Update on Maine Laws and Associated Rules on Prescribing Opioid Medication

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Maine Medical Association
www.mainemed.com

Disclosure

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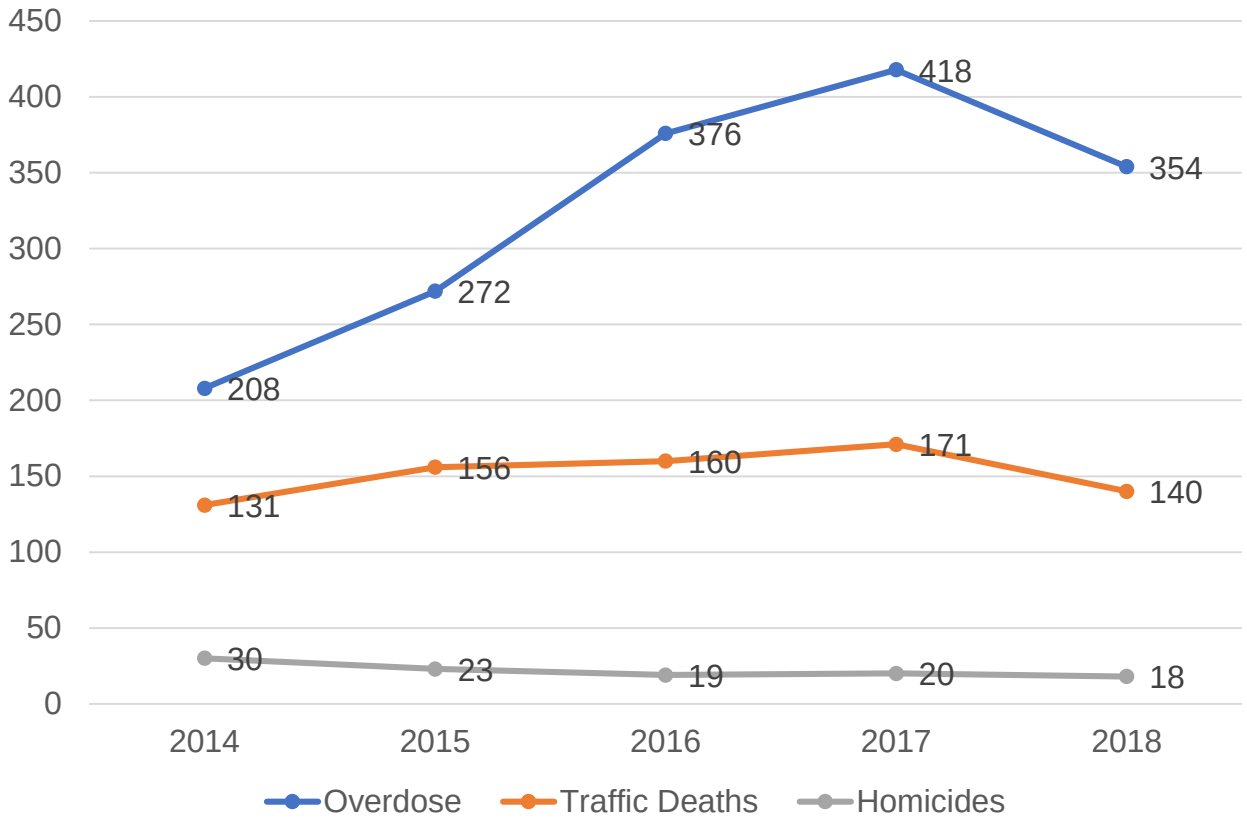
Opioids: the difficult truth

We’re (still) a long way from solving the problem(s).

