Update on Maine Laws and Associated Rules on Prescribing Opioid Medication

Maine Rural Health Collaborative
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www.mainemed.com

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Opioids: the difficult truth

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

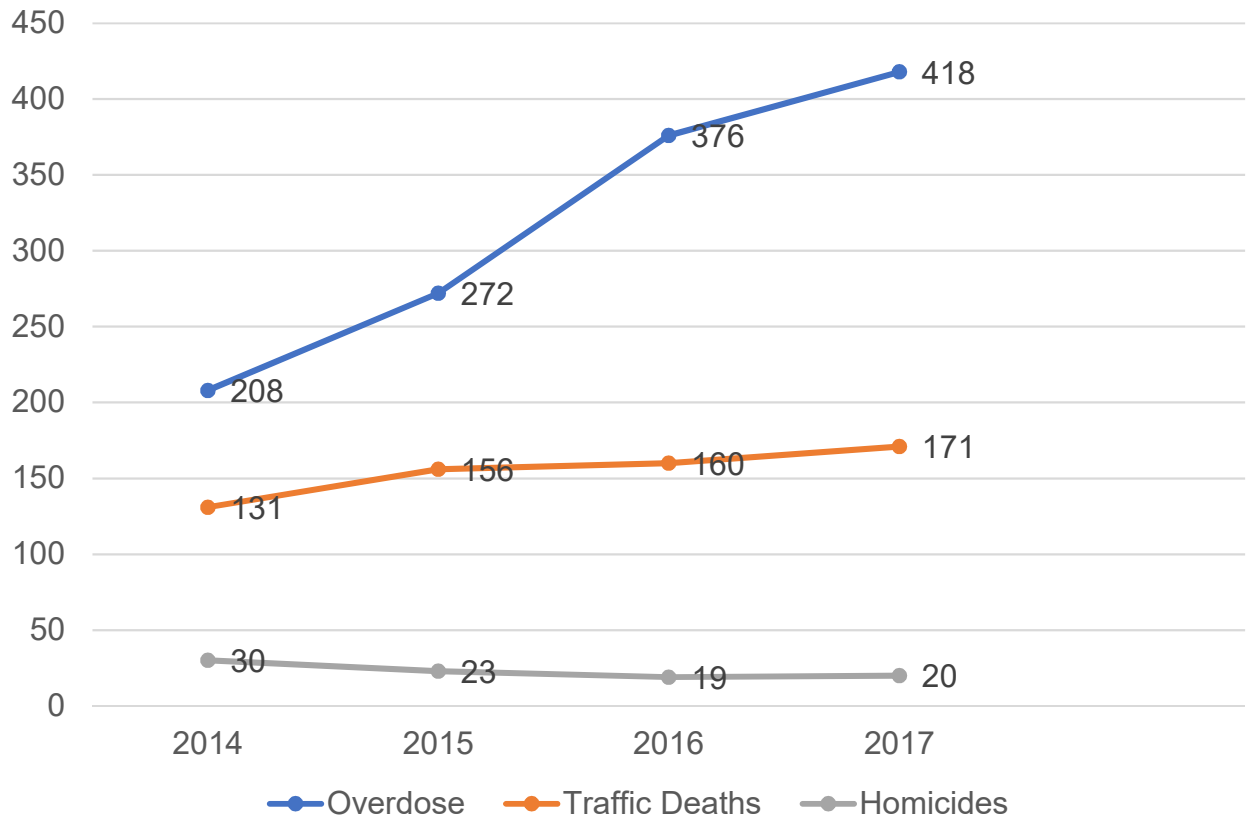
NEJM: 374;16 4-21-16

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
- 272 Mainers lost to overdose death in 2015
- 376 overdose deaths in 2016 (313 involving opioids)
- 418 overdose deaths in 2017 (31 per 100,000)

Maine Death Rates



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Maine Babies Born Drug Affected

- Maine's infant mortality rate (7.1/1000) exceeds the national average
- 1 out of every 11 babies in Maine was born drug-affected in 2016
- A reduction in 2017 but still more than 3 drug affected babies born each day

