

K&L GATES

TRIAGE: RAPID LEGAL LESSONS FOR BUSY  
HEALTH CARE PROFESSIONALS



The Opioid Epidemic: Laws  
Impacting Prescribers and  
Care Givers

Carla M. DewBerry

## INTRODUCTION

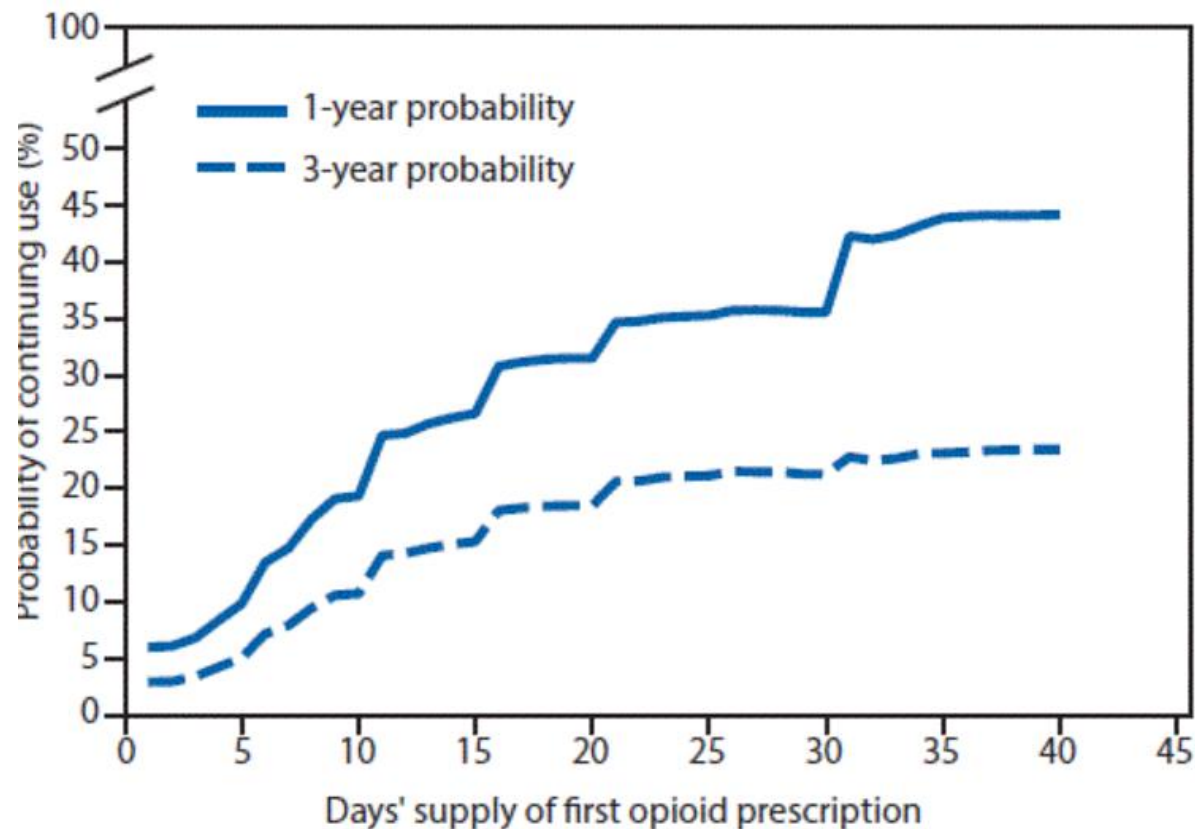
This segment is the first in a series focused on the opioid crisis. Over the course of this series, we will examine various legal and regulatory considerations of the opioid crisis.

This episode will focus specifically on the laws and regulations impacting health care providers who care for patients who may be at risk of opioid addiction.

## WHY ARE OPIOIDS A CHALLENGE?

- Opioids are commonly prescribed for pain.
- No historic consensus among clinicians on how to use opioids in pain management.
- Drug and alcohol abuse is often complex.
  - It is not difficult to become opioid dependent.

