Update on Maine Laws and Associated Rules on Prescribing Opioid Medication

Andrew MacLean, JD
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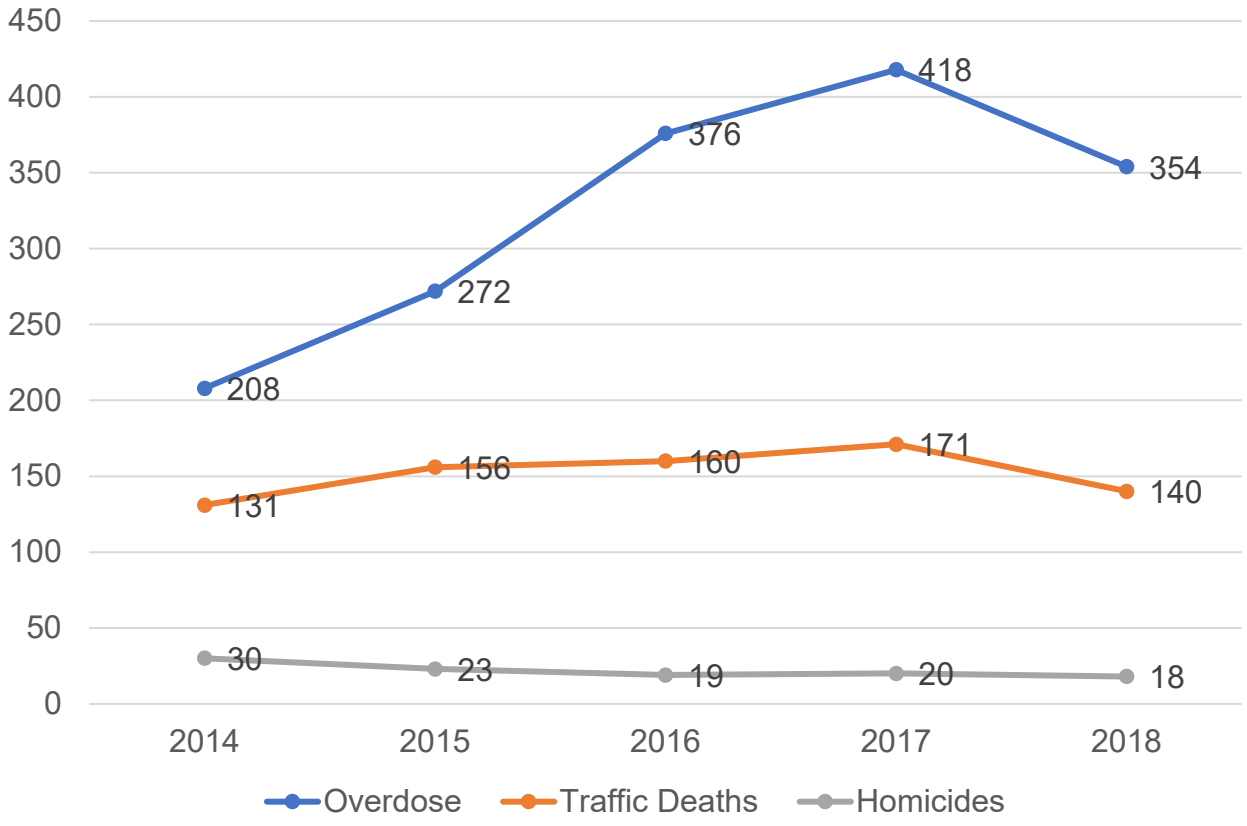
Opioids: the difficult truth

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

Maine Death Rates



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Maine Babies Born Drug Affected

