The opioid crisis

Becoming part of the solution

Andrew Keller MD., CMO, CMIO
Christine Keenan PA-C., Risk Manager

Western Connecticut Medical Group
Opioids played a role in dozens of lost medical licenses

RESEARCH NEWS

Report: Americans Are Now More Likely To Die Of An Opioid Overdose Than On The Road

January 14, 2019 · 12:01 AM ET

‘The Numbers Are So Staggering.’ Overdose Deaths Set a Record Last Year.

By JOSH KATZ and MARGOT SANGER-KATZ NOV. 29, 2018
Were we part of the problem?

We had some clues...

- Doctor's Complaints about covering a colleague’s vacation, "I don’t write for that stuff".

- Notices from pharmacies (via fax) to providers with warnings as to medication dosages/combinations - “just thrown out”.

- Questions about the CT Prescription Monitoring program mandate requirements (Oct 2015).. months and months after it became law.

- No clear process to validate compliance with CT-PMP.
Department of Justice
U.S. Attorney’s Office
District of Connecticut

FOR IMMEDIATE RELEASE

Fairfield Doctor Pleads Guilty to Illegally Prescribing Oxycodone

Deirdre M. Daly, United States Attorney for the District of Connecticut, today announced that [Name of physician] M.D., 56, of Trumbull, pleaded guilty yesterday in Hartford federal court to one count of issuing unlawful prescriptions for oxycodone.

“Medical practitioners play a critical role in battling the epidemic of opioid abuse that we are experiencing,” said U.S. Attorney Daly. “The strict rules associated with prescribing controlled substances are in place for a reason: to help ensure that these highly-addictive narcotics aren’t abused or illegally diverted. Those who knowingly prescribe opiates in violation of federal law will be prosecuted.”

According to court documents and statements made in court, [Name of physician] is a physician with an office in Fairfield. Two of [Name of physician]’s longtime patients were a married couple who lived in Connecticut until approximately 2011, when they relocated to Florida.

[Name of physician] knew that, prior to moving to Florida, the couple had unlawfully obtained forged prescriptions for opioid medications from [Name of medical assistant], former medical assistant and, as a result, he should have been aware of the possibility that the couple was abusing or diverting their medications.
So we were part of the problem
We needed to be part of the solution

This is the story of where we started and are today..

First a little about us....

New England Regional Healthcare Risk Management Conference
Western Connecticut Medical Group

- 380 Physicians
- 179 Advanced Practice Providers
- 559 Total Providers
- 1,267 employees including providers
- 65 locations in 15 cities/towns
- 450,000 ambulatory office visits per year

New England Regional Healthcare Risk Management Conference
Western Connecticut Medical Group

- 71 Primary Care Providers
- Specialists include GI, Cardiology, Endo, Pulmonary, Oncology, Nephrology, Surgery, Physiatry, Pain Management (1), Psychiatry, Obstetrics, Pediatrics

- Hospital Providers (Anesthesia, ED, Hospitalists)
- No Orthopedic Surgery. No Dentists
- No Addiction Services.
Scope of our problem

- Multiple office sites
  - Many newly acquired providers:
    - Inherited patients on opioids, benzos and/or stimulants
- Variability in office management
- Three EHR’s without interface capability
- Vertical organizational management system (not manageable)
- Lack of clear organizational guidance or policy
- Absence of clear transition/ patient management processes
- Non electronic prescriptions
Risk

- Professional Licensure Investigation of the Clinician
- Medical Staff actions against the Provider
- Patient Harm/Malpractice action against the provider and/or organization
- Civil action against the physician
- Criminal action against the physician and possibly the organization
- Reputational harm to both the physician and organization
March 15, 2016: CDC Issues Guideline for Prescribing Opioids for Chronic Pain

- The CBS Evening News (3/15, story 11, 1:45, Pelley, 5.08M) reported, “Today, the CDC urged” physicians “to stop over-prescribing opioids.”
- The AP (3/15, Perrone) reports, “Under the new guidelines,” physicians “would prescribe painkillers only after considering non-addictive pain relievers, behavioral changes and other options.” Additionally, “the CDC…wants” physicians “to prescribe the lowest effective dose possible.” Meanwhile, “for short-term pain, the CDC recommends limiting opioids to three days of treatment, when possible.”
CDC Guideline: 12 Steps

- Non-pharmacologic therapy first
- Review PMP, H&P
- Set goals and duration of therapy
- Discuss known risks and realistic benefit
- Initiate with immediate, not long acting
- Lowest effective dose. AVOID increases to >90MME /day
- Minimal Expected Use: Not more than 3 days
- Reevaluate in 1-4 weeks, every three months thereafter
- Evaluate for misuse
- Urine testing (at least annually)
- AVOID combining opioids and benzodiazepines.
- Treat opioid use disorder
Medical Group Response: Controlled Substance Agreement (CSA) and Policy - October 2016

- Policy
  - Succinct
  - Based on CDC Guidelines and State Statute
  - Emphasis on required actions by provider and documentation
  - Discussed timing for Renewals/Role of Ordering Provider

- CSA
  - Designed for Opioid, Benzodiazepines, Stimulants and Testosterone.
Did we resolve (or mitigate) the risk?

