,000 people between 1999-2016
- The leading cause of death for people under age 50

*From the November 1, 2017 letter from the President’s Commission on Combating Drug Addiction and The Opioid Crisis to the President. (Letter accompanying the 138 page report of the Commission).
Downstream Cost of Untreated Addiction

- $500,000 per inpatient stay
  - 8-12 patients on any given day at MMC for related medical conditions

- Emergency Department Utilization

- At least 40% uninsured
  - Maine has not expanded Medicaid eligibility

- Washington State study reported a 50% decrease in medical costs for individuals who received substance use disorder treatment
How Did We Get Here?

• **3400 BC** - Opium poppies were cultivated in lower Mesopotamia. The poppy was known as the “joy plant”
• **1827** - E. Merck & Co. of Germany begins commercial manufacturing of morphine (active opium ingredient)
• **1898** - Heroin is created and introduced commercially. *It is marketed as a cure to morphine addiction.*
• **1903 - 1905** Heroin addiction rises significantly. US Congress bans opium but it has gained a foothold as a black market drug.
• **1916** - First synthesis of oxycodone with goal it would retain analgesic effects of morphine with less dependence
• **1996** - Purdue Pharma begins marketing of OxyContin in “Partners Against Pain” campaign claiming addiction risk is small. By 2001 it is *best-selling narcotic in U.S.*
• **1999** - Promotion of pain as “5th Vital Sign” by VA intended as quality measure for pain management; became Joint Commission standard in 2001 “Rate pain management” continues as key question on patient experience surveys
• **1999 to 2010** - Opioid related deaths quadrupled
Some characteristics of counties with higher opioid prescribing:
- Small cities or large towns
- Higher percent of white residents
- More dentists and primary care physicians
- More people who are uninsured or unemployed
- More people who have diabetes, arthritis, or disability

The amount of opioids prescribed per person in the US increased by **350%** between 1999-2015.
Evidence of Over-Prescribing

- **General surgery patients**
  - 75% partial mastectomy patients did not take any of their prescribed opioids
  - 34% lap cholecystectomy patients took no prescribed opioids
  - 45% lap inguinal hernia patients took no prescribed opioids
  - Patients reported having 67% to 85% opioid pills remaining

- **Wisdom tooth extraction patients**
  - 10 million wisdom teeth removed annually in 3.5 million surgeries
  - On average, patients received 20 pills but only 8 used leaving 42 million pills vulnerable to misuse and abuse

---


Prescribing of Opioid Medication for Pain is Declining

- Since 2011
- Number of high dose prescriptions (greater than 90 MME) fell 41.4% from 2010 to 2015
- Maine’s prescribing declined 32% from 2013-2017, the 5th largest drop in the nation
- In 2017 alone, Maine saw a decline of 13.2% in opioid prescribing
- Based upon one year data ending 12/31/2017, Maine had the largest decline in opioid dosing in the nation
Maine Opioid Prescriptions
2013 - 2017
(Retail filled prescriptions)
Maine Opioid Prescriptions
2013 - 2017
(% Decrease, 2013=baseline)

Maine
New England
U.S. Average
Maine Opiate Collaborative and the Task Force to Address Opioid Crisis in the State

Task Force to Address the Opioid Crisis in the State
Final Report
December 2017

Staff:
Anna Brooks, Legislative Analyst
Paul Landberg, Legislative Analyst
Office of Policy & Legal Analysis
13 State House Station
Room 215
State House Building
Augusta, ME 04333-0024
(207) 287-1670
www.maine.gov/legis/opla

Members:
Sen. Andre K. Cushing III, Chair
Rep. Joyce "Joy" McCroghy, Chair
Sen. Scott W. Cukierman
Sen. James F. DiPullo
Sen. Geoffrey M. Grant
Rep. Anne "Penny" Bechard
Rep. Harold "Frog" Stewart III
Rep. Karen Vohs

Stevie Davis
Robert Fowler
Version Gardner
Katie Lilly
Mark F. Miller
Malory Shangrue
Gordon H. Smith
Renee, William K. Stokes
Jeffrey Treaden
Christopher Pizzello
Overview of P.L. 2015, Chapter 488