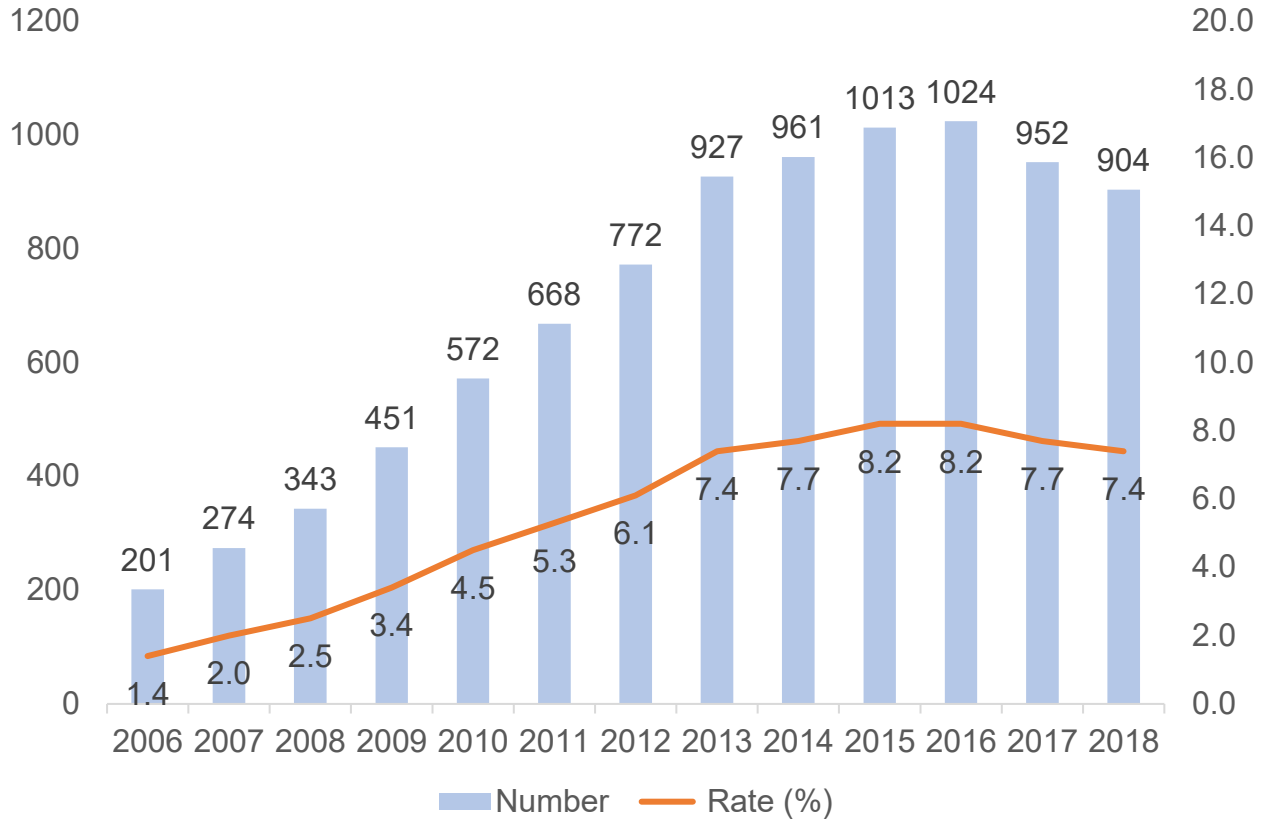
- Maine's 2018 infant mortality rate (5.7/1000) dipped below the national average (5.8/1000) for the first time since 2014