One Death per Day in Maine

- 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 (27.0 per 100,000) (Nat'l rate 19.8)
- 418 overdose deaths in 2017 (31 per 100,000) (Nat'l rate 21.7)
- 354 overdose deaths in 2018 (26 per 100,000)

Maine Death Rates



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Maine Babies Born Drug Affected

- Maine's 2018 infant mortality rate (5.7/1000) dipped below the national average (5.8/1000) for the first time since 2014

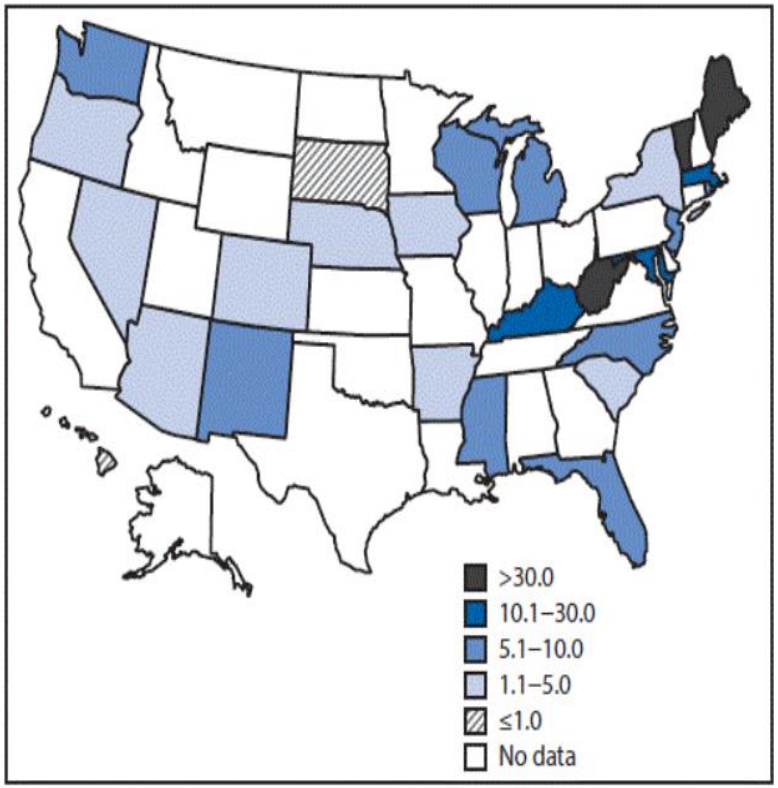
  (source: U.S. CDC)

- 1 out of every 14 babies in Maine was born drug-affected in 2018

- A reduction in 2017 (952) and 2018 (904)…but still too many drug affected babies born each day

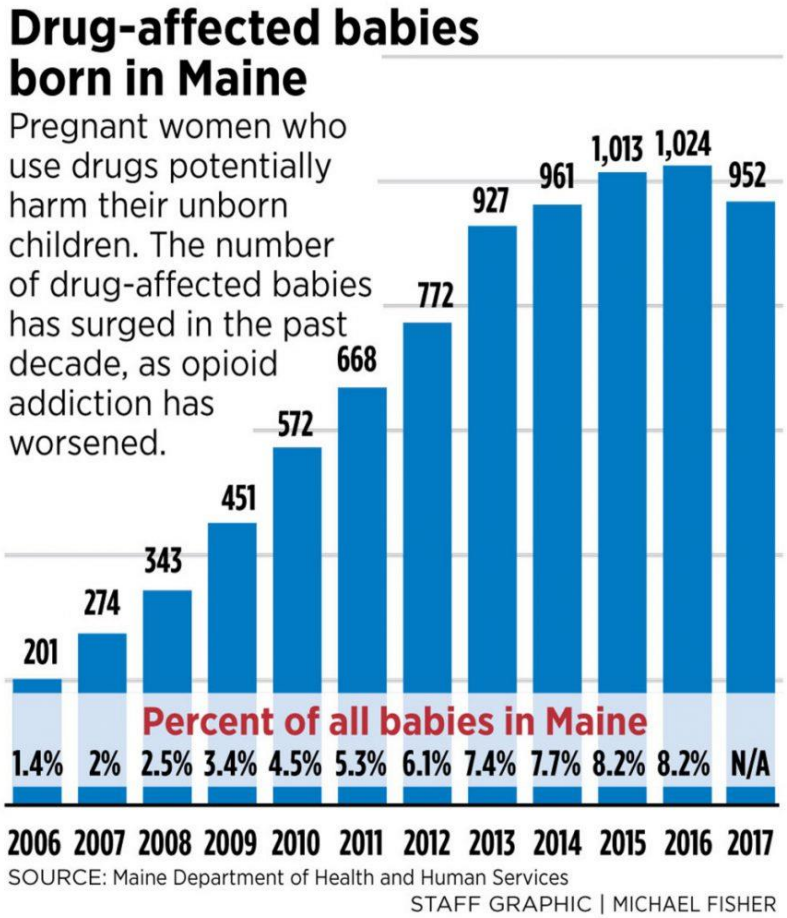
The Opioid Epidemic By the Numbers
Drug-Affected Babies