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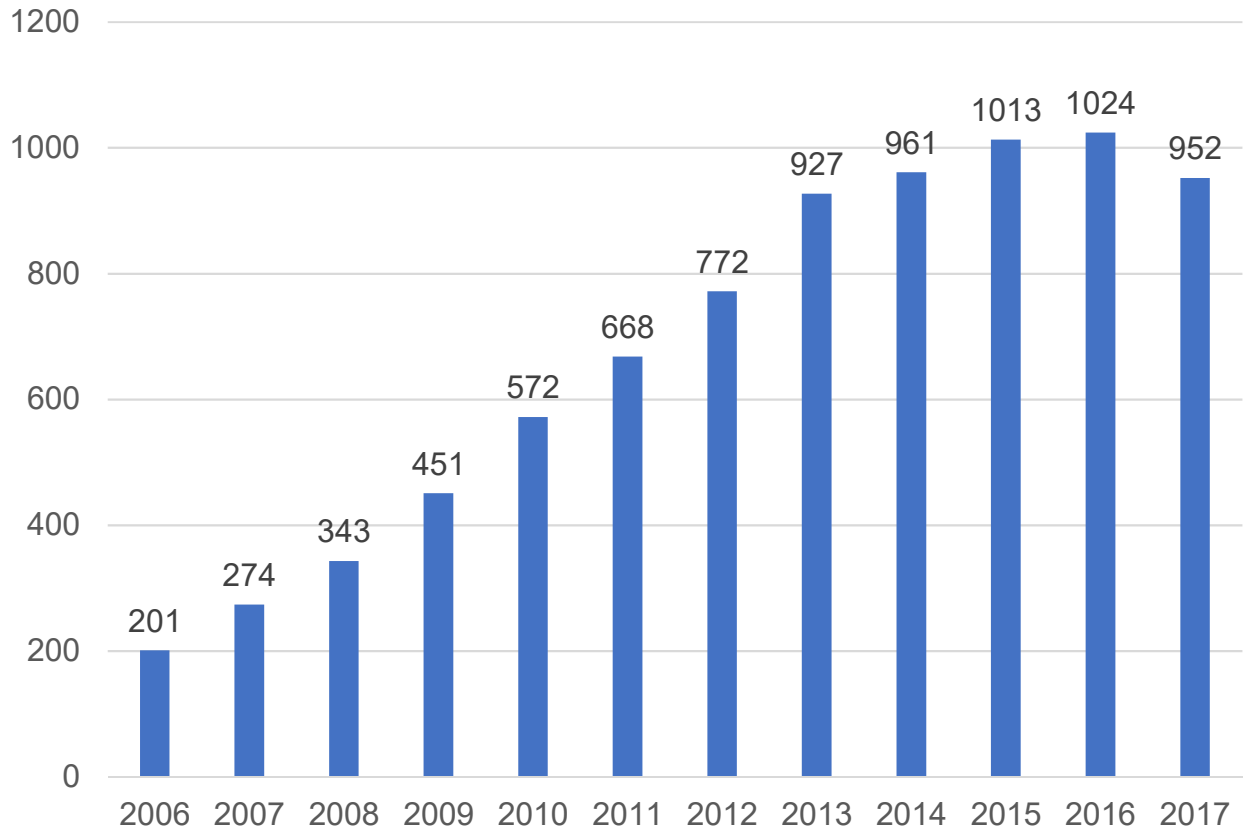
Maine Drug Affected Babies



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National Public Health Emergency

- Over 62,000 overdose deaths nationally in 2017, with more than 42,000 of those deaths being caused by opioids.*
- One hundred seventy-five (175) lives lost every day with 115 of these deaths due to opioids.
- If a terrorist organization was killing 175 Americans a day on American soil, what would we do to stop them?

*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).

Opioid Use Disorder

- In 2015, an estimated 15,000 people received treatment for substance-use disorder (SUD) in Maine, while another 25,000 could not get treatment because of a lack of capacity or lack of insurance.
- Nationally, only 10.6% of youth and adults who need treatment for a substance use disorder receive that treatment. (From Report of President's Commission)
- Nationally, 1.6 million Americans have an OUD (President's Commission)


HEROIN
FENTANYL
CARFENTANIL

Evidence of Over-Prescribing

- C-Section patients[1]
  - 53% report taking no or very few (<5) opioid pills prescribed post-operatively
  - 83% report taking half or fewer
- Thoracic surgery patients[1]
  - 45% report taking no or very few (<5) opioid pills prescribed post-operatively
  - 71% report taking half or fewer