  (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

Maine Drug-Affected Births



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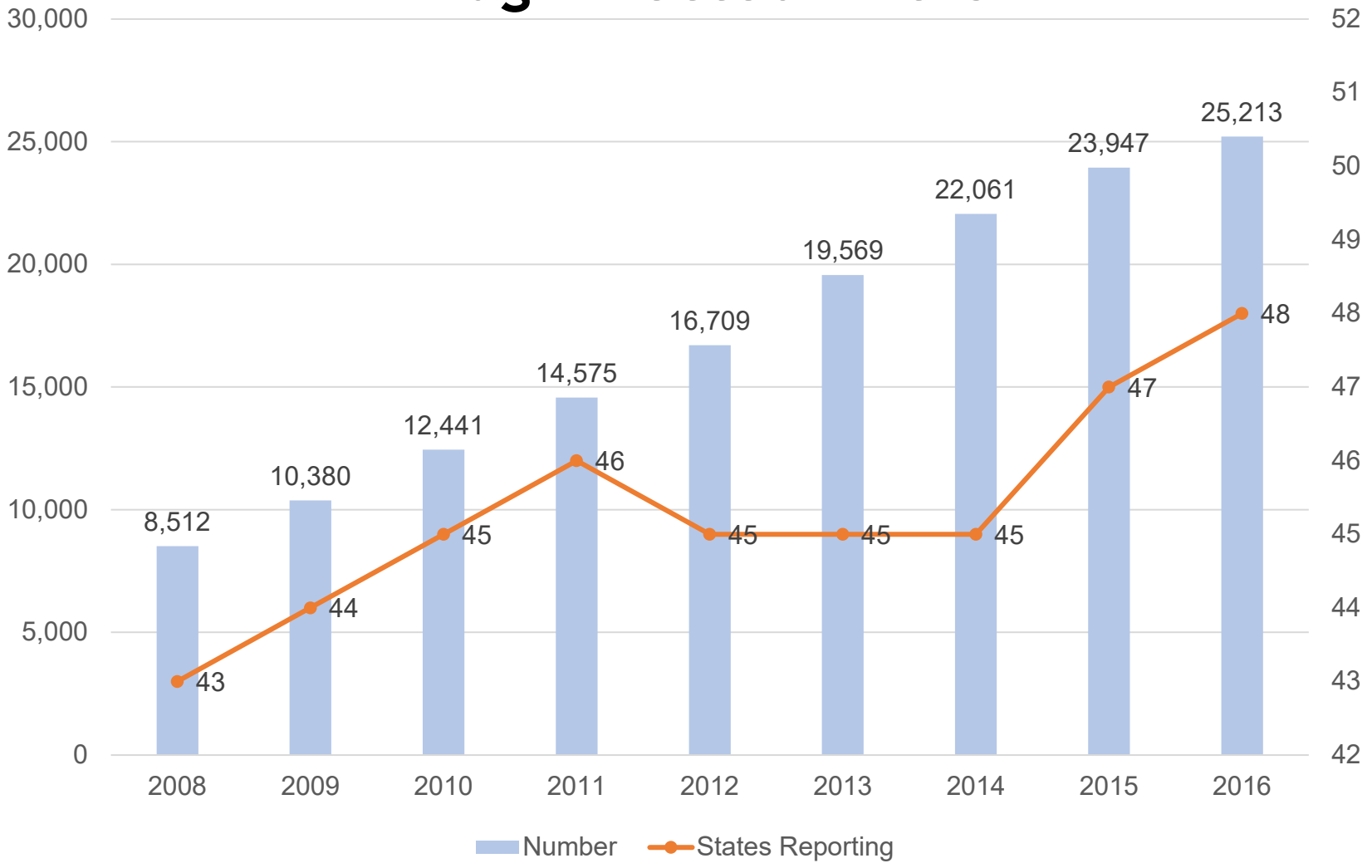
National Numbers: Drug-Affected Births



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 are rural)

[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
- (These figures do NOT include opioids for MAT)

Government Actions to Combat the Crisis

Early 2016

- Governor LePage proposes major opioid prescribing legislation
  - Also establishes Opioid Health Homes
- Intensive negotiations (including MMA)
- Legislature passes PL 2015 ch. 488
  - Effective 7/1/16

2017-2018

- Licensing boards pass Chapter 21
  - Effective 3/24/18

Government Actions to Combat the Crisis

Mills administration names Director of Opioid Response

Opioid Health Homes:

- Integrated care management, office-based MAT, counseling
- Increased funding in 2018
- Now 32 OHH programs (71 locations) in Maine serving 1740 individuals

Medication Assisted Treatment (MAT):