FIGURE. Neonatal abstinence syndrome (NAS) incidence rates* — 25 states, 2012–2013



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

* NAS cases per 1,000 hospital births.



National Public Health Emergency

- Drug overdose deaths surpassed 70,000 in 2017, an increase of 9.5% from 2016. Over 28,000 deaths involved fentanyl (sharp increase from 2014). 24.2% involved Rx drugs.
- More than 47,000 of 2017 deaths caused by opioids; most involved multiple substances
- One death every eight minutes
- 2016 to 2017 increase primarily driven by a surge in deaths involving synthetic opioids, including fentanyl
- Drug overdoses killed 630,000 people between 1999-2016
- Overdose is the leading cause of death for people under age 50

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Evidence of Over-Prescribing

- **General surgery patients**[2]
  - 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**[3]
  - 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
- **Rates highest in rural counties** (14 of 15 highest-rate counties)

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

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

Why did we need a law?

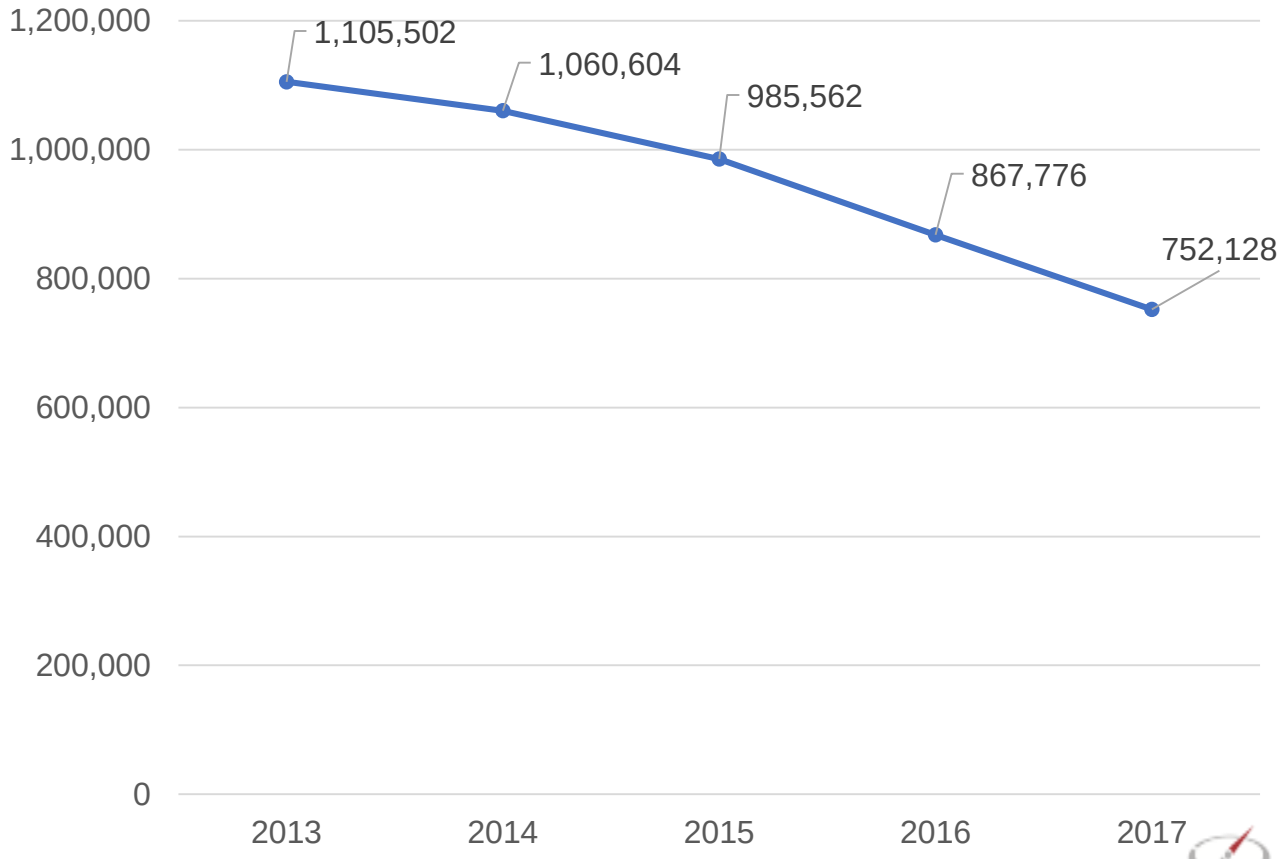
- Over 16,000 Mainers exceeded 100 MME in early 2016
- 1200 exceeded 300 MME

