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Prescription Audits: Anticipating and Responding to Increased Scrutiny of Prescribing and Dispensing Practices

WEDNESDAY, SEPTEMBER 4, 2019

1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

Today's faculty features:

Lindsay P. Holmes, Attorney, **BakerHostetler**, Washington, D.C.

Dennis A. Wichern, Managing Partner, **Prescription Drug Consulting**, Chicago

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PRESCRIPTION AUDITS: ANTICIPATING AND RESPONDING TO INCREASED SCRUTINY OF PRESCRIBING AND DISPENSING PRACTICES

Introduction

Lindsay P. Holmes

- Associate, Baker & Hostetler
- Focus of practice is pharmacy and FDA

DEA Audit/Inspection Process

I. Why do DEA audits happen?
   - A. Ensure compliance with the CSA
   - B. Investigation of a tip
   - C. Investigation of irregular activities
   - D. Outside pressures – opioid crisis

DEA Audit/Inspection Process

I. What is the frequency of audits?
   A. DEA audits are routine
   B. Frequency depends on the type of DEA registration held
      1. Out of the registrants control
         a. Practitioners
         b. Other registrants

DEA Authority to Inspect

I. DEA is permitted to enter a controlled premises and conduct administrative inspections thereof, for the purpose of:

   A. Inspecting, copying, and verifying the correctness of records, reports, or other documents required to be kept or made under the CSA including, but not limited to, inventory and other records, order form records, prescription and distribution records, records of listed chemicals, tableting machines, and encapsulating machines, import/export records of listed chemicals, shipping records identifying the name of each carrier used and the date and quantity of each shipment, and storage records identifying the name of each warehouse used and the date and quantity of each storage.

   B. Inspecting within reasonable limits and to a reasonable manner all pertinent equipment, finished and unfinished controlled substances, listed chemicals, and other substances or materials, containers, and labeling found at the controlled premises relating to the CSA.

DEA Authority to Inspect

C. Making a physical inventory of all controlled substances and listed chemicals on-hand at the premises.

D. Collecting samples of controlled substances or listed chemicals (in the event any samples are collected during an inspection, the inspector shall issue a receipt for such samples on DEA Form 400 to the owner, operator, or agent in charge of the premises).

E. Checking of records and information on distribution of controlled substances or listed chemicals by the registrant or regulated person (i.e., has the distribution of controlled substances or listed chemicals increased markedly within the past year, and if so why).

F. All other things therein appropriate for verification of the records, reports, documents referred to above or otherwise bearing on the provisions of the Act and the regulations thereunder. 21 CFR §1316.03.

DEA Authority to Inspect

I. DEA generally does not have the authority to inspect:
   A. Financial data;
   B. Sales data (other than shipping data); and,
   C. Pricing data.

DEA Authority to Inspect

I. What is required for the DEA to enter my facility?
   A. Inspector must:
      1. State his/her purpose
      2. Present appropriate credentials
      3. Provide written notice of inspection and receive informed consent
         a. DEA Form 82
      4. Or through the use of administrative warrant shall have the right to enter such premises and conduct inspections at reasonable times and in a reasonable manner
   B. Is a search warrant required? Generally, no. Unless there is a criminal investigation.

AG Inspections/Audits

I. Can state agencies inspect? Yes.

II. Authority

   A. Broad under state law

      1. Review of records

      2. May include patient charts

III. Warrant required?

   A. Search warrant

   B. Board of Medicine or Dept. of Health administrative inspection

Outcomes

I. Letter of admonition

II. MOU

III. Surrender for cause of registration

IV. Order to show cause

V. Immediate suspension of registration

VI. Immediate revocation of registration

Letter of Admonition and MOU

I. Informal sanctions

II. For mainly technical violations where no diversion has occurred

III. Imposes additional requirements

   A. Enhanced record-keeping

   B. May be more severe, e.g., restrictions on practice

Surrender for Cause

I. "For cause" means a surrender in lieu of, or as a consequence of, any federal or state administrative, civil, or criminal action resulting from an investigation of the individual's handling of controlled substances.

