Maine's New Opioid Prescribing Law & the Opioid Crisis: Implications for Providers

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Disclosure:

"There are no significant or relevant financial relationships to disclose."

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

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272 Lives Lost in 2015

- 272 Mainers lost to opioid/heroin deaths in 2015
- Overdose death rate in Maine increased 31% from 2014 to 2015
- Maine leads nation in rate of long-acting opioid prescriptions

1013 Maine Babies Affected in 2015

- 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 2015

Facing the Opioid Crisis Today

- Opioid abuse epidemic gains attention of state and federal policymakers throughout 2015
- About a half dozen relevant bills submitted for consideration by the 127th Maine Legislature during the 2016 session
- Opioid abuse issue has substantial political energy behind it; legislative action seemed certain from the session's start
- MMA and other advocates sought health care practitioner licensing board regulatory action rather than legislative intrusion into the physician-patient relationship
- Finally, preventing legislative action not a realistic strategy; MMA and other advocates successfully moderated LePage Administration proposal through lengthy negotiations

Key Bills in 2016 Session

- LD 1537, *An Act To Combat Drug Addiction through Enforcement, Prevention, Treatment and Recovery* (PL 2015, Chapter 378) – submitted by Speaker of the House and President of the Senate
- LD 1646, *An Act To Prevent Opiate Abuse by Strengthening the Controlled Substances Prescription Monitoring Program* (PL 2015, Chapter 488) - introduced by the Governor to provide limits on the prescription of opioids
- LD 1648, *An Act To Amend the Laws Governing the Controlled Substances Prescription Monitoring Program and To Review Limits on the Prescription of Controlled Substances* – introduced by Sen. Roger Katz (R-Kennebec) as an alternative to LD 1646; did not pass, but some concepts included in final version of LD 1646

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Overview of Chapter 488

- **Effective 90 days after adjournment, though some provisions have other timeframes specified (July 29, 2016)**
- **Components include:**
  - Required PMP check for prescribers and dispensers
  - Prescribing limits on MMEs per day
  - Prescribing limits on length of scripts
  - Exception for emergency rooms, inpatient hospitals, long-term care facilities, or residential care facilities
  - Exception for medication-assisted treatment for substance use disorder
  - Exception for active and aftercare cancer treatment, palliative care, and end-of-life and hospice care
  - Other exceptions may be determined by rule
  - Mandatory CME
  - Mandatory electronic prescribing
  - Partial filling of prescriptions at patient request

Key Definitions

- **Acute pain**
  - Normal, predicted physiological response to a noxious chemical or thermal or mechanical stimulus.
  - Typically associated with invasive procedures, trauma and disease and is usually time-limited.
- **Chronic pain**
  - Persists beyond the usual course of an acute disease or healing of an injury.
  - May or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years

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Key Definitions

- **Prescriber**
  - Licensed health care professional with authority to prescribe controlled substances
  - Includes veterinarians
- **Administer**
  - Action to apply prescription drug directly to a person
  - Does not include delivery, dispensing, or distribution of a prescription drug for later use

Key Definitions

- **Palliative care**
  - Patient-centered, family-focused medical care that optimizes quality of life by anticipating, preventing, and treating suffering caused by 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
  - Manages pain and symptoms comprehensively

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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

Prescriber Responsibilities

- Required PMP check
  - Upon initial prescription of benzodiazepine or opioid medication
  - Every 90 days following
- Exception
  - 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, or a residential care facility

Prescriber Responsibilities

- **Electronic Prescribing**
  - Beginning July 1, 2017, prescribers with the capability to electronically prescribe must prescribe all opioid medication electronically
  - A waiver may be available in some circumstances
- **Continuing Education**
  - A prescriber must complete 3 hours of CME on the prescription of opioid medication every 2 years as a condition of prescribing opioid medication

Prescription Limits

- **Morphine Milligram Equivalents (MMEs)**
  - **New** opioid patients after effective date of law (July 29, 2016)
    - May not prescribe any combination of opioid medication in an aggregate amount of more than 100 MMEs per day
  - **Existing** opioid patients with active prescription in excess of 100 MMEs per day as of effective date of law ("Legacy patients")
    - From effective date of law (July 29, 2016) until July 1, 2017, may not prescribe any combination of opioid medication in an aggregate amount of more than 300 MMEs per day
  - **Exception** for medical necessity documented in the medical record until January 1, 2017 or the effective date of DHHS rulemaking on exceptions, whichever is later

Prescription Limits

- **Acute Pain**
  - Script may not be written for more than 7-day supply within a 7-day period
- **Chronic Pain**
  - Script may not be written for more than 30-day supply within a 30-day period
- Scripts may be renewed without limit based on medical necessity
- Limits apply only to opioid medications