[1] *PLoS One 2016 29;11(1); e0147972. Epub 2016 Jan*

More Evidence of Over-Prescribing

- **General surgery patients[2]**
  - 75% partial mastectomy pts did not take any of their prescribed opioids
  - 34% lap choly pts took no prescribed opioids
  - 45% lap inguinal hernia pts took no prescribed opioids
  - Pts reported having 67% to 85% opioid pills remaining
- **Wisdom tooth extraction patients[3]**
  - On average, patients received 28 pills but used <50% of amount prescribed
  - Extrapolates to >100 million opioid pills unused nationally

[2] *Ann Surg, Hill et al, Sept 14, 2016*

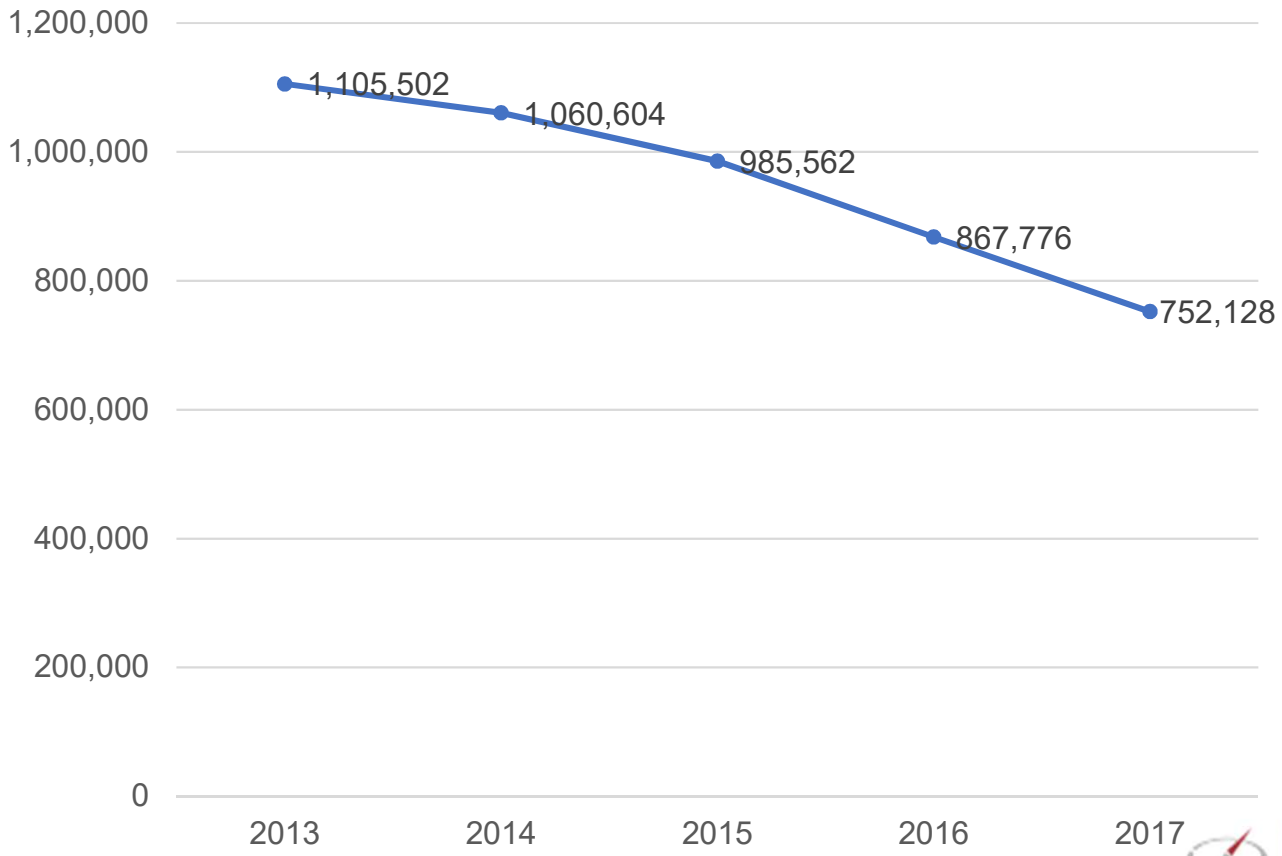
[3] *Drug Alcohol Depend. 2016 Nov 1; Epub 2016 Sep 20.*

Prescribing of Opioid Medication for Pain Continues to Decline

- Has declined since 2011
- Number of high dose prescriptions (greater than 90 MME) fell 41.4% 2010 to 2015
- Maine's prescribing declined 32% 2013-2017, the 5th largest drop in the nation
- In 2017 alone, Maine saw a decline of 13.2% in opioid prescribing.