Order to Show Cause

I. If, upon examination of the application for registration from any applicant and other information gathered by the Administration regarding the applicant, the Administrator is unable to make the determinations required by the CSA to register the applicant, the Administrator shall serve upon the applicant an order to show cause why the registration should not be denied.

II. If, upon information gathered by the Administration regarding any registrant, the Administrator determines that the registration of such registrant is subject to suspension or revocation the Administrator shall serve upon the registrant an order to show cause why the registration should not be revoked or suspended.

III. The order to show cause shall call upon the applicant or registrant to appear before the Administrator at a time and place stated in the order, which shall not be less than 30 days after the date of receipt of the order. The order to show cause shall also contain a statement of the legal basis for such hearing and for the denial, revocation, or suspension of registration and a summary of the matters of fact and law asserted.

IV. Upon receipt of an order to show cause, the applicant or registrant must, if he/she desires a hearing, file a request for a hearing. If a hearing is requested, the Administrator shall hold a hearing at the time and place stated in the order.

DEA Pharmacy Actions

I. DEA revokes pharmacy registrations for “willful blindness” and red flags of diversion
   A. Trinity Pharmacy II
   B. Zion Clinic Pharmacy

DEA Audits/Inspection in Action

Drug Enforcement Administration

DEA Headquarters

@DEAHQ

April 02, 2018 **FOR IMMEDIATE RELEASE**

Contact: National Public Affairs Office

Phone Number: (202) 307-1000

DEA Surge In Drug Diversion Investigations Leads To 28 Arrests And 147 Revoked Registrations

Surge part of Administration's focus on combatting the opioid epidemic

WASHINGTON - For 45 days in February and March, the U.S. Drug Enforcement Administration surged its enforcement and administrative resources to identify and investigate prescribers and pharmacies that dispensed disproportionately large amounts of drugs. The ultimate goal of the surge was remediating or removing those whose actions perpetuate the controlled prescription drug crisis in America, particularly opioid drugs.

During that period, the DEA surged the efforts of special agents, diversion investigators, and intelligence research specialists to analyze 80 million transaction reports from DEA-registered manufacturers and distributors, as well as reports submitted on suspicious orders and drug thefts and information shared by federal partners, such as the Department of Health and Human Services. This resulted in the development of 366 leads to DEA field offices, 188 of (51 percent) resulted in active investigations by DEA's 22 field divisions.

"DEA will use every criminal, civil, and regulatory tool possible to target, prosecute and shut down individuals and organizations responsible for the illegal distribution of addictive and potentially deadly pharmaceutical controlled substances," said Acting DEA Administrator Robert W. Patterson. "This surge effort has demonstrated an effective roadmap to proactively target illicit diversion of dangerous pharmaceuticals. DEA will continue to aggressively use this targeting playbook in continuing operations. Attorney General Sessions and the Department of Justice have provided tremendous leadership and support in this critical mission. We must stop the loss of our loved ones to these drugs. "

DEA Audits/Inspection in Action

The culmination of those investigations was 28 arrests, 54 other enforcement actions including search warrants and administrative inspection warrants, and 283 administrative actions of other types. These additional actions included scheduled inspections, letters of admonition, memoranda of agreement/understanding, surrenders for cause of DEA registrations, orders to show cause, and immediate suspension (the immediate revocation of registrations).