Prescription Limit Exceptions

- When prescribing for:
  - Active or aftercare cancer treatment
  - Palliative care
  - End-of-life and hospice care
  - Medication-assisted treatment for substance use disorder
  - Other circumstances determined by rulemaking
- When directly ordered or administrated in:
  - An emergency room
  - An inpatient hospital
  - A long-term care or residential care facility

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Partial fill

Upon patient request, pharmacist may dispense lesser quantity of medication than is prescribed

- Remainder of prescription is void
- Pharmacist must, within 7 days, notify prescriber of quantity actually dispensed
- Notification may be by notation in patient's EHR, by electronic transmission or fax or telephone

Deadlines

- **Effective date is 90 days after adjournment (July 29, 2016)**
- **January 1, 2017**
  - Mandatory checks of the PMP
  - Limits on scripts for acute and chronic pain
- **July 1, 2017**
  - Mandatory electronic prescribing
  - Patients with active prescriptions in excess of 100 MMEs must be tapered to an aggregate amount of 100 MMEs or less per day
- **December 31, 2017**
  - CME requirement

Penalties

- Civil violation
- Subject to fine of $250 per incident up to a maximum of $5000 per calendar year
- **But** no penalties may be imposed for violating prescribing limits until PMP enhancements are implemented

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Other Provisions

- Prescription Monitoring Program (PMP)
  - PMP data access by certain hospital and pharmacy staff and a province of Canada
  - Automatic registration of pharmacists and veterinarians
  - “Enhancements” to PMP
    - “Dosage converter” to/from MME
    - Automatic distribution of de-identified peer data to prescribers annually
    - Improved delegation to non-prescriber staff
    - Improved speed and communication
- DHHS and Bureau of Insurance reporting requirements

LD 1547
PL 2015 c. 508

An Act to Facilitate Access to Naloxone Hydrochloride

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Effective Dates

Statute: July 29, 2016

Pharmacy Rules: No later than July 1, 2017

Not yet proposed

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What is Naloxone?

- Highly specific, high-affinity opioid antagonist used to reverse effects of opioids (including respiratory depression)
- Effects last 30-90 minutes
- In 2014, 829 patients in Maine received naloxone from EMS responders
- Can be safely & effectively administered by lay persons

Forms available

- Injectable
- Prefilled intranasal syringe
- Nasal spray
- Auto injector

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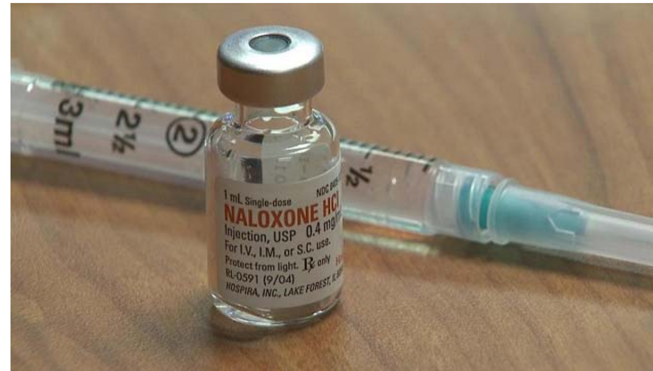
Injectable



Naloxone HCI (vial) $26.48

IM injection (3ml, 25g 1″ syringes recommended) 0.4mg/1ml

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Prefilled syringe (intranasal)

Naloxone HCl (prefilled syringe) $22.32

Mucosal atomization device 2mg/2ml

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Nasal spray

Narcan nasal spray $132.50

Nasal spray 4mg

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Auto-injector

Evzio auto-injector $3743.00 (not a typo!)

Auto-injector 0.4mg

23 MRSA §2353

Subsection 2:

A pharmacist may dispense naloxone according to rule-based protocol:

- to a person at risk of an opioid overdose
- To a family member or friend or "another person in a position to assist" a person at risk
- If prescribed or provided, person may administer if good faith belief of overdose

23 MRSA §2353

Subsection 3:

- A law enforcement agency or fire department may obtain a supply of naloxone and may administer **if trained to do so** according to protocols of Medical Direction and Practices Board *(EMS governing body)*

23 MRSA §2353

Subsection 5:

Immunity from criminal & civil liability AND professional discipline

- Immunity for **healthcare professional or pharmacist** storing, dispensing or prescribing
- Immunity for "**person acting in good faith and with reasonable care**" possessing, providing or administering
  - Requires good faith belief of overdose

32 MRSA §13815

Pharmacy board to establish procedures and standards to authorize pharmacists to dispense naloxone by **prescription** or **standing order** or **collaborative practice agreement** (with person authorized to prescribe drugs).

Rule must establish **training requirements and protocols for dispensing.**

PMP ACCESS

DHHS: https://mepdm-ph.hidinc.com /melogapp/bdmepdmqlog/pmqaccess.html

HealthInfoNet: Single click sign-on from inside HIN for registered PMP users

- Contact HealthInfoNet Customer Care at (207) 541-9250 for an HIN account

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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, etc.

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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