• Prescribing limits on MMEs per day
• Partial filling of prescriptions at patient request
• Required PMP check for prescribers and dispenser
• Prescribing limits on length of scripts
  • Exception for emergency rooms, inpatient hospitals, long-term care facilities, or residential care facilities or in connection with a surgical procedure.
  • Exception for medication-assisted treatment for substance use disorder
  • Exceptions for active and aftercare cancer treatment, palliative care, and end-of-life and hospice care, pregnancy, acute-over-chronic, intolerance, active taper
• Mandatory CME
• Mandatory electronic prescribing
Note

- Over 16,000 Mainers exceeded 100 MME in early 2016
- 1200 exceeded 300 MME
- How many could be safely tapered?
Key Definitions

• **Palliative care** (in connection with a serious illness)
  
  • Patient-centered, family-focused medical care that optimizes quality of life by anticipating, preventing, and treating suffering caused by serious medical illness or physical injury or condition that substantially affects quality of life
  • Addresses physical, emotional, social, and spiritual needs
  • Facilitates patient autonomy and choice of care
  • Provides access to information
  • Discusses patient’s goals for treatment and treatment options, including hospice care, when appropriate
  • Manages pain and symptoms comprehensively
  • Palliative care does not always include a requirement for hospice care or attention to spiritual needs.
  • Note: Does not require a terminal condition
Key Definitions

• **Serious illness**
  
  • Medical **illness** or physical **injury** or **condition** that substantially affects quality of life for more than a short period of time
  
  • Includes, **but is not limited to**, Alzheimer’s disease and related dementias, lung disease, cancer and heart, renal or liver failure and **chronic**, unremitting or intractable pain such as neuropathic pain.
Prescriber Responsibilities

Required PMP check

• Upon initial prescription of benzodiazepine or opioid medication
• Every 90 days following
• The only part of c. 488 affecting benzodiazepine Rx

Delegation of PMP check

• Prescribers may delegate PMP check to “any staff member duly authorized” by prescriber/practice and PMP Office
• Despite delegation, prescriber must review patient’s aggregate MME (including new prescription); number of prescribers currently prescribing controlled substances to patient; and number of pharmacies currently dispensing
Exceptions to PMP Check

• No PMP check is required for benzodiazepine or opioid medication directly administered in an emergency room setting, an inpatient hospital setting, a long-term care facility (assisted living or nursing home), or a residential care facility, or in connection with a surgical procedure.

• No PMP check is required for hospice or end-of-life patients.
Exceptions to limits on opioid medication prescribing

By Statute

1. Pain associated with active and aftercare cancer treatment. Providers must document in the medical record that the pain experienced by the individual is directly related to the individual’s cancer or cancer treatment. Exemption Code A

2. Palliative care in conjunction with a serious illness (includes injury). Code B, (ICD-10 Code must be included on script as well as “Code B”)

3. End-of-life and hospice care. Code C

Exceptions to limits on opioid medication prescribing

By Rule

5. A pregnant individual with a pre-existing prescription for opioids in excess of the 100 Morphine Milligram Equivalent aggregate daily limit. Exemption applies only during the duration of the pregnancy. Code E

6. Acute pain over an existing opioid prescription for chronic pain. The acute pain must be postoperative or new onset. Seven day prescription limit applies. Code F

7. Active taper of opioid medications, 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

8. Prescription of a second opioid after proving intolerant to a first opioid, thereby exceeding the 100 MME limit. Neither prescription may exceed 100 MME. Code H
Prescriber Responsibilities

• Required notations on opioid prescriptions
  • DEA number
  • “Acute” or “Chronic” for all prescriptions (including suboxone) under 100 MME and Exemptions F and H
  • For “acute on chronic” pain (Exemption Code F), use “Acute”
  • For palliative care (Exemption Code B), note the diagnosis (ICD-10) code
  • Where an exemption is claimed, the exemption code (A through H) must be noted
  • New: Pharmacists may contact prescribers by telephone to verify and document missing information on the script.
Prescriber Responsibilities

• Continuing Education
  • Every prescriber must complete 3 hours of CME on the prescription of opioid medication every 2 years as a condition of prescribing opioid medication
  • ALL MDs must complete 3 Hours CME by 12/31/2018 even if they do not prescribe opioid medication (BOLIM Rule Chapter 21)

• Electronic Prescribing
  • Prescribers with the capability to electronically prescribe must prescribe all opioid medication electronically
  • A waiver may be available in some circumstances:
    • Written waiver application required
  • Penalties for failure to comply
E-prescribing Mandate

• No exceptions for any specialties, locations

• Exemption from limits/PMP checks is NOT an exemption from E-prescribing requirement
E-prescribing Mandate: Exceptions