DEA works with various federal and state partners on data sharing agreements to enhance its ability to identify individuals and companies who are contributing to the prescription opioid crisis, including a coalition of 41 state attorneys general and the Department of Justice's Opioid Fraud and Detection Unit now operating in 12 federal districts, an initiative of Attorney General Jeff Sessions. It is also dedicating additional resources to its domestic divisions to carry out investigations.

https://www.dea.gov/press-releases/2018/04/02/dea-surge-drug-diversion-investigations-leads-28-arrests-and-147-revoked

Increased Pharmacy Scrutiny

I. 2017 DOJ Opioid Fraud and Abuse Detection Unit

II. 2018 DEA push to focus on dispensers and prescribers

III. February 2018 DOJ launched the Prescription Interdiction & Litigation ("PIL") Task Force – will focus on manufacturers and distributors

IV. State prosecution of prescribers and pharmacies – including criminal charges

V. Pharmacy Boards have become active in enforcement related to opioids

Response to Opioid Crisis

President Donald J. Trump

ADDRESSING THE DRIVING FORCES OF THE OPIOID CRISIS: President Donald J. Trump's Initiative to Stop Opioid Abuse is confronting the driving forces behind the opioid crisis.

- This Administration secured $6 billion in new funding over two years to fight opioid abuse.
- The President's Initiative to Stop Opioid Abuse will:
  - Reduce drug demand through education, awareness, and prevention efforts.
  - Cut off the flow of illicit drugs across our borders and within communities.
  - Save lives by expanding opportunities for evidence-based treatments for opioid addiction.
- On September 19, 2018, the Administration awarded more than $1 billion in funding to State and local entities to address the opioid crisis.

State Pharmacy Action

I. Larry's Drive-In Pharmacy – West Virginia

II. Settled with WV AG for $550,000 and ceased operations in 2018

III. Dispensed 10 million prescription painkillers to a community of less than 25,000 over 11 years

IV. AG prosecuted under WV's Consumer Protection and Credit Act, among other violations

V. Several other WV pharmacies facing similar prosecution under similarly alleged facts

DEA Registration

I. Registration basics:

   A. A separate registration is required for every principal place of business, unless a registrant is only prescribing at a second location.

   B. If a registrant maintains supplies of controlled substances, administers, or directly dispenses controlled substances at that second location, a separate registration must be obtained.

   C. No separate registration is required for an agent or employee of any registrant if acting in the usual course of the employment.

   D. Can administer or dispense under another practitioner's registration as an employee or an agent but must be licensed individually to prescribe.

II. Problems often arise:

   A. With new practices

   B. Expansions

   C. Sale or merger

   D. Affiliating with another healthcare entity

Recordkeeping Requirements

I. 21 CFR Parts 1300-1321

II. 21 USC Sections 801-971

III. Incorporate into SOPs

Commonly Cited Violations

I. Failure to Maintain Complete and accurate records in violation of 21 USC 842(a)(5)

II. Failure to perform adequate inventory

III. Failure to properly maintain CS records 21 CFR 1304.04(f)

IV. Prescriptions missing dates and patients' addresses in violation of 1306.08

V. Prescription forms lacking various security features (as required under state laws), 21 USC 842(a)(2)

VI. Theft/loss not reported in timely manner as required by 21 CFR 1301(b)

VII. Improper filled Forms 222 in violation of 1305.13

VIII. Missing POA (or failure to properly execute) in violation of 1305.12(d)

Corresponding Responsibility

I. Failure to exercise corresponding responsibility in violation of 1306.04

   A. Provider ignored the red flags present when dispensing CS, such as long travel, cash payments, early refills, cocktail prescriptions, prescription patterns

   B. Prescriptions written by problematic prescribers

   C. Failure to run PDMP reports

Mitigating Risks

I. Train staff

II. Perform due diligence in relation to each patient – document everything

III. “Do-not-fill” policy for some of the “problematic” prescribers

IV. Running PDMP on all existing (periodically) and new patients

V. Review and update SOPs dispensing CS

Red Flags Cited

I. Excessive filling (compared to similarly situated pharmacy)

II. Unusual combination of CS

III. Patients obtaining CS from multiple practitioners

IV. Filling CS prescriptions for patients with the address of a drug treatment facility

V. Customers paying in cash

VI. Filling prescriptions without obtaining a PDMP report.

VII. Early refills

Penalties for Violations

I. Monetary penalties

II. Surrendered registration

Case Study

I. Trinity Pharmacy

II. Zion Clinic Pharmacy

FDA's Involvement in the Opioid Crisis

I. Guidelines "Abuse-Deterrent Opioids— Evaluation and Labeling"

II. Naloxone

III. Risk Evaluation and Mitigation Strategies (REMS)

IV. FDA innovation challenge "to spur the development of medical devices, including diagnostic tests and digital health technologies (mobile medical applications) to help combat the opioid crisis and achieve the goal of preventing and treating opioid use disorder."

