

# Opioid Crisis Response

Key Legal Developments Every Health Lawyer and  
Compliance Officer Should Know

Presented by:

Marguerite Ahmann, Andrew Holm, Katherine Ilten,  
Chelsey Jonason and Pari McGarraugh

February 19, 2020

**Fredrikson**  
& BYRON, P.A.

# Agenda

- Introduction
- Prescribing matters
- Pharmacy issues
- EKRA
- Medicare and Medicaid reimbursement
- Privacy and health records
- State and local response
- Civil and criminal enforcement

# Opioid Crisis in the Headlines

- “Insys Founder Gets 5 ½ Years in Prison in Opioid Kickback Scheme.”
- “The Opioid Epidemic Cost \$2.5 Trillion Over 4 Years.”
- “D.C. Opioid Deaths are Surging Again, Reversing Previous Year’s Decline.”
- “As Tens of Thousands Died, F.D.A. Failed to Police Opioids.”
- “The Hidden Drug Epidemic Among Older People.”

# Statistics

- From 1999 to 2017, more than 702,000 people in the U.S. died from a drug overdose.
- At least two of three drug overdoses in the U.S. involve an opioid.

CDC.gov

# Statistics

- 1999 to 2015: Opioid-related overdose death rose 401%, non-opioid related overdose deaths rose 150% and unspecified overdose deaths rose 220%.
- Breakdown by type of opioid: prescription opioid pain relievers (41.5%); heroin (25.4%); methadone (20.3%); other and unspecified (14.4%); synthetic other than meth (14.2%); and opium (0.01%).

Office of the Surgeon General

# Statistics

- States with highest death rates due to drug overdoses (2017): WV, OH, PA, D.C. and KY.
- States with statistically significant increase in overdose death rates (2016-2017): AL, AZ, CA, CT, DE, FL, GA, IL, IN, KY, LA, ME, MD, MI, NJ, NY, NC, OH, PA, SC, TN, WV and WI.

# Background Reading

- “The Family That Built an Empire of Pain.” Patrick Raddan Keefe. *The New Yorker*. October 23, 2017.
- “The True Cause of the Opioid Epidemic.” Olga Khazan. *The Atlantic*, January 2, 2020.
- *Pain Killer: An Empire of Deceit and the Origin of America’s Opioid Epidemic*. Barry Meier. May 2018.
- *Dopesick: Dealers, Doctors, and the Drug Company that Addicted America*. Beth Macy. August 2018.

# Resources

- [hhs.gov/opioids](https://www.hhs.gov/opioids)
- [hrsa.gov/opioids](https://www.hrsa.gov/opioids)
- [justice.gov/opioidawareness/file/896776/download](https://www.justice.gov/opioidawareness/file/896776/download)
- [healthlawyers.org/find-a-resource/HealthLawHub/Pages/Opioids.aspx](https://www.healthlawyers.org/find-a-resource/HealthLawHub/Pages/Opioids.aspx)



# Resources

- [deadiversion.usdoj.gov](https://deadiversion.usdoj.gov)
- [time2actmissouri.com](https://time2actmissouri.com)
- [fsmb.org](https://fsmb.org)
- [cdc.gov/drugoverdose/prescribing/guideline.html](https://cdc.gov/drugoverdose/prescribing/guideline.html)

# Prescribing

- State medical boards.
- State PDMPs.
- Prescribing limitations in telehealth.
- Potential red flags in prescribing.

# State Professional Boards

- 50 different approaches, always changing.
  - Guidance and resources.
  - Education.
  - Form pain management contract.
  - Dosage limits.

# State Prescription Drug Monitoring Programs (PDMPs)

- Who must use it?
- What is the use requirement?
- What must be reported?
- Timeframe for reporting?
- Who has access?

# State Prescription Drug Monitoring Programs (PDMPs)

- Limitations.
  - Limits on data sharing.
  - Lack of standardization.
  - Lack of funding.
  - Lack of integration into the EMR.

# Telemedicine Prescribing

- Federal Ryan Haight Online Pharmacy Consumer Protection Act of 2008 – designed to combat rogue internet pharmacies selling controlled substances online.
  - Prohibited form-only online prescribing for controlled substances.
  - Permitted prescribing of controlled substances via telemedicine if practitioner has conducted an in-person exam or meets a “practice of telemedicine” exception (limited to hospitals, registrant in the room).
  - Practice of telemedicine exceptions are outdated. Counter to direct-to-patient service models (e.g., substance use disorder treatment).
  - No “special registration” rules from the DEA.

# Telemedicine Prescribing

- 2018 SUPPORT Act included the “Special Registration for Telemedicine Act of 2018” requiring DEA to promulgate special registration regulations by October 24, 2019.
- November 22, 2019: Justice Department announced plans to issue a proposed rule on special registration requirements.
- Still awaiting issuance...