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

Overview of P.L. 2015, Chapter 488

- https://legislature.maine.gov/legis/bills/bills_127th/chapters/PUBLIC488.asp
- Required **PMP check** for prescribers and dispenser (some exceptions)
- Prescribing **limits on MMEs** per day (100)
- Prescribing limits on **length of scripts** (7 days for Acute Pain, 30 days for Chronic Pain)
  - **Exceptions** for emergency rooms, inpatient hospitals, long-term care facilities, or residential care facilities, or in connection with a surgical procedure
  - **Exception** for MAT for substance use disorder
  - **Exceptions** for cancer treatment, palliative care, end-of-life and hospice care, pregnancy, acute-over-chronic, intolerance, active taper
- **Partial filling** of prescriptions at patient request
- **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 E-prescribing

- A few **exceptional circumstances** allow written prescriptions
  - System crash, electrical failure, long term care, Indian Health Service pharmacies, unusual settings, etc.

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

Maine Licensing Boards Joint Rule Chapter 21
(Medicine, Osteopathy, Nursing, Podiatry boards)

Effective March 24, 2018

- https://www.maine.gov/md/laws-statutes/docs/Chapter%2021%20effective%2003.24.18.docx
- 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)

Note on Exemptions

- The licensing boards are in the process of modifying the Chapter 21 rule to exempt custodial care (nursing homes) and hospice care. Changes are also being made relating to cancer care.
- Changes must be approved by all prescriber boards and pass public comment process (opportunity to object/suggest changes)
- Anticipated effective date: by the end of 2019

“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

(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 consults

(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 dose of any controlled substances to a patient for **acute or chronic** pain
- To determine whether potential benefits of prescribing controlled substances outweigh risks
- Include factors involved in 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** 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, other CNS medications.

2. Risk Assessment (chronic)

(f) Receipt of opioids from **more than one prescriber** or group.

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

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

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

(j) Comorbidities that may affect **clearance and metabolism** of 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 determined by the patients' risk factors, medication dose and other clinical indicators (evaluate at least annually for lowest risk patients on lowest doses)
    - **Review must include** changes 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!)

NOTE: This language is due to be changed by the Boards to remove mandatory "shall…follow" language.

Reportable Acts

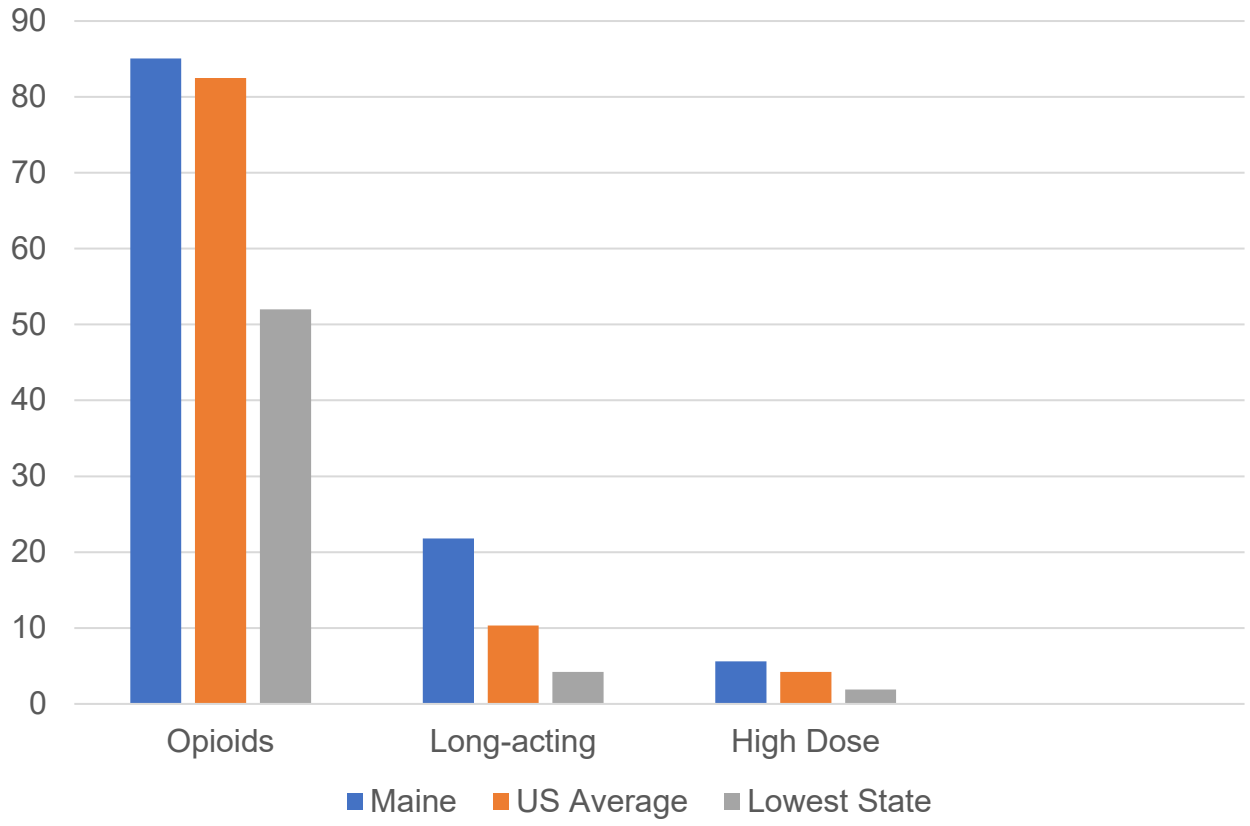
From the Maine licensing boards' Chapter 21:

"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."

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 per 100 persons (2012). US rate was 10.3/100.
- Maine's prescribing declined 32% from 2013-2017, the 5th largest drop in the nation (to 55.7 per 100 persons)
- 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

2012 Opioid Prescribing Rates
(Rx per 100 persons)



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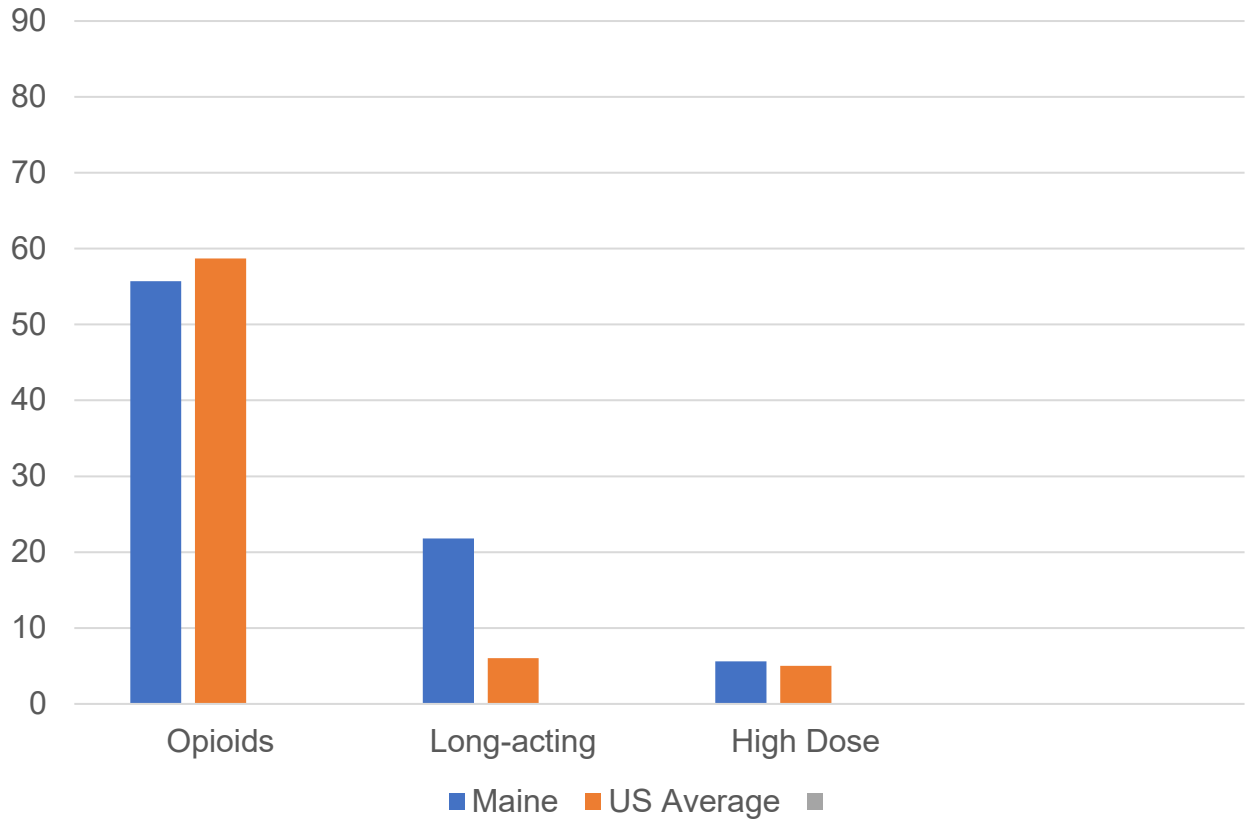
2017 Opioid Prescribing Rates
(Rx per 100 persons)