# WHY ARE OPIOIDS A CHALLENGE?



One- and 3-year probabilities of continued opioid use among opioid-naïve patients, by number of days' supply\* of the first opioid prescription — United States, 2006–2015.

Source: Centers for Disease Control and Prevention (2017)

## THE TWO GOALS OF NEW LAWS

- Reverse overdoses.
- Prevent and remediate dependency.

## REVERSE OVERDOSES

- Naloxone is a medication which reverses an overdose.
- Naloxone is a prescription drug.
  - Problem: State prescription laws.
  - Problem: Fears of liability.

# ACCESS TO NALOXONE

- Solution: Laws addressing access in all 50 states (but approaches differ).
- Solution: Good Samaritan laws (majority of states).

## EXAMPLE: OREGON LAW

- Pharmacy or health care professional can dispense unit-of-use packages of naloxone to trained lay people;
- A trained lay person is immune from civil liability for any act or omission committed during the course of providing the treatment pursuant to the authority granted by state law, if:
  - the person is acting in good faith, and
  - the act or omission does not constitute wanton misconduct.



# THE TWO GOALS OF NEW LAWS

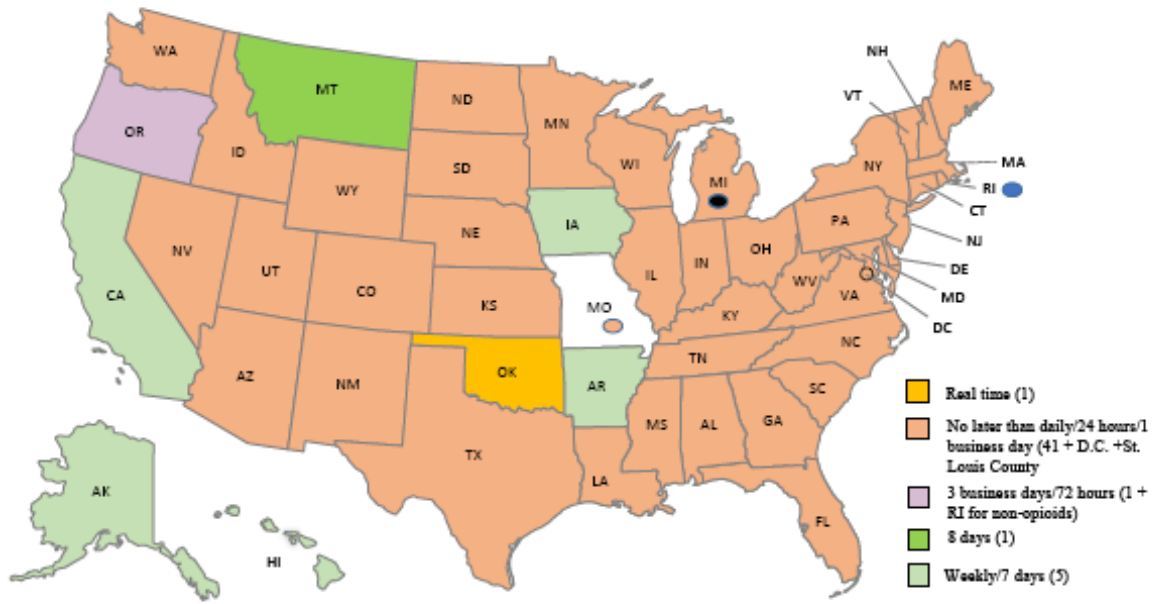
- Reverse overdoses.
- **Prevent and remediate dependency.**

# DEFINITIONS

- Acute Pain: Pain, whether resulting from disease, accident, trauma, or other cause, that the practitioner reasonably expects to last for three months or less.
- Chronic Pain: Pain that typically lasts for longer than three months or that lasts beyond the time of normal tissue healing.
- Exceptions Based on Diagnosis: Pain being treated as part of cancer care, hospice care, palliative care, or medication-assisted treatment for substance use disorder.

