

The Opioid Crisis: Creating Opportunity and Managing Risk

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Agenda

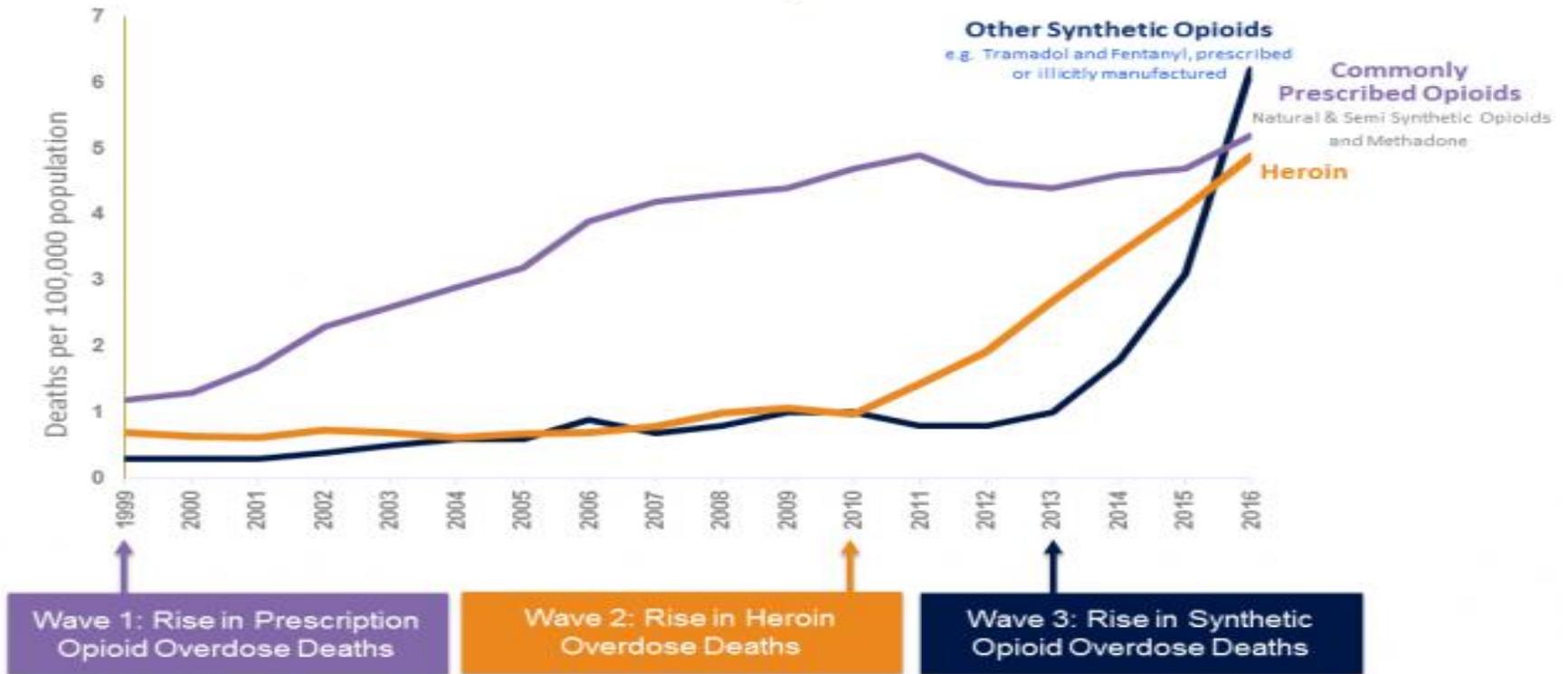
- Overview of the underlying causes and nature of the opioid crisis
- Key laws and regulations
- State and federal opioid litigation
- Role of health plans in existing or potential future opioid litigation
- Health plan success stories