- Was our prescription rate “appropriate”?
- Was there compliance with regulatory agencies and statute?
- Were the tools for offices effective?
- Was the scope of the problem and the solution defined to front lines?

- Had the risk really been minimized?
Perspective of State Drug Control Division

- F2F meeting with Director of Drug Control (DCP)
  - Interested in Diversion
  - Investigate all Complaints (Patients/Pharmacies/Others)
- RED FLAGS:
  - 2 or more controlled substances
  - >5 providers or >5 pharmacies
  - 90 MME/ day.
What was the prescription rate?

- Clinical data hurdles
  - Three Different Electronic Medical Records
  - Limited Reporting Capability
- One example of our clinical report
  - All patients by provider with
    - Over 300 pills in any one prescription for controlled substance
      - Look for diversion
    - Two or more controlled substance active prescriptions
      - Looking for opioid / benzodiazepines combinations
  - Include patient and prescription demographics
  - *Initial report* ....
Assessment with consultant

- CSA not comprehensive
  - Not fully protective for providers, staff, organization
  - Ineffective patient monitoring
- Front Line not fully aware of issues
- Policy was incomplete

- So... the risk was not yet mitigated
Planning the solution

► ROOT CAUSE ANALYSIS MODEL
  ► Psychiatry, Primary Care, Medical Specialty, Risk, Legal and Leadership

► RCA - ACTION ITEMS - WITH TIME LINES
  ► Education
  ► Process Changes
  ► Guidelines / CSA
  ► Toxicology
  ► Audits and Accountability
  ► Addiction resources
RCA-Education

- Media/Legislative Focus on the Patient
- Our Education Focus: On the Providers—The Prescriber
- Organizational Financial Support with Expert Educators
- Grand Rounds X 2 in Both Hospitals
  - Video Conferenced - Archived for Later View
- Risk Management Education (ongoing) to Departments, Sections, Office Practices.

- Audit for compliance with educational recommendations
RCA - Process changes

- Improved the Ability to Review the CT-PMP
  - Improved the ability for our providers to access the system DIRECTLY from the EHR
  - Developed EHR Macros (templated language) that eased the ability to document
  - Operational support to assure that DELEGATES were identified, registered and available
- FUTURE: Embed the CT-PMP into the EHR
RCA - Process changes

- Required all CS prescriptions to be entered into the EHR

- Redesigned the prescription pads to be serialized, registered and audited for use
GUIDELINE: MUST HAVES

- Recognition of the High Risk Patient
- Treatment Options
- Monitoring Guidelines for that High Risk Patient
- Evaluation of the Patient ON Chronic Opioids
- Using the Controlled Substance Agreement
- Tapering
- Changing the treatment plan without terminating the patient
** Western Connecticut Medical Group **

**CONTROLLED SUBSTANCE AGREEMENT**

Statement of Purpose: The purpose of this agreement is to create a voluntary treatment plan that includes the use of a prescription medication or medications listed below. This treatment plan will include remedies other than just medications. These remedies may be non-opioid medications, exercise, physical therapy, stress reduction, relaxation therapy, cognitive-behavioral therapy, biofeedback, lifestyle modification, weight loss, acupuncture, yoga, massage, support groups or other recommendations.

Goals of Treatment: The primary goal of the prescription medication is to improve your functioning. These medications will hopefully decrease pain or anxiety, but will probably not eliminate these symptoms completely. Because prescribed medications should be helpful either than harmful we will not continue these medications unless they are safe and remain the best treatment for your problem. To increase safety we will provide you with monitoring and care coordination. Strict compliance with this agreement is the best way to achieve the goals of improved functioning and decreased pain and/or anxiety.

YOU HAVE BEEN PRESCRIBED an OPIOID, BENZODIAZEPINE, STIMULANT OR OTHER medication as part of your treatment for:

PLEASE BE AWARE OF THE FOLLOWING SIDE EFFECTS:

Opioids and Benzodiazepines: Sleepiness, drowsiness, constipation, nausea, itching, vomiting, diziness, allergic reaction, inability to urinate, low blood pressure, irregular heartbeat, insomnia, depression, sexual dysfunction, impotence, slowing of breathing rate, slowing of reflexes or reaction time, physical and emotional dependence, tolerance to pain medications, addiction and death. It is unsafe to drive or operate machinery.

Stimulants: headache, loss of appetite, insomnia, anxiety, nausea/vomiting, diarrhea, rapid heart rate, fever, infection, sexual dysfunction, motor tics, elevated blood pressure, growth suppression, mania, psychosis, aggressive behavior, heart attack, stroke, seizures, physical and emotional dependence, withdrawal and sudden death.

Testosterone: headache, difficulty urinating, acne, anxiety, asthma, prolonged erections, breast enlargement, fatigue, hypertension, elevated blood lipid levels, prostate cancer, blood clots, heart attack, stroke, liver cancer, anxiety, depression, dependence and abuse.