# STATES ENACT PRESCRIPTION MONITORING PROGRAMS (PMP)

**Frequency of Data Reporting Authorized by Bill/Statute/Rule/Ordinance\***  
 (exceptions for veterinarians or others may apply; effective dates may vary)



● Michigan requires daily reporting for online reporting of dispensing information and weekly for mail-in submission of data.  
 ● Rhode Island's daily reporting requirement applies to opioid prescriptions. Data for non-opioid prescriptions must be reported 3 business days/72 hours after dispensing.  
 \* PLEASE NOTE: Preparation for implementation may result in a time difference between the enactment or effective date and the date of implementation of the reporting frequency.

## PMP EXAMPLE: NORTH CAROLINA

- Limits on prescriptions;
- Notices to practitioners;
- Required practitioner review of data base;
- Department of Health and Human Services;
  - Audits of use of data base by prescribers, allows report of prescribers in violation to the North Carolina Medical Board;
- Eventual mandated e-prescribing.

## PMP EXAMPLE: WASHINGTON

- Data base which allows access to information re: some prescriptions and medications dispensed;
- Data may be available to:
  - Professional licensing, certification or regulating agencies/entities;
  - Law enforcement
  - Medicaid agency (limited uses, not including value-based purchasing)
  - Health care provider group (limited uses)

# REGULATING PROVIDERS TO PREVENT AND REMEDIATE

- Weeding out pill mills.
- Using licensing and other state laws.
- Investigations.

# REGULATING PROVIDERS

- Attorney's General vow to;
  - Work with institutional stakeholders (including State Insurance Commissioners)
  - Review incentive structures in an effort to identify those practices that are conducive to these efforts and those that are not.

## WHAT MAY BE COMING

- National principles of care for substance use disorder treatment.
- Insurance companies removing certain drugs (such as OxyContin) from the formulary.
- Kickback enforcement, including
  - Office labs using point of care testing cups.
- Federal funding of state efforts.



# FEDERAL FOCUS - ADDICTION RECOVERY

- Federal funding to states
  - Opioid State Targeted Response (STR) grant funding

# FEDERAL FOCUS - ADDICTION RECOVERY

- HHS five-point Opioid Strategy
  - 1) Improving access to prevention, treatment, and recovery support services, including medication-assisted treatment;
  - 2) Promoting the targeted availability and distribution of overdose-reversing drugs;
  - 3) Strengthening public health data reporting and collection;
  - 4) Supporting cutting-edge research on addiction and pain; and
  - 5) Advancing the practice of pain management

## NEW SAMHSA REGULATIONS

- Substance Abuse and Mental Health Services Administration's (SAMHSA) new regulations governing the Confidentiality of Substance Use Disorder Patient Records.
- Goal
  - Better align the regulations with advances in the U.S. health care delivery system while retaining important privacy protections.
- Addressed in our next pod cast.

## Today's Presenter



**Carla M. DewBerry**

Seattle

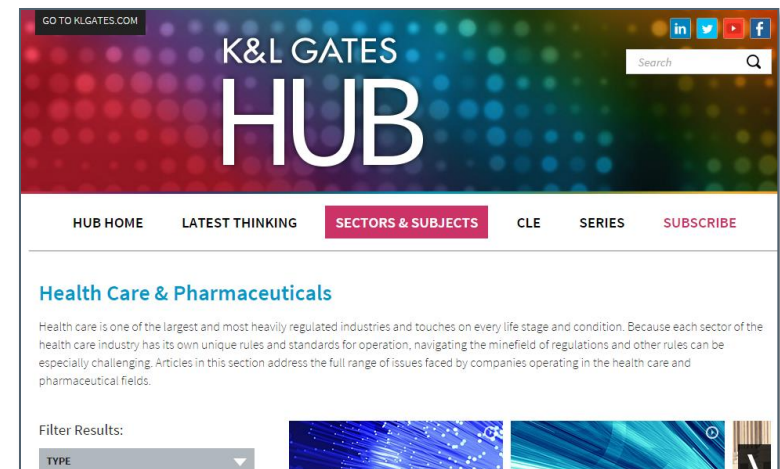
+1.206.370.8317

Carla.DewBerry@klgates.com

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