- Exceptional circumstances allowing written prescriptions:
  - Temporary technological or electrical failure
  - Long term care facilities may use fax per DEA rules
  - For homeless patients, use address of shelter, street name, if possible; if no address, may prescribe on paper
  - To be dispensed by VA or Indian Health Service pharmacy, or outside Maine
  - Prescriber reasonably determines that it would be impractical, patient could not obtain medication timely, and delay would adversely impact patient’s medical condition
Penalties

• Civil violation

• Subject to fine of $250 per incident up to a maximum of $5000 per calendar year

• More serious concern is Licensing Board action
  
  • PMP will report violations to Board, prescriber will receive 2 weeks’ advance notice and opportunity to comment
Maine Licensing Boards
Joint Rule Chapter 21
(Medicine, Osteopathy, Nursing boards)

Repels and replaces a previously existing joint rule regarding the use of controlled substances for treatment of pain.

• Defines terms

• Requires that clinicians achieve and maintain competence in assessing and treating pain

• Requires that clinicians consider use of non-pharmacologic modalities and non-controlled drugs in treatment of pain prior to prescribing controlled substances

• Requires use and documentation of Universal Precautions when prescribing controlled substances (except in case of "genuine medical emergency"-- an acute injury or illness that poses an immediate risk to a person’s life or long-term health)
Universal Precautions

• Patient evaluation
• Treatment plan
• Informed consent
• PMP check
• Treatment agreement (chronic only)
• Drug screens (chronic only)
• Medical records
Patient Evaluation:  
1. History & Physical Exam

Before prescribing any controlled substances to a patient for acute or chronic pain, a clinician shall perform an initial medical history and appropriate physical examination and evaluation of the patient, which must be documented in the patient’s medical record. The documentation shall include:

(a) Duration, location, nature and intensity of pain.
(b) The effect of pain on physical and psychological function, such as work, relationships, sleep, mood.
(c) Coexisting diseases or conditions.
(d) Allergies or intolerances.
(e) Current substance use
(f) Any available diagnostic, therapeutic or laboratory results.
(g) Current and past treatments of pain including consultation reports.
(h) Documentation of the presence of at least one recognized medical indication for the use of controlled substances if one is to be prescribed.
(i) All medications with date, dosage and quantity
2. Risk Assessment

• Required Before prescribing or increasing the dose of any controlled substances to a patient for **acute or chronic** pain

• To determine whether the potential benefits of prescribing controlled substances outweighs the risks

• Includes factors involved in a patient’s overall level of risk of developing adverse effects, abuse, addiction or overdose

• For **acute** pain, a basic consideration of short term risk shall be assessed
2. Risk Assessment (chronic)

For the treatment of chronic pain, the use of an appropriate risk screening tool is encouraged. The following factors must be considered as part of the risk assessment:

(a) Personal or family history of addiction or substance abuse/misuse.
(b) History of physical or sexual abuse.
(c) Current use of substances including tobacco.
(d) Psychiatric conditions; especially poorly controlled depression or anxiety. Use of a depression screening tool may be helpful.
2. Risk Assessment (chronic)

(e) Regular use of benzodiazepines, alcohol, or other central nervous system medications.

(f) Receipt of opioids from more than one prescribing practitioner or practitioner group.

(g) Aberrant behavior regarding opioid use, such as repeated visits to an emergency department ("ED") seeking opioids.

(h) Evidence or risk of significant adverse events, including falls or fractures.

(i) History of sleep apnea or other respiratory risk factors.

(j) Comorbidities that may affect clearance and metabolism of the opioid medication.

(k) Possible pregnancy. Assess pregnant women taking opioids for opioid use disorder. If present, refer to a qualified specialist.