IF YOU EXPERIENCE ANY OF THE ABOVE, PLEASE CONTACT YOUR PROVIDER IMMEDIATELY.

Please read this entire document and write your initials in the areas indicated. Bring this document and questions or concerns with you to your follow-up appointment for discussion with your provider.

I UNDERSTAND THAT BY INITIALIZING THE FOLLOWING STATEMENTS AND SIGNING THIS AGREEMENT, I VOLUNTARILY CONSENT TO TREATMENT WITH OPIOIDS, BENZODIAZEPINES OR OTHER CONTROLLED SUBSTANCES.

I will follow the treatment plan and all provisions listed below.

I will not take anyone else’s medications.

I will not use any other medications or drugs, prescribed or otherwise without notifying my provider. If an emergency occurs and medication is prescribed, I will notify my primary care provider within 24 hours and will bring my prescription bottles to my next appointment.

I will not drink alcohol while taking this medication.

I am responsible for my medications. I will not share, trade, give, sell or donate my medications to other people. I will not break, chew or crush oral medications or cut my medication patches.

I will take my medications as prescribed. Taking more medication is not helpful and not part of the treatment plan. Taking more medication may be an indication of tolerance which can lead to addiction and other negative consequences.

I will keep my medication in a safe place. These medications can be very dangerous especially to children. Use of a prescription safe or lock box to secure the medications is advised.

I will dispose of any unused medications by returning them to my pharmacy or other designated drop off site. Saving unused medications increases the risk of diversion, theft or other dangerous use of the medications. Flush unused medications down the toilet can cause contamination of the water supply.

I understand that regular appointments will be necessary with my treating provider and that my diagnosis and treatment plan will be reviewed and may be revised.

I understand that this medication may be considered a trial or a test. A change in treatment plan including the need to taper or stop the medication might be necessary to maintain the goals of safety and improved functioning.

Refills

I understand that refills will be written or sent electronically after I call the office to request one.

• I understand that refills will ONLY be available during office hours (Monday through Friday) and after seeing my treating physician or other medical practitioner.

• No refills will be given after hours or by the on-call provider for any circumstance.

• No refills will be given early or in the case of an emergency such as lost or stolen medication.
RCA - Controlled Substance Guideline and CSA

POSITIVES: Instructive/Educational
- Alternatives when the patient fails
- Resources listed
- BOXED Warning
- CSA had been introduced, process in place

NEGATIVES: Long
- Office Operational Guidance (15 minute visit)
- Acceptance/ Understanding
RCA - Toxicology & Monitoring

- MEETING WITH LABORATORY LEADERSHIP IDENTIFIED
  - Internal testing not sufficiently granular
  - Sensitivity and Specificity issues
  - Send out markedly increased turn around time

- AND WITH COOPERATION AND THEIR INPUT
  - Office sends directly to outside vendor
  - Urine with 48 hour turnaround/saliva 72 hours
  - Clinical support for the providers readily available
RCA - Toxicology & Monitoring

- Pill Counts

- Considered a standard method for review
- Operational challenges for our offices
- GOAL: 2020 to have resolved
RCA - Audit and Accountability

- Manual Audit
- New Concept for Ambulatory Providers
- Utilized the Peer Review Model
- Evaluated the - Basic Elements First
  - Documentation of the Review of the CT PMP
  - Documentation of the Risks/Benefits of the Medication
  - Completion of the CSA for all chronic patients.
- FEEDBACK to each Provider in Writing
- MD/DO first. Then APPs
RCA - Addiction Resources

- Limited availability of formal addiction resources
- Embedded Behavioral Health Social Workers in Primary Care
- Future State:
  - MAT training in primary care
  - Collaborate with Population Health
THE VOICE OF OUR CLINICIANS...

2016: “There’s nowhere to refer these patients”
   “I inherited all of the them”
   “No organizational support. These are difficult patients”
   “I have only 15 minutes, what can I do in that time...”

2018: “Patients are complying with the process”
   “The toxicology testing has been very telling”
   “I have stopped prescribing to at least half of these patients.
   “They weren’t really needing it”
January 1, 2018: EPCS in CONNECTICUT

WAIVER FOR ALL PROVIDERS (CHANGE TO NEW EHR)

FALL 2018: OPERATIONAL INITIATIVE TO GET >500 providers the ability to be compliant

AUDIT: DECEMBER 2018 - COMPLETE....
Office Leadership and Accountability

- Governance of Offices
  - Horizontal dyad structure

- Ambulatory Peer Review
2019..WHERE WE ARE TODAY...

- New EHR with ongoing optimization
- Continued Audit of controlled substances
- Compliance with EPCS
- Simplification process
- Delegates for PMP
- CSA completed at home
- “dot command” autotext templates for compliance with CT statute
- Current use rates and monitoring tools
Current use rates and monitoring tools
Lessons Learned

- Be proactive
- Don’t assume you’re not part of the problem
- Start monitoring use now
- Clinicians want to do the right thing - give them the tools/support
- **Support:** *The conversations with the patient ARE NOT EASY*
- “When someone protests loudly...there may be an alternative agenda”
QUESTIONS?