# Compliance Tips

- Know your state board requirements.
- Integrate the PDMP check into practice.
- Be aware of commercial payer policies.
- Work with a clinician to review records.



# Red Flags in Prescribing

- Excessive Rx numbers.
- High morphine milligram equivalents.
- Dangerous combinations (opioid, benzodiazepine, muscle relaxer).
- Quantity or strength increases indefinitely.
- Prescriber direction to particular pharmacies.
- Rx to multiple family members at same address.
- No or cursory medical exam.

# Red Flags in Prescribing

- Ignoring complaints by family members, other professionals.
- Brief visits.
- No medical history requested or obtained.
- Lack of diagnostic testing.
- Rx history not in patient file.
- Urine drug screens not documented or addressed.

# The Role of Pharmacies

- Lessons learned:
  - Monitor suspicious orders and prescribers.
  - Maintain effective controls against diversion.

# Red Flags in Pharmacies

- High proportion of controlled substances dispensed.
- Insured patients pay cash.
- Customers are patients of known overprescribing physicians.
- Dispense overlapping prescriptions.

# Eliminating Kickbacks in Recovery Act of 2018 (“EKRA”)

- Section 8122 of the SUPPORT Act.
- All-payor anti-kickback prohibition that extends to arrangements with recovery homes, clinical laboratories, and clinical treatment facilities.
- Criminal penalties:
  - Fines up to \$200,000, imprisonment of up to 10 years, or both.

# EKRA – Key Considerations

- Applies to “health care benefit programs” – i.e., both government and commercial payors.
- Applies with respect to the soliciting or receipt of remuneration for *any* referrals to recovery homes, clinical treatment facilities, or clinical laboratories, whether or not related to treating substance use disorders.

# EKRA – Text

- ...with respect to services covered by a health care benefit program, in or affecting interstate or foreign commerce, knowingly and willfully—
  - (1) solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient or patronage to a recovery home, clinical treatment facility, or laboratory; or

# EKRA – Text, cont.

- (2) pays or offers any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
  - (A) to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory; or
  - (B) in exchange for an individual using the services of that recovery home, clinical treatment facility, or laboratory...



# EKRA – Exceptions

- Discounts.
  - Discounts obtained by providers or entities under a health care program, if the discounts are disclosed and reflected in the provider's or entity's costs or charges; also mirrors the federal AKS safe harbor for Medicare coverage gap drug discounts.
- Personal Services and Management Contracts (AKS safe harbor).
- Patient Copayments or Coinsurance.
  - Non-routine, good-faith waivers or discounts .
- Federally Qualified Health Center Remuneration (AKS).
- Payments made as part of an approved alternative payment model.

# EKRA – Exceptions, cont.

The prohibition does NOT apply to:

- (2) a payment made by an employer to an employee or independent contractor (who has a bona fide employment or contractual relationship with such employer) for employment, if the employee's payment is not determined by or does not vary by—
  - (A) the number of individuals referred to a particular recovery home, clinical treatment facility, or laboratory;
  - (B) the number of tests or procedures performed; or
  - (C) the amount billed to or received from, in part or in whole, the health care benefit program from the individuals referred to a particular recovery home, clinical treatment facility, or laboratory.

# New Medicare Part B Benefit

- OUD treatment services furnished by an Opioid Treatment program (OTP).
  - New benefit pursuant to SUPPORT Act.
  - Covered services include certain medications, counseling, individual and group therapy and toxicology testing.

# Medicare Enrollment of OTPs

- Opioid Treatment Program (OTP) enrollment:
  - Current, valid accreditation by an accrediting body or other entity approved by SAMHSA.
  - Current, valid certification by SAMHSA.
  - CMS-855B application and fee.
  - Provider Agreement.