The Causes



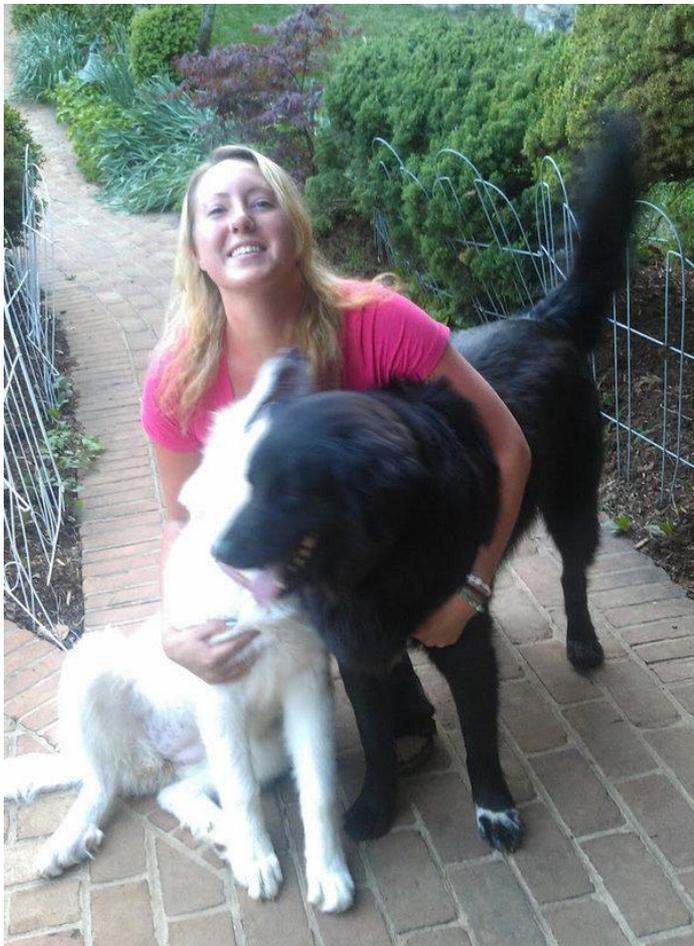
The Numbers

3 Waves of the Rise in Opioid Overdose Deaths



SOURCE: National Vital Statistics System Mortality File.

The Names: Asa, Tess, and Prince



Regulatory

FDA & CDC

- Approval of drugs to market and approved indication use
- REMs program requirements for high risk medications

DEA & Controlled Substance Act

- Controlled Substance Act and drug classification for C1-V
- Dispensing guidelines vary based upon CII-Cv
- Issuing license to prescribe controls
- Regulatory oversight and enforcement

Professional Standards & Licensure

- Board certification and licensure and re-licensure
- Continuing education credits
- “ Do no Harm”

Key Laws and Regulations

ACA

- Medicaid Expansion
- Essential Health Benefits
- Mental Health Parity

CARA

- Funding for programs to reduce the impact of opioids.
- Expanded buprenorphine access