Opioid Medication Prescribing for Pain Declining

- Peaked nationally in 2012 (81.3 per 100 persons)
- Number of high dose prescriptions (greater than 90 MME) fell 41.4% from 2010 to 2015
- Maine led nation in rate of **long-acting** opioid prescriptions at 21.8 Rx/100 persons (2012)
- 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 dosing (largest decline in the nation)
- U.S. rate in 2017: 58.7 per 100 persons)

Maine Opioid Prescriptions 2013 - 2017

(Retail filled prescriptions)



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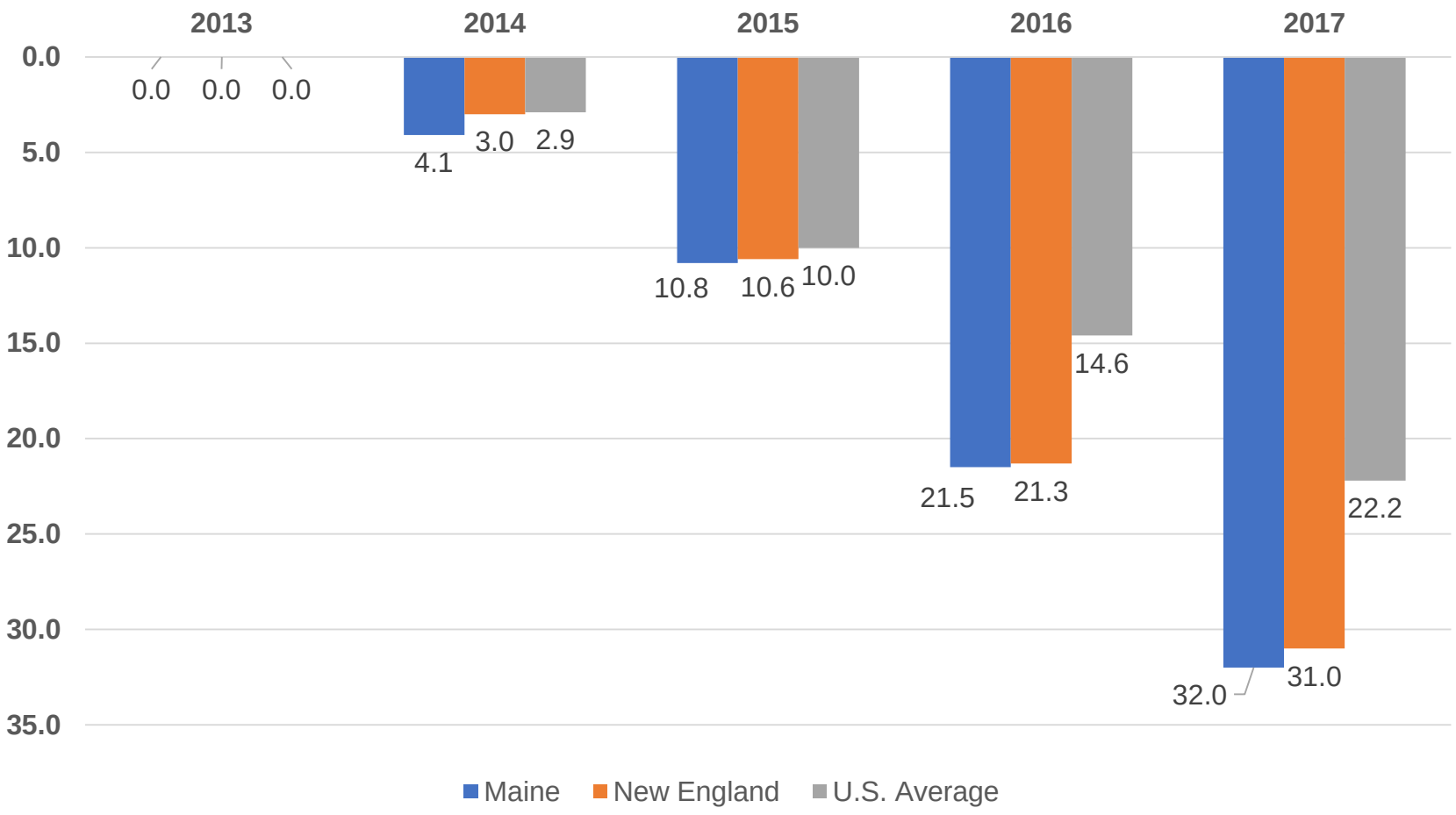
Maine Opioid Prescriptions
2013 - 2017
(% Decrease, 2013=baseline)