Practice Tips

I. PDMP verification is a must on all new patients.

II. On the existing patients, run PDMP regularly.

III. Verify prescribers' DEA registrations

IV. Train pharmacy staff on "red flags"

V. Document due diligence!

VI. Consider e-prescribing

VII. Ensure telepharmacy compliance

Prescription Audits

Dennis Wichern

DEA Special Agent in Charge (Ret.)

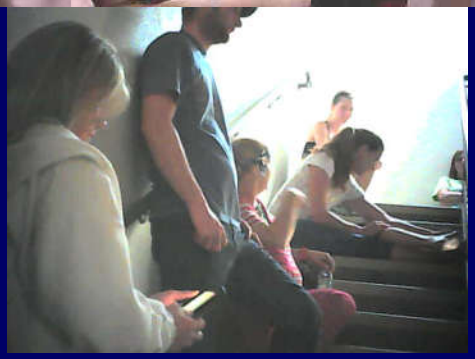
Prescription Drug Consulting LLC

Give Me a Example of a Typical DEA Investigation

Medical Office?

Medical Office?

Medical Office?



Medical Office?

Source: Miami Herald
http://media.miamiherald.com/static/media/projects/2014/innocents-lost/stories/pill-mills/

What are the Red Flags?

- Complaints from LE, pharmacists & family members.
- Overdose deaths.
- Lines outside the office.
- Irregular hours.
- Cash only.
- And others.
- Usually not one thing but a combination of several.

DEA's Role with Medical Providers

DEA's authority under the CSA is not equivalent to that of a State medical board. DEA does not regulate the general practice of medicine.

The responsibility for educating and training physicians so that they make sound medical decisions in treating pain (or any other ailment) lies primarily with medical schools, post-graduate training facilities, State accrediting bodies, and other organizations with medical expertise.

DEA's authority is limited to controlled substances only.

DEA's Role with Controlled Substances

DEA's statutory responsibility under the Controlled Substance Act (CSA) is twofold:

1) prevent diversion and abuse of drugs

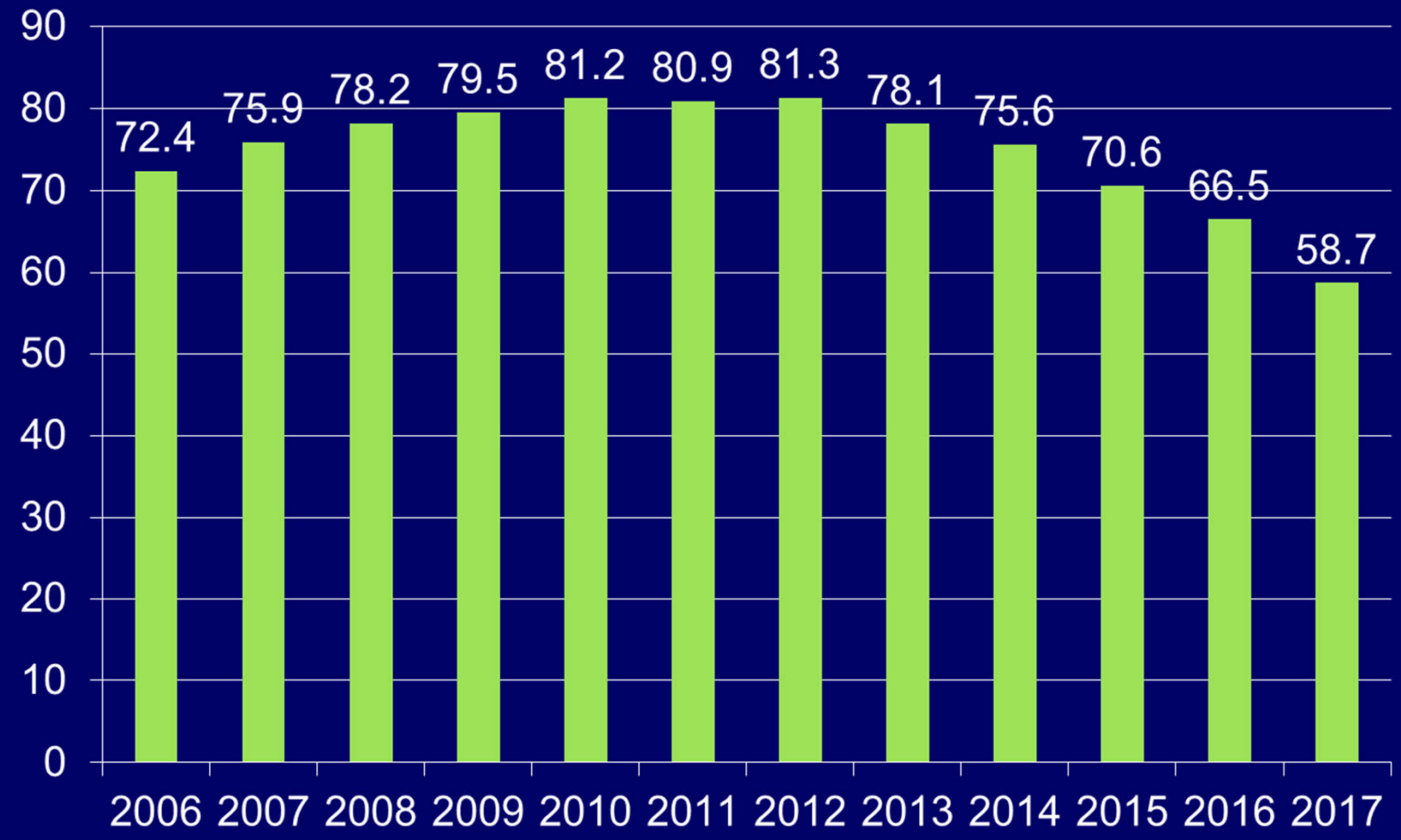
2) ensure an adequate and uninterrupted supply is available to meet the country's legitimate medical, scientific, and research needs.

<u>DEA has no medical doctors on staff.</u>

The Latest Numbers
DEA Registrants

- Approximately 305,510 pharmacists in 2016.
  (4% to 6% annual growth rate)
- 72,000 Pharmacies
- 17,700 hospitals/clinics
- Approximately 400,000 pharmacy techs.
- Approximately 1.25 million MD's & DO's
  - 970,000 MD's & DO's
  - 200,000 Dentists
  - 73,000 Vets
  - 330,000 NP's & PA's

U.S. Opioid Prescriptions per 100 Persons



https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html

"U.S. Medical Regulatory Trends and Actions"
Federation of State Medical Board Study
2018 Year Data