Maine Opioid Prescriptions 2013 - 2017

(Retail filled prescriptions)



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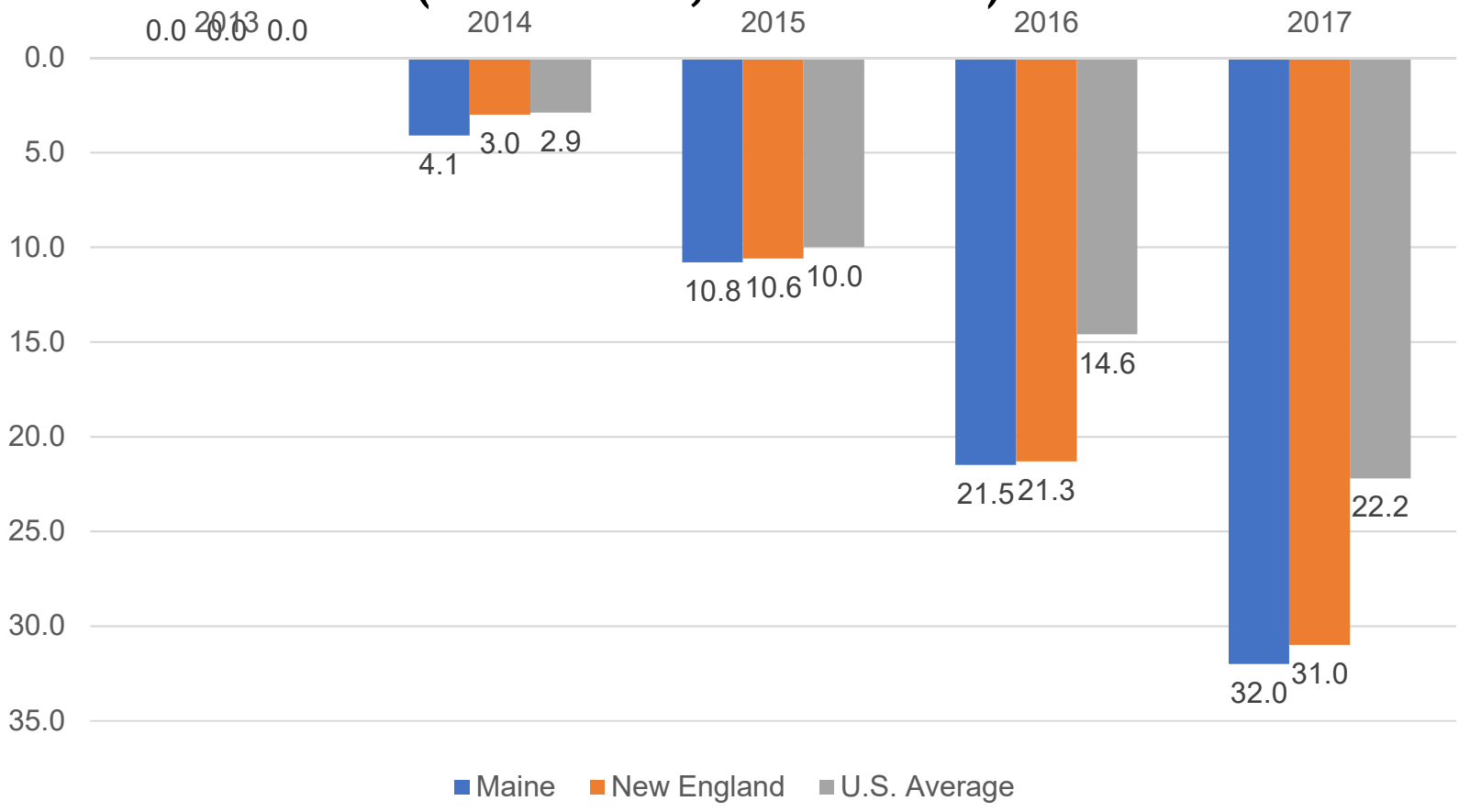
Maine Opioid Prescriptions 2013 - 2017

(% Decrease, 2013=100%)