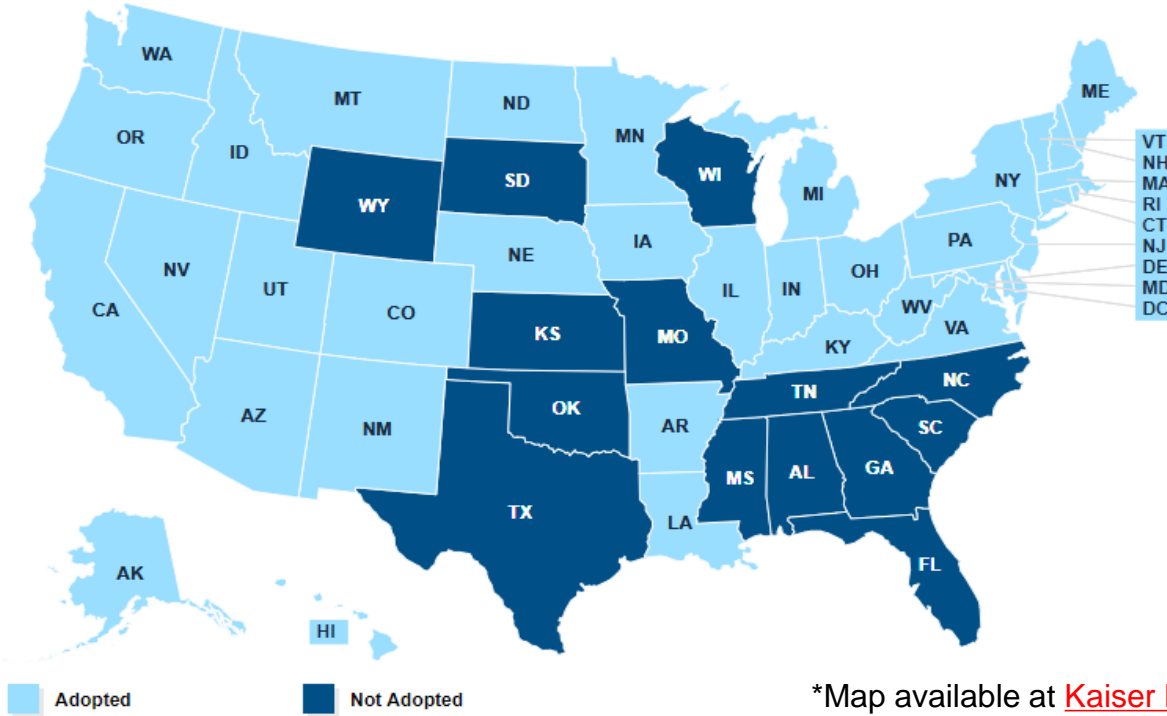
# Bundled Payments to OTPs

- Payments to OTPs are Bundled.
  - Bundle covers OUD treatment services that are furnished by the OTP to an individual during an “episode of care.”
- OTP Site of Service (Telecommunications).
  - Certain OUD services furnished by OTPs may be provided via telehealth.
  - Beneficiaries may receive services from home.

# Payment for Telehealth Services

- CMS added 3 new HCPCS G codes covering treatment for OUD in 2020.
  - HCPCS code G2086.
  - HCPCS code G2087.
  - HCPCS code G2088.

# Medicaid Expansion\*



\*Map available at [Kaiser Family Foundation](#)'s website

# Other Federal Measures

- SUPPORT Act.
  - MAT covered from October 2020 through September 2025 unless limited exception applies.
- Treatment at Institutions for Mental Disease (IMDs).
  - SUPPORT Act.
  - Section 1115 waivers.



# Increasing Access via Telehealth

- Mandated coverage.
- Payment parity.
- Types of authorized practitioners.
- Location requirements.
- Facility or program certification.
- State practice boards.

# Privacy and Health Records

- 42 C.F.R. Part 2.
  - Applies to “Part 2 Programs.”
  - Generally requires written consent to disclose information that identifies a person as having a Substance Use Disorder.
  - Changes coming!

# State & Local Response

- Pain clinic regulation.
- Local treatment programs funding.
- Licensure of treatment programs.
- Professional licensure.
- Other state policies.

# Pain Clinic Regulation

- Regulation and oversight of facilities responsible for prescribing opioids and other pain medication, including:
  - Prescribing and dispensing restrictions;
  - Ownership restrictions; and
  - Inspection, recordkeeping and reporting requirements.

# Funding/Programs

- State and local responses vary.
- Federal funding sources, including SAMHSA State Targeted Response and State Opioid Response Grants.
- Integrated vs. carve out OUD/SUD services.

# Program Licensure

- Many states are enhancing or modernizing existing facility/program licensure laws.
- Emphasis on MAT-specific requirements.
- Office-based opioid treatment.

# Professional Licensure

- Expanding and inconsistent set of providers engage to provide substance use disorder treatment:
  - Licensed or certified alcohol and drug counselors, marriage and family therapists, professional counselors, psychologists, psychiatrists, nurses, physician assistants, etc.
  - Peer recovery support personnel.

# Professional Licensure, cont.

- Refining, modernizing, clarifying and expanding licensure categories.
  - E.g., revising “chemical dependency” professionals to “substance use disorder” professionals; revising of supervision and practice requirements.
- State and national credentialing bodies.



# Other State Policies

- Using data analytics to inform policies:
  - Medicaid claims and prescriber data.
  - Program reporting requirements.
- Mini-EKRA legislation.
- Specialty drug courts.