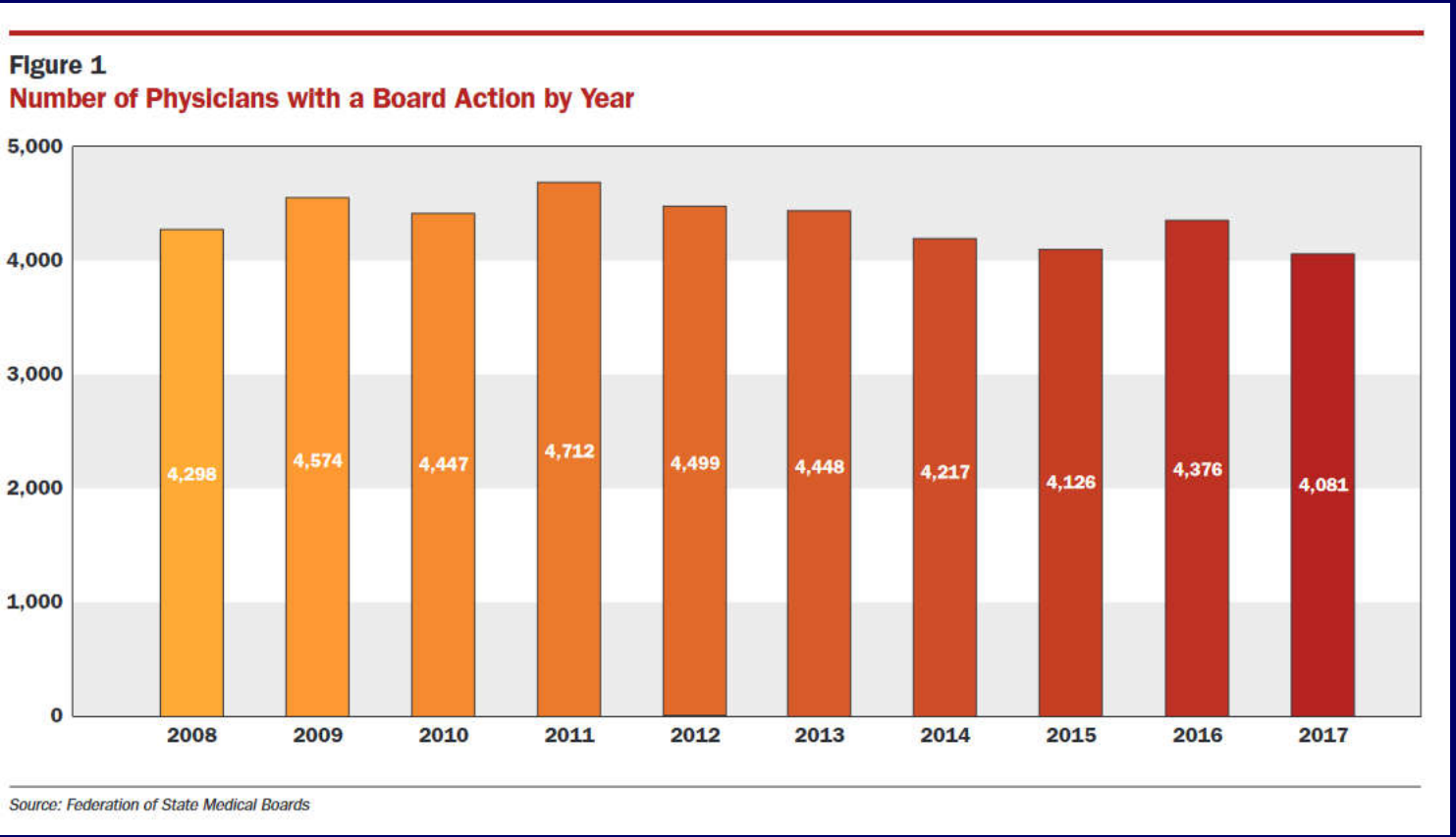
970,090 active physicians

4,081 physicians disciplined

Surrendered	570
Revoked	264
Denied	97
Total	931

https://www.fsmb.org/siteassets/advocacy/publications/us-medical-regulatory-trends-actions.pdf

"U.S. Medical Regulatory Trends and Actions"
Federation of State Medical Board Study
2018 Year Data



https://www.fsmb.org/siteassets/advocacy/publications/us-medical-regulatory-trends-actions.pdf