Government Actions to Combat the Crisis

Medication Assisted Treatment (MAT):

- Mills administration (DHHS) increases reimbursement rates for providers of MAT
- Increased federal funding: $2.3 million in new federal money to Maine (March 2019)
- *Smith v. Aroostook County*: Federal judge orders continued MAT during incarceration
- Commissioner Randall Liberty (Dept. of Corrections) plans MAT in state correctional facilities

Opioid Health Homes:

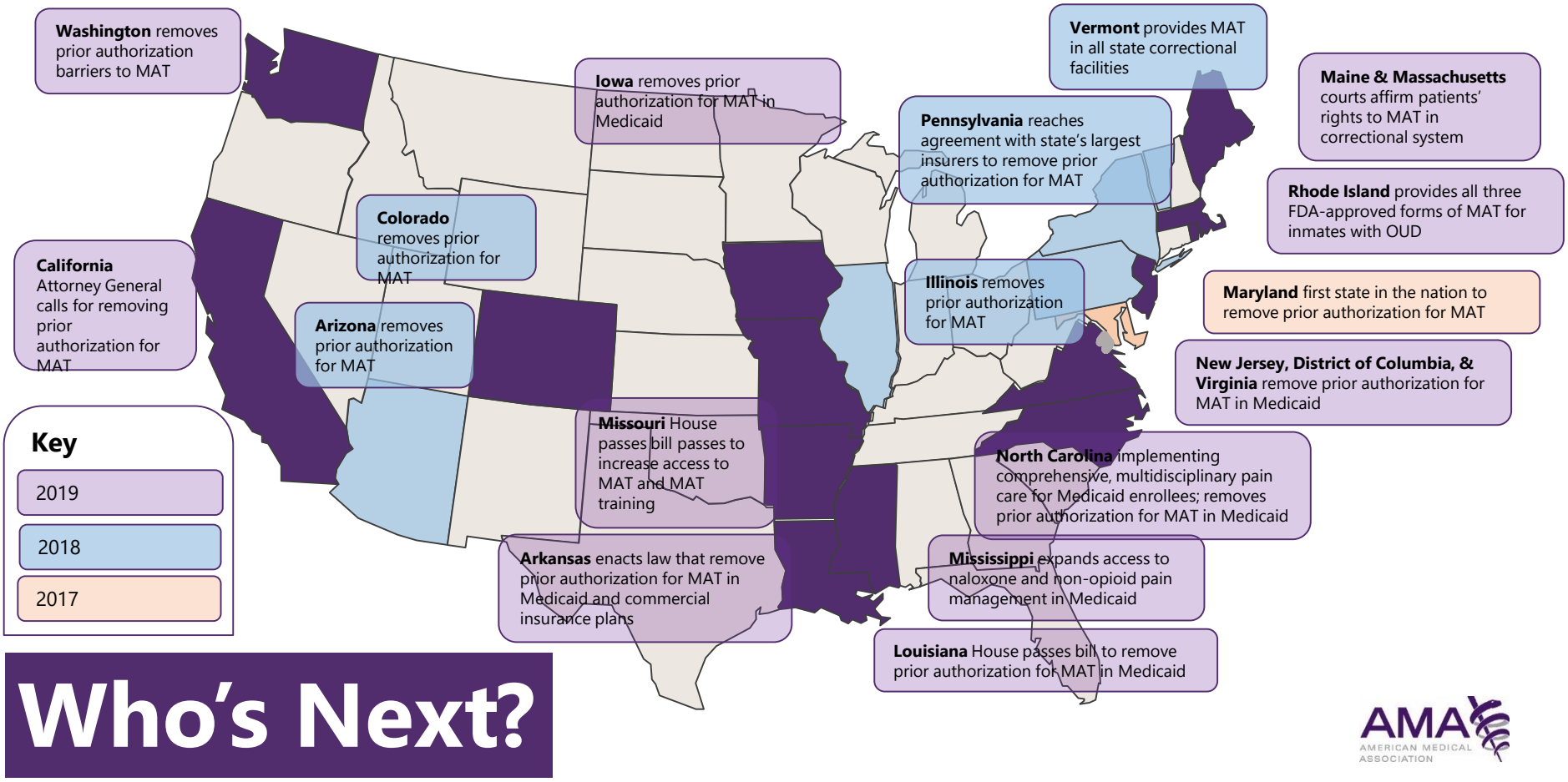
- Integrated care management, office-based MAT, counseling
- Increased funding in 2018
- Now 22 OHH programs (48 locations) in Maine