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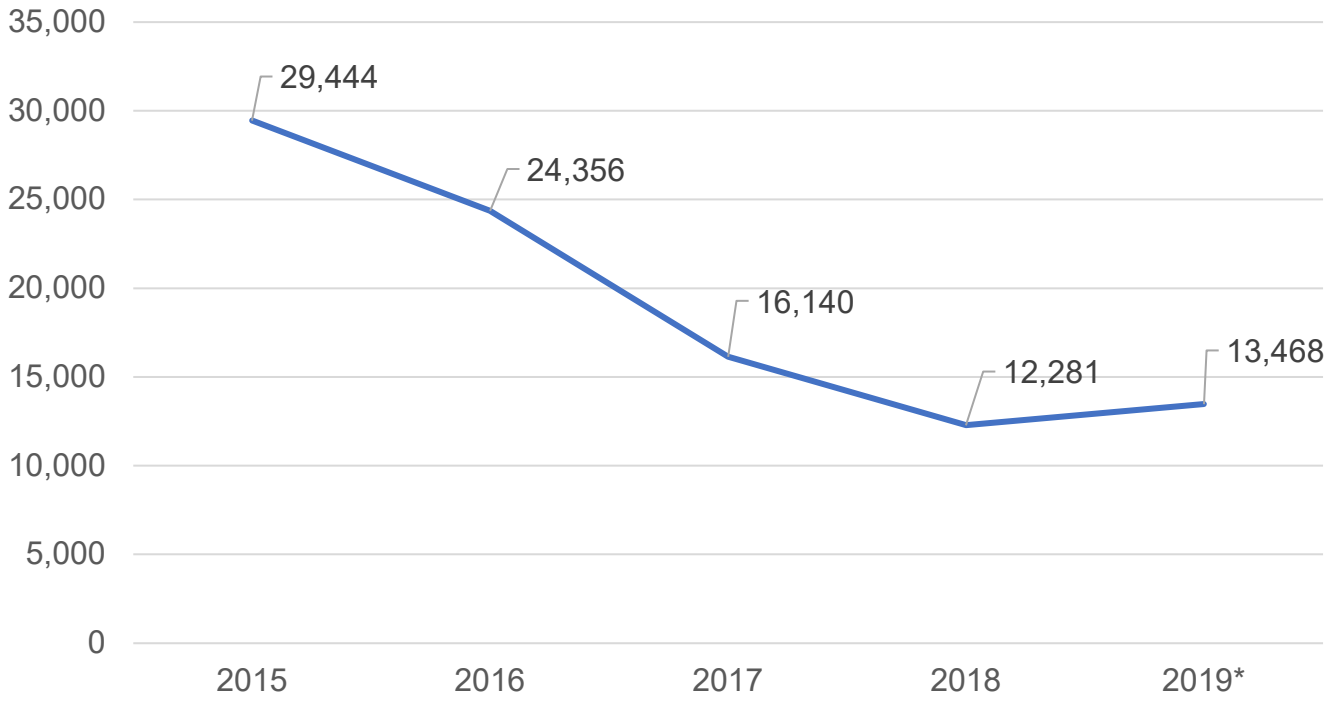
Maine Opioid Patients > 100 MME Daily