# Civil & Criminal Enforcement

- Themes and trends.
- Federal enforcement initiatives.
- Recent actions.
- What's next.
- Opioid MDL update.

# Themes and Trends

- Data-driven enforcement.
- Increased funding.
- Focus up the food chain and up the supply/distribution chain.
- Criminal vs. civil.

# Opioid Fraud and Abuse Detection Unit

- Announced in August 2017 by DOJ.
  - See <https://www.justice.gov/opa/pr/attorney-general-sessions-announces-opioid-fraud-and-abuse-detection-unit>
- Focused on data analytics:
  - Prescribing and dispensing patterns outside the norm.
  - Patient outcomes (overdoses).
  - Demographic analysis.

# Opioid Fraud and Abuse Detection Unit

- Additional federal prosecutors focused on “investigating and prosecuting health care fraud related to opioids, including pill mill schemes and pharmacies that unlawfully divert or dispense prescription opioids for illegitimate purposes.”

# Opioid Fraud and Abuse Detection Unit, cont.

- Geographic focus: M.D. Fla., E.D. Mich., N.D. Ala., E.D. Tenn., D. Nev., E.D. Ky., D. Md., W.D. Pa., S.D. Ohio, E.D. Cal., M.D. N.C., and S.D. W.V., and likely to grow.

# Prescription Interdiction & Litigation Task Force

- Announced in February 2018 by DOJ.
  - See <https://www.justice.gov/opa/pr/attorney-general-sessions-announces-new-prescription-interdiction-litigation-task-force>
- “[A]ggressively deploy and coordinate all available criminal and civil law enforcement tools.”

# Prescription Interdiction & Litigation Task Force

- Focus on “every level of the distribution system” including manufacturers, pharmacies, pain management clinics, drug testing facilities and individual physicians.



# Prescription Interdiction & Litigation Task Force

- Coordinate with state authorities.
- Encourage data sharing across the federal government.
- Evaluate and recommend regulatory and statutory changes.

# Practice Fusion Settlement

**Department of Justice**

Office of Public Affairs

---

FOR IMMEDIATE RELEASE

Monday, January 27, 2020

## **Electronic Health Records Vendor to Pay \$145 Million to Resolve Criminal and Civil Investigations**

**Practice Fusion Inc. Admits to Kickback Scheme Aimed at Increasing Opioid Prescriptions**

# Dr. Thomas Keller

- Being tried for murder in California after five patients overdosed.
- Jury trial scheduled for June on Medicare fraud charges.

# Rochester Drug Settlement

---

FOR IMMEDIATE RELEASE

Tuesday, April 23, 2019

## **Manhattan U.S. Attorney And DEA Announce Charges Against Rochester Drug Co-Operative And Two Executives For Unlawfully Distributing Controlled Substances**

**First Ever Felony Criminal Charges Against a Distributor and its Executives for  
Illegal Distribution of Controlled Substances**

# Effingham Health System Settlement

---

FOR IMMEDIATE RELEASE

Wednesday, May 16, 2018

## **Southern District Of Georgia Announces Largest Hospital Drug Diversion Civil Penalty Settlement in U.S. History**

# What's Next

- More powerful uses of data.
- More funding.
- Increase in DEA administrative enforcement?
- Opioid MDL litigation.

# Collateral Consequences

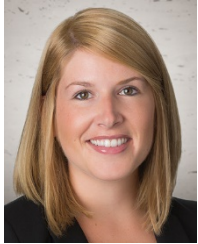
- Addiction issues affect health professionals.
- Be aware of collateral consequences.
  - Medicare billing privileges.
  - Exclusion.
  - Licensing.

# Opioid Multi-District Litigation Update

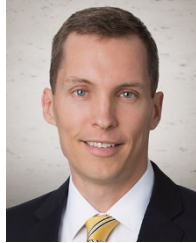
- Bellwether trial is currently scheduled for November.
- Test cases are two Ohio counties against major pharmacy retailers.
- Ongoing scope and discovery disputes.



# The Presenters



**Marguerite Ahmann**  
612.492.7495  
[mahmann@fredlaw.com](mailto:mahmann@fredlaw.com)



**Andrew Holm**  
612.492.7221  
[aholm@fredlaw.com](mailto:aholm@fredlaw.com)



**Katherine Ilten**  
612.492.7428  
[kilten@fredlaw.com](mailto:kilten@fredlaw.com)



**Chelsey Jonason**  
612.492.7284  
[cjonason@fredlaw.com](mailto:cjonason@fredlaw.com)



**Pari McGarraugh**  
612.492.7480  
[pmcgarraugh@fredlaw.com](mailto:pmcgarraugh@fredlaw.com)