Medication Assisted Treatment

Obtaining your X-waiver (it's not difficult!)

- Drug Addiction Treatment Act of 2000 (DATA 2000) first allowed prescription of lower risk opioids (buprenorphine) outside opioid treatment programs (methadone clinics)
- "X-waiver" waives special registration requirements
  - Physicians: 8-hour instruction, online application
  - NPs and PAs: 24-hour instruction, online application (CARA Act 2016)
  - Much of the education is free
- Maine 2019:
  - 87 physicians with 30 patients
  - 20 physicians with 100 patients
  - (in 2013, 20/11)

States taking action to end opioid epidemic:



Who's Next?

AMA
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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**

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 also be included on script)**
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

- **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
  - Pharmacists may contact prescribers by telephone to verify and document missing information on the script.

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 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
- Exemption from limits/PMP checks is **NOT** an exemption from E-prescribing requirement

Penalties

- Civil violation
- Subject to fine of $250 per incident up to a maximum of $5000 per calendar year
- 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)

Effective March 24, 2018

- 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)
- Documentation

Patient Evaluation:
1. History & Physical Exam

Documentation required:

(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 outweigh the risks
- Include 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 pain)

Use of an appropriate risk screening tool is encouraged. The following factors 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.
(e) **Regular use** of benzodiazepines, alcohol, or other central nervous system medications.

2. Risk Assessment (chronic)

(f) Receipt of opioids from **more than one prescriber** 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 Required)

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

Treatment Agreement (Violation)

"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."

Documentation

Medical records must include <u>at least</u> 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 "

(It's an EXTENSIVE document!)

Reportable Acts

From the Maine licensing boards' Chapter 21:

"Generally, information gained as part of the clinician/patient relationship remains **confidential**. However, the clinician has an **obligation to deal with** persons who use the clinician to perpetrate illegal acts, such as illegal acquisition or selling of drugs; this **may include reporting** to law enforcement. Information suggesting inappropriate or drug-seeking behavior should be addressed appropriately and documented. Use of the **PMP is mandatory** in this situation."

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:

- 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.

MICIS page:

- https://www.micismaine.org
- Toolkit for prescribers, naloxone information, etc.

Questions?

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