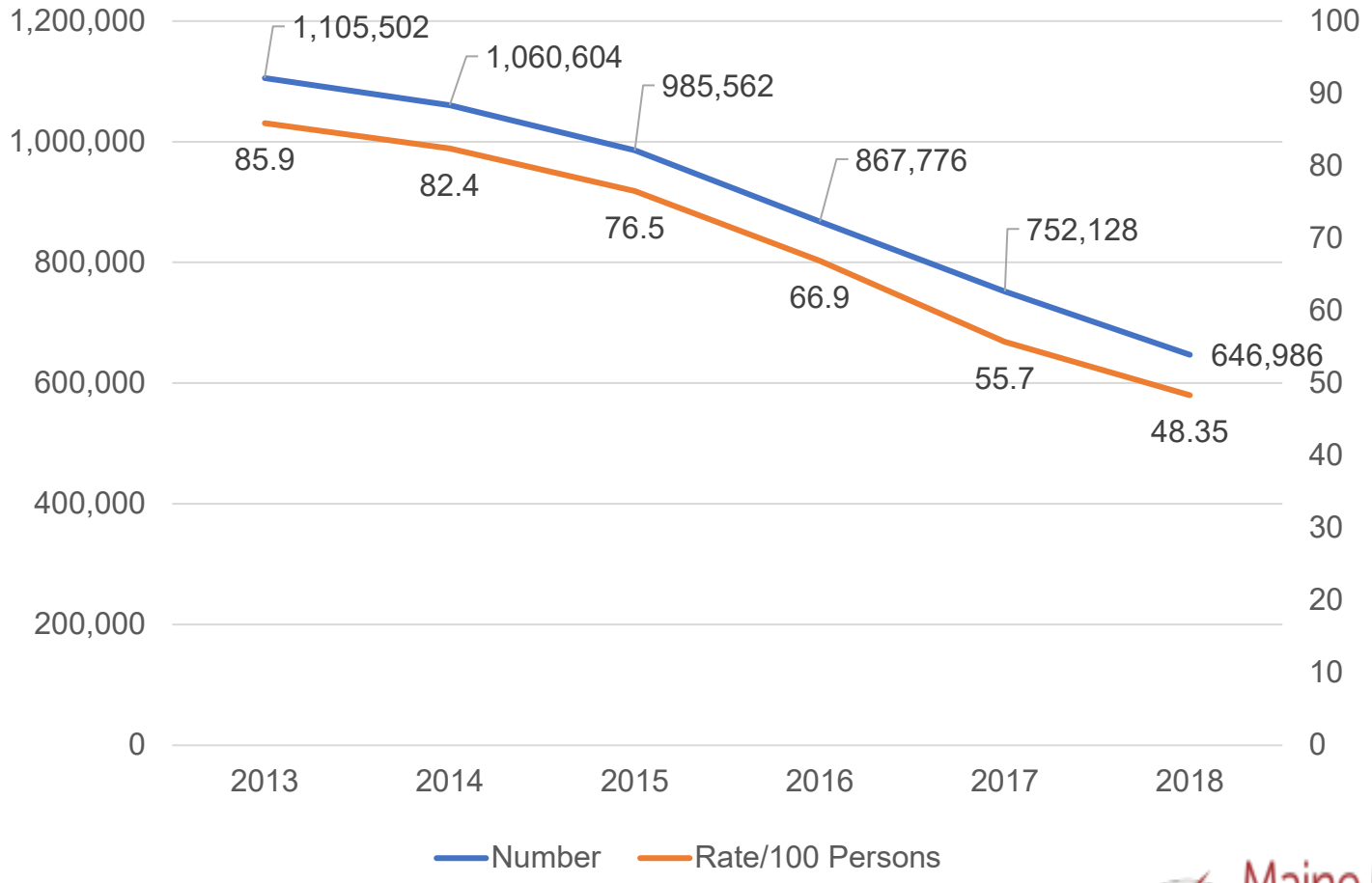
2015 - 2019 (includes MAT)