The clinician shall document in the patient’s medical record a statement that the risks and benefits have been assessed.
Treatment Plan

- Objectives to determine treatment success
- Any further diagnostic evaluations or other treatments
- Specific functional goals
- Discuss realistic outcomes and expectations with patient, including regular physical activity
- Prescribe lowest possible dose to naïve patient, then titrate to effect based on documented functional assessment; begin with immediate-release form
- For chronic pain, present as therapeutic trial for <30 days, then evaluate benefits & harms within 1-4 weeks
Treatment Plan (Chronic Pain)

• “Inherited patients” must be re-assessed
• Frequency of periodic review of treatment efficacy shall be determined by the patients’ risk factors, the medication dose and other clinical indicators (evaluation at least annually for lowest risk patients on lowest doses)
  • Review must include change in pain, function, quality of life based on patient history and collateral information; whether continuation or modification of prescription needed; new or ongoing comorbidities or meds; patient adherence; PMP check (q 90 days)
• Toxicology drug screens at least annually, based on pt. risk
• “Random pill counts are an additional tool…”
• Consult or refer for higher risk patients
Informed Consent
(Chronic Pain-Minimum Req’d)

1. Benefits:
   • Reduced pain
   • Improved function

2. Risks:
   • Side effects
   • Vehicle operation
   • Allergy
   • Drug interaction
   • Tolerance/psychological dependence
   • Misuse-addiction-overdose (dose dependent)
   • Withdrawal (list symptoms)
   • Accidental overdose to others (especially children)
   • Adverse pregnancy outcomes
Treatment Agreement (Chronic Pain)

1. Requirements
   • All medical conditions & medications
   • Requirement of patient discretion in possessing & storing controlled meds, avoid theft
   • Take only as prescribed, no use of illegal substances or excessive alcohol
   • Clinician prescribing policies & expectations
     • Opioids from only one practice
     • Use of single, designated pharmacy
     • Policy on early/after hours refills, lost or stolen meds
   • Responsibility to inform all clinicians of all opioids
   • Keep appointments, comply with pill counts & drug screens
   • Statement that clinician may “notify proper authorities” if concern of illegal activity
   • Statement that violation of contract may result in opioids being reduced or discontinued, or patient may be discharged
2. “If the agreement is violated, the violation and the clinician’s response to the violation will be documented in the patient’s medical record. In addition, the clinician shall document the rationale for changes in the treatment plan such as weaning the patient off medication, reporting to legal authorities, etc.”
Medical Records

Records must include at least the following:
1. Copies of signed informed consent and treatment agreement
2. Medical history
3. Documentation of PMP checks
4. Physical exam & labs
5. Results of risk assessment, including results of any screening instruments/tools used
6. Description of all treatments and meds provided (date, type, dose, quantity)
7. Patient instructions, including risks/benefits
8. Results of ongoing progress monitoring (pain management, functional improvement)
9. Specialist evaluations/consultations, if any
10. “Any other information used to support the initiation, continuation, revision, or termination of treatment, and the steps taken in response to any aberrant medication use behaviors”
Follow CDC Guidelines

From the Maine licensing boards’ Chapter 21:

“Clinicians shall be aware of and follow the “CDC Guideline for Prescribing Opioids for Chronic Pain – United States 2016” as published in the U.S. Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report, Early Release/Vol. 65, March 15, 2016. Copies of the CDC guideline may be obtained at:

http://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm”
Payor Policies: MaineCare

When prescribing opioids for chronic pain:

1. Drug testing
   - Urine drug test (UDT) or other appropriate toxicology test to be completed before prescribing
   - UDT to be “considered” at least quarterly, on a random basis (required at least annually)
   - Results of drug testing to be documented in patient record
   - Results to be reviewed with patient
   - Testing must follow federal and state guidelines including Chapter 11, Section 55 “Laboratory Services” of the Maine Care Benefits Manual

2. Harm-Benefit evaluation
   - Prescribers must evaluate benefit and harms of continued opioid therapy with patients who have continued therapy beyond three (3) months at least once every six (6) months during a face to face appointment or more frequently thereafter
Resources

MMA’s Opioid Crisis page:
- Opioid laws & rules, Maine Opiate Collaborative task force Reports, CDC guidelines, naloxone, Q and A, DHHS clarifications.

Caring for ME page:
- [https://www.mainequalitycounts.org/page/2-1488/caring-for-me](https://www.mainequalitycounts.org/page/2-1488/caring-for-me)
- Webinars, opioid laws & rules, information on pain management and tapering, etc.

MICIS page:
- [https://www.micismaine.org](https://www.micismaine.org)
- Toolkit for prescribers, naloxone information, etc.
Questions?

Maine Medical Association
30 Association Drive, P.O. Box 190
Manchester, Maine 04351
207-622-3374 Ext. 210
207-622-3332 Fax

Gordon Smith, Esq.  gsmlth@mainemed.com  Cell: 215-7461
Andrew MacLean, Esq.  amaclean@mainemed.com
Peter Michaud, Esq.  pmichaud@mainemed.com