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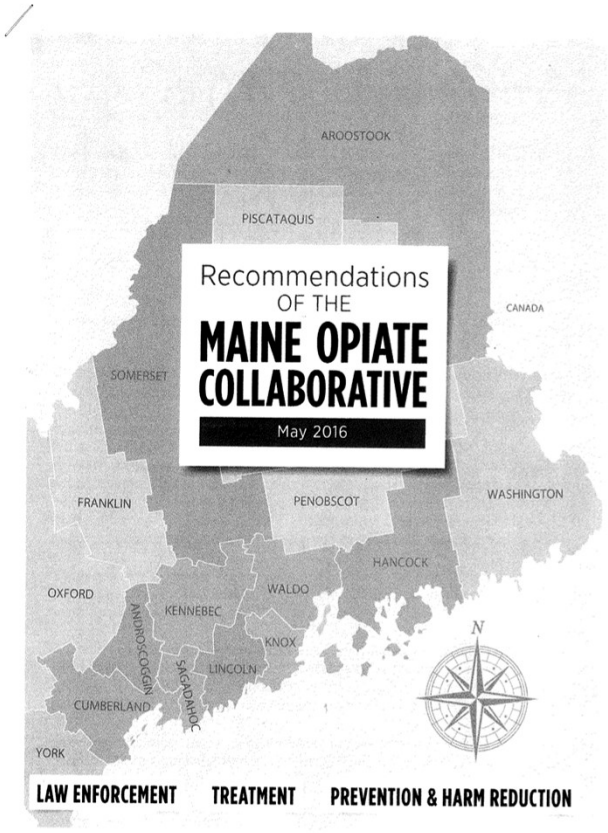
Maine Opiate Collaborative and the Task Force to Address Opioid Crisis in the State



STATE OF MAINE
128th LEGISLATURE
FIRST REGULAR SESSION

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

Members:
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Overview of P.L. 2015, Chapter 488

- Prescribing **limits on MMEs** per day (July 1, 2016)
- **Partial filling** of prescriptions at patient request (July 1, 2016)
- Required **PMP check** for prescribers and dispenser (Jan 1, 2017)
- Prescribing limits on **length of scripts (Jan 1, 2017)**
  - **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 (Dec 31, 2017)**
- Mandatory **electronic prescribing (July 1, 2017)**

Note

- Over 13,000 Mainers exceeded 100 MME in early 2016
- How many could be safely tapered?

Key Definitions

- **Palliative care**
  - 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 (part of palliative care exception)**
  - 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

- **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.

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.

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**
4. Medication-Assisted Treatment for **substance use disorder**. **Code D**

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

- **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 1)

- **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** 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

Licensing Boards Joint Rule Chapter 21 (Medicine, Osteopathy, Nursing board)

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

Universal Precautions

- Evaluate the patient including conducting a risk assessme nt
- Develop a treatment plan (chronic only)
- Periodic review of treatment efficacy
- Obtain written informed consent (chronic only)
- Toxicologic drug screens (chronic only)
- Random pill counts (not mandatory)
- Reporting of illegal acts encouraged
- Required compliance with state and federal controlled su bstance laws and CDC guidelines
- CME requirements

Evaluation of Patient

Medical History and Physical

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

Risk Assessment

Before prescribing or increasing the dose of any controlled substances to a patient for acute or chronic pain , a clinician shall perform and document a risk assessment of the patient. The risk assessment is meant to determine whether the potential benefits of prescribing controlled substances outweighs the risks, and 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.

Risk Assessment

For the treatment of chronic pain, the use of an appropriate risk screening tool is encouraged. The following factors ~~shall~~ should 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.

Risk Assessment continued

(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.

<u>The clinician shall document in the patient's medical record a statement that the risks and benefits have been assessed.</u>

Additional Provisions

- “Inherited patients” must be re-assessed (chronic only)
- Prescribe lowest dose possible
- Prescribe immediate-release opioids instead of extended release when first initiating pain treatment
- When prescribing for chronic pain initially, consider it a therapeutic trial for a defined period of time and for no more than 30 days
- Frequency of periodic review of treatment efficacy shall be determined by the patients’ risk factors, the medication dose and other clinical indicators
- Toxicology drug screens at least annually (chronic only)

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
- 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:

- https://www.mainemed.com/advocacy/opioid-crisis
- 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
- Webinars, opioid laws & rules, information on pain management and tapering, etc.

Questions?

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