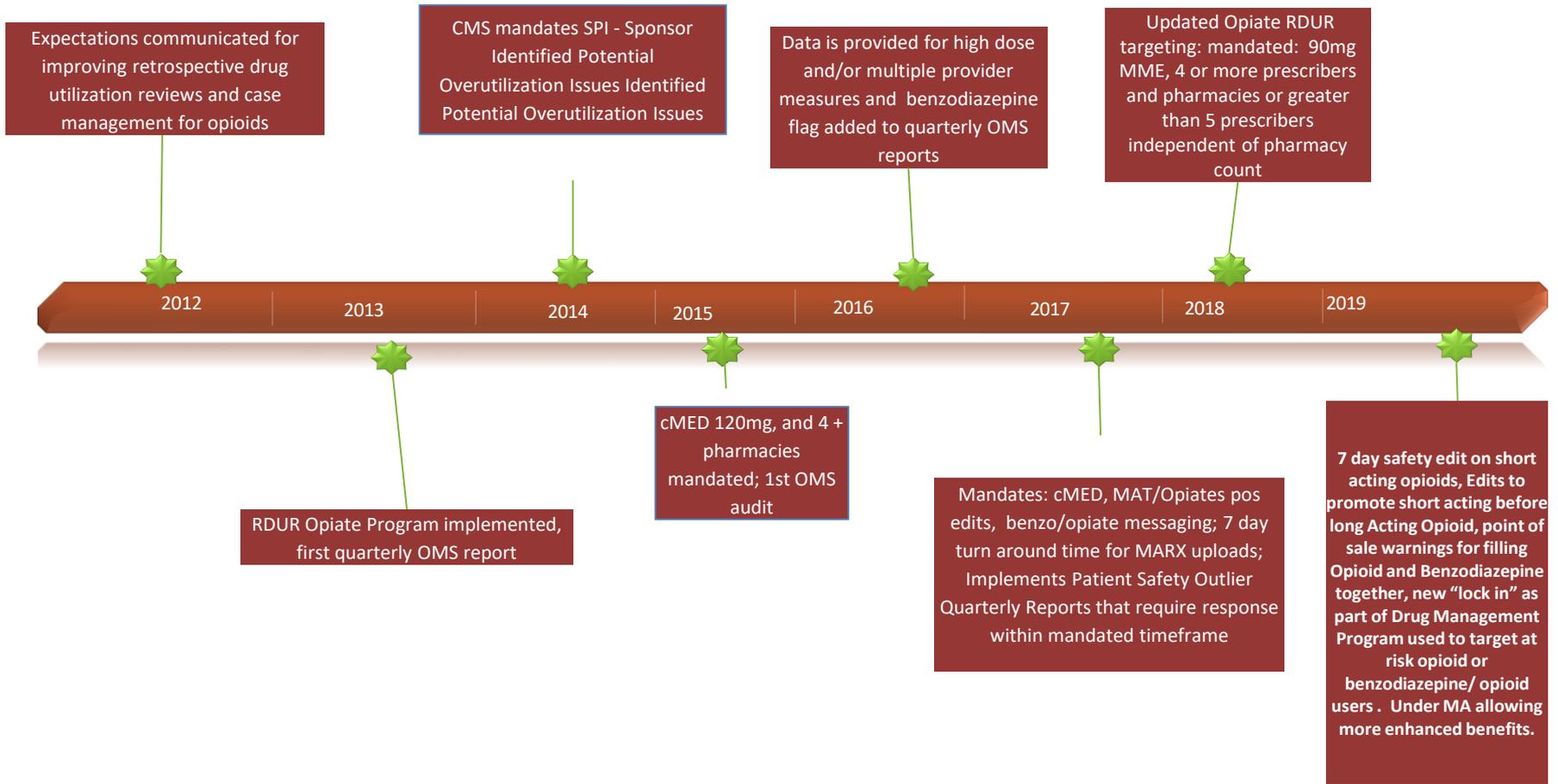
21st Century Cures Act

- Funding
- Medicaid
- Parity
- MA Risk Adjustment
- Part D

Medicare Part D

- Part D insurers may cover opioids, as well as many non-opioid pain medication options, including abuse deterrent formulations
- Medically necessary Part D drug therapies for opioid dependence are covered.
 - Suboxone (buprenorphine and naloxone), Zubsolv, Sublocade,
 - Methadone (when used to treat pain, but not opioid dependence)
- Utilization Management
 - Prior Authorization
 - Quantity Limits
- Point of Sale edits and messaging
- Retrospective Drug Utilization Review
- Data Sharing: Overutilization Monitoring System
- Concern:
 - Fraud, abuse, and misuse of opioids obtained under Part D and redirection of prescription drugs for illegal purposes
 - Clinical case management of health and safety risks of overuse
 - Not blocking access by those who need opioids

Evolution of Medicare Part D and Opioid Controls



Medicare Part D: Controlling Access

Point of Sale Edits

Naïve Patients

Hard safety edit to limit first time Rx fill to 7 day supply

Chronic Users

Soft edit: 90mg
 Hard edit: 200 mg
 Care Coordination and Safety Edits

Concurrent Users

Safety edits for opioids +benzodiazepines or buprenorphine

“Lock In” for High Risk Users

Plans are asked to identify members at risk for adverse drug outcomes from opioids using the following criteria:

- use of opioids with an average MME greater than or equal to 90 mg for any duration during the most recent six months **and**
- either 3 or more opioid prescribers and 3 or more opioid dispensing pharmacies or 5 or more opioid prescribers, regardless of the number of dispensing pharmacies
- Optional: any MME and 7 or more prescribers or pharmacies
- Exempted beneficiaries: hospice, long-term care facility (with single pharmacy), and cancer patients

Lock-In

KEY: Prescriber outreach, case management, coordination of care.

- After identification, (detailed) notice, case management, and waiting-period, Plan can limit access through:
 - Pharmacy lock-in and,
 - As a last resort, prescriber lock-in.
- Maximum 12- month lock-in (renewable)
- Data disclosure and sharing among CMS and plans
- Special enrollment period for low-income subsidy eligible beneficiaries is not available for those who are identified as potentially at-risk.



Medicare Advantage



- New flexibility for supplemental benefits in 2019
 - “Primarily health related” includes medically approved non-opioid pain management services.
 - Reinterpreted uniformity requirement: targeted benefits for identified disease states, including opioid dependency
 - Methadone in MAT as a supplemental benefit
- Bipartisan Opioids Bill.....