*2019 estimate based on data through 6/30/19

Maine Opioid Prescriptions 2013 - 2018

(Retail filled prescriptions)



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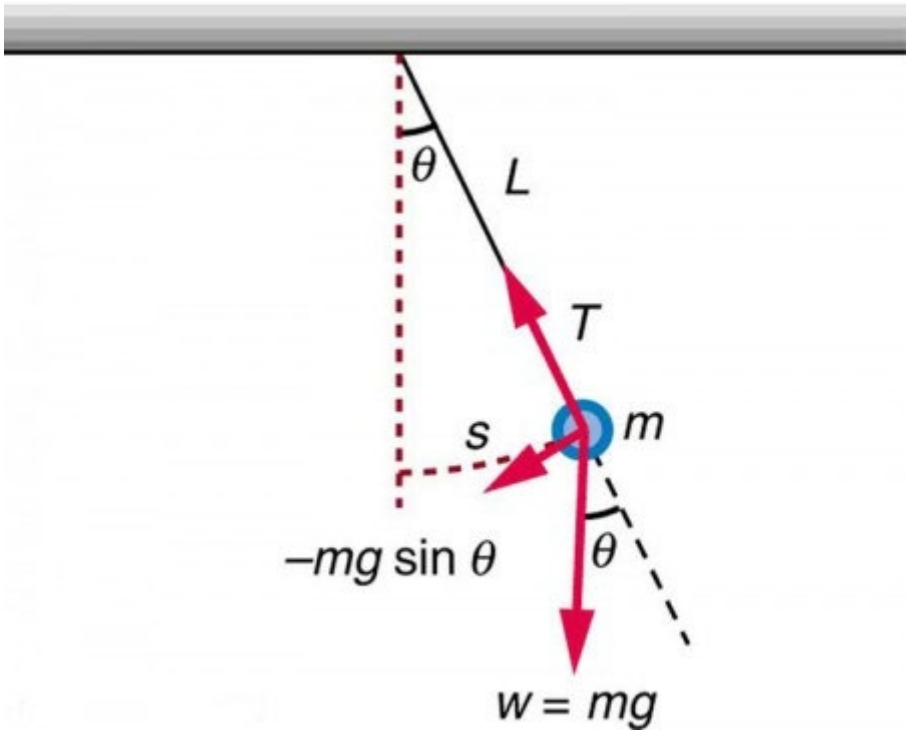
Have We Gone Too Far?



The Ethics of Treating Pain

- Conflicting public health crises: SUD and chronic pain
- “This practice does not prescribe opioids”
- Weaning elderly patients from opioid pain meds
- “Inherited” patients: who wants them?
- “Adequate management of pain is a medical obligation rooted in classical Greek practice”
- “Dilemmas associated with this treatment are best approached using patient-centered clinical ethics” rather than “principle-based, deontological [motivation-based], and classical Hippocratic ethical approaches”

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:
  - 620 physicians can prescribe buprenorphine
    - 2/3 are limited to ≤30 patients
  - 218 NPs, 42 PAs
  - (in 2013, 20 physicians, 0 NPs or PAs)

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?

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

Andrew MacLean, Esq. amaclean@mainemed.com