The State Approach

- Prescription Drug Monitoring Programs/ Controlled Substance Reporting Systems
 - Mandatory
 - Comprehensive and ongoing
- Opioid Prescription Limits
 - 3-7 day supply and/or MMEs
- Prescriber and dispensing restrictions and requirements
 - Electronic prescribing
- Naloxone access and harm reduction provisions
- Medicaid

Pause: HIPAA Privacy Rule

- Defines and limits the circumstances in which an individual's protected health information may be used or disclosed by covered entities:
 - As the Privacy Rule permits or requires; or
 - As the individual authorizes
- Permission examples:
 - Treatment, Payment, and Health Care Operations
 - Public Health Activities
 - Health Oversight Activities
- Concerns: Patient healthcare information ends up in the hands of law enforcement or patient's employer leading to patient being punished.

HIPAA Privacy Rule

10/27/17: OCR released new guidance on when and how healthcare providers can share a patient's health information when that patient may be in crisis and incapacitated, such as during an opioid overdose.

- <https://www.hhs.gov/sites/default/files/hipaa-opioid-crisis.pdf>

12/18/17: OCR launched an array of new tools and initiatives in response to the opioid crisis while implementing the 21st Century Cures Act. OCR continues its work to ensure that patients and their family members can get the information they need to prevent and address emergency situations, such as an opioid overdose or mental health crisis

- <https://www.hhs.gov/about/news/2017/12/18/hhs-highlights-office-civil-rights-ongoing-response-opioid-crisis-implementing-21st-century.html>



Part 2

- Generally: Part 2 governs the use and disclosure, by federally-assisted substance use disorder facilities and other lawful holders (like third-party payers), of records and patient identifying information that would identify the patient as having a substance use disorder, either directly or indirectly [42 CFR 2.12]
- Purpose: eliminate the negative consequences that can impact individuals with substance use disorders, allowing those individuals to seek treatment without fear of reprisal
- Practically: very restrictive in disclosures allowed – more restrictive than HIPAA. Consult with your Privacy Officer.

Part 2, too.

- January 3, 2018 SAMHSA Final Rule
 - Builds on January 18, 2017 Final Rule updating 42 CFR Part 2, which addressed Confidentiality of Substance Use Disorder Patient Records held by substance abuse disorder treatment programs receiving federal financial assistance
- Key Changes:
 - Provides examples of permissible payment and health care operations activities for which disclosure without patient consent is permitted in the preamble.
 - Permits disclosures to contractors, subcontractors, and legal representatives for purposes of carrying out certain audits and evaluations.

Safe Disposal PSA

You can be as mentally and physically tough as you want to be. I think I've seen a lot. I've probably seen a lot more than a lot of people. And I've experienced a ton. You can't prepare for it, though. When it comes to your own child, I cannot express the feeling and the loss. It never gets easier. Because that void will always be there. Our children are supposed to bury us. We're not supposed to bury them."

Billy Merrifield (43, a county sheriff's captain, visiting the grave of his daughter, Brandi, who died from a heroin overdose at age 22).

Time: The Opioid Diaries

Payer Roles: Government Action and Litigation

Government Opioid RFIs

- Can take many forms – all agencies involved
 - DOJ grand jury subpoenas
 - CMS/MEDIC requests
 - MFCU requests
 - HHS-OIG
 - State DOIs
 - State and federal legislators
 - Congressional testimony

RFIs – Best Practices

- Develop protocol for handling
 - Commonly requested items – where to locate, how to obtain
 - Centralize the process
 - Have oversight – consistency is key
- Let the requestor know where you are looking (and where you are not)
- Know what you have and what you are producing
- Communicate what you are producing and why
 - Be mindful of representations
 - “All” of a category of documents? Doubtful.

RFIs – Best Practices

- Keep track of:
 - Who is asking
 - What you are producing
 - Date of production
- Why?
 - Supplemental requests
 - Know what is going out the door

RFIs – Privilege

- DO NOT produce privileged documents
- What may be covered?
 - Emails
 - Discussions with legal
 - SIU referencing consult with legal – redact
- Common examples:
 - Pharmacy terminations
 - Adverse actions taken against pharmacy

RFIs – Privilege

- Why is this important?
 - Privilege can be waived as to all future suits
 - Includes private civil actions
 - Cannot produce for one purpose and hold back for another
- *USA ex rel James Garbe, et al. v. K-Mart Corp.*, 2014 WL 2218758 (S.D. Ill. May 29, 2014)
- Example:
 - Provider investigated for potential Medicare fraud.
 - Turned over privileged materials to the government.
 - Months later, provider sues payer for non-payment and wrongful termination
 - Privileged documents now fair game for disclosure to provider.

Government RFIs – Witnesses

- More likely than not going to have to produce a witness on opioids at some point
 - Congressional hearing or otherwise
- Take the identification of the witness seriously
- Will be the “face” of the payer at trial with respect to opioids
 - Public proceedings
- Want to put your best foot forward
- Prep with an attorney

Opioid MDL – Overview

- **Plaintiffs:**
 - States
 - Municipalities
 - Native American tribes
 - Individuals
- **Defendants:**
 - Manufacturers
 - Distributors
 - Pharmacies

Opioid MDL – Overview

- Northern District of Ohio
- Judge Dan Polster
- Over 433 lawsuits and counting

Opioid MDL – Overview

- State and Municipality allegations (original cases):
 - Manufacturers overstated benefits, downplayed the risks, and aggressively marketed these drugs to physicians
 - Distributors failed to monitor, detect, investigate, refuse and report suspicious orders of opioids
 - Retail pharmacies should have done more...

U.S. Judicial Panel on Multidistrict Litigation, MDL No. 2804, Document 328

Opioid MDL – Overview

- State and Municipality common questions of law and fact
 - Defendants' knowledge of and conduct regarding diversion
 - Defendants' alleged improper marketing
 - Obligations under Controlled Substances Act and similar state laws

U.S. Judicial Panel on Multidistrict Litigation, MDL No. 2804, Document 328

Opioid MDL – Overview

- State and Municipality causes of action
 - RICO
 - Consumer protection laws
 - State analogues to Controlled Substances Act
 - Public nuisance
 - Negligence
 - Negligent misrepresentation
 - Fraud
 - Unjust enrichment

U.S. Judicial Panel on Multidistrict Litigation, MDL No. 2804, Document 328

Opioid MDL – Overview

- Individual plaintiff class action cases – recent development
- Theory of the case:
 - Defendants’ wrongful conduct resulted in increased insurance premiums for everyone
- State classes
- Opposed participation in MDL
- Transferred into the MDL in August 2018

U.S. Judicial Panel on Multidistrict Litigation, MDL No. 2804, Document 328

Opioid MDL – Overview

- Individual plaintiff class action cases – causes of action
 - RICO
 - Conspiracy to violate RICO
 - Public nuisance
 - Unjust enrichment
 - Negligence
 - Negligent misrepresentation
 - Civil conspiracy

Opioid MDL – Current State of Affairs

- New cases being filed every day
- Judge Polster pushing the case
 - Originally set trial date of March 18, 2019
- Many experts predict global resolution is the only way to go
- Defendants insist that certain allegations have to be tried and have no merit

Opioid MDL – Track One Cases

- Cases moving quickly
- October 25, 2018 (parties other than retail pharmacies)
 - Document production substantially complete
 - “Traditional” 30(b)(6) depositions complete
- November 9, 2018 (retail pharmacies)
 - Same as above

Opioid MDL – Current State of Affairs

- January 25, 2019
 - All fact depositions completed, including 30(b)(6)
- February 8, 2019
 - Plaintiff expert reports
- March 26, 2019
 - Defendant expert reports
- May 13, 2019
 - Daubert and dispositive motions
- September 3, 2019
 - Trial

Payer Roles in Opioid Litigation

- Plaintiffs? – millions of dollars in claims
- Third party subpoena respondents
 - Claims payment information
 - Total exposure relating to certain drugs
 - Manufacturer representations
 - Prior authorizations
 - Coverage policies
 - Premium information?

Payer Roles – Subpoena Responses

- Things to consider:
 - Multiple subpoenas, overlapping responses
 - Coordinated response – keep consistent
 - Centralize the process as with RFIs
 - Know what you are producing
 - Keep potential exposure in mind
- **DO NOT PRODUCE PRIVILEGED DOCUMENTS**

Opioid Litigation...Against Payers?

- Potential risk areas:
 - Member coverage issues
 - Access to care
 - Prescribers bringing in payers
 - Aiding and abetting

Conclusion

- The opioid epidemic is a public health emergency, many years in the making.
- While it may seem overwhelming, health plans can help make a difference.
- The opioid epidemic also has given rise to much litigation, in which health plans may find themselves involved and for which they should prepare.