Controlled Substances Act of 1970
21 USC

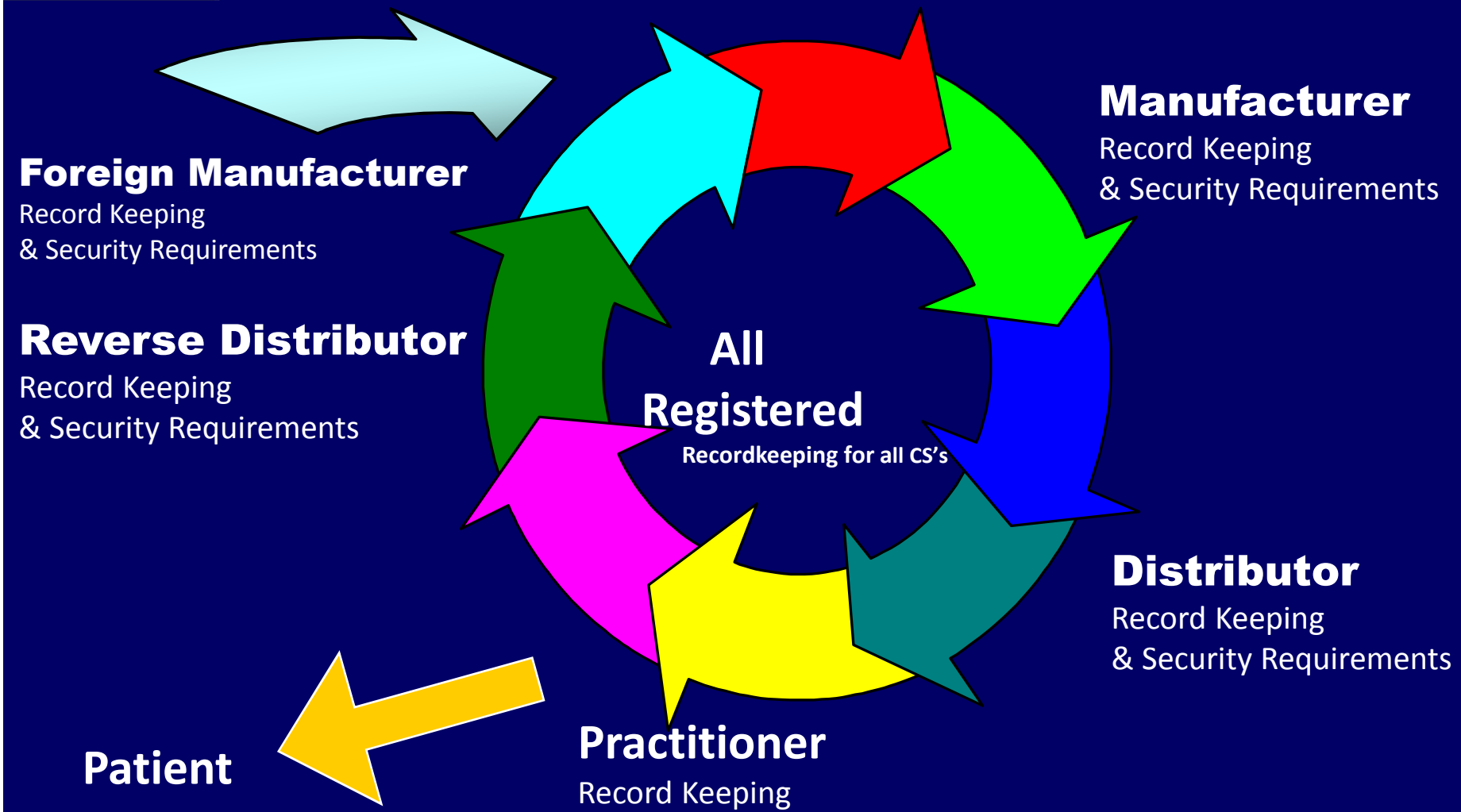
Legal foundation of federal government's authority for controlled substances and listed chemicals.

Under the CSA, Congress established a "closed system" of distribution to prevent the diversion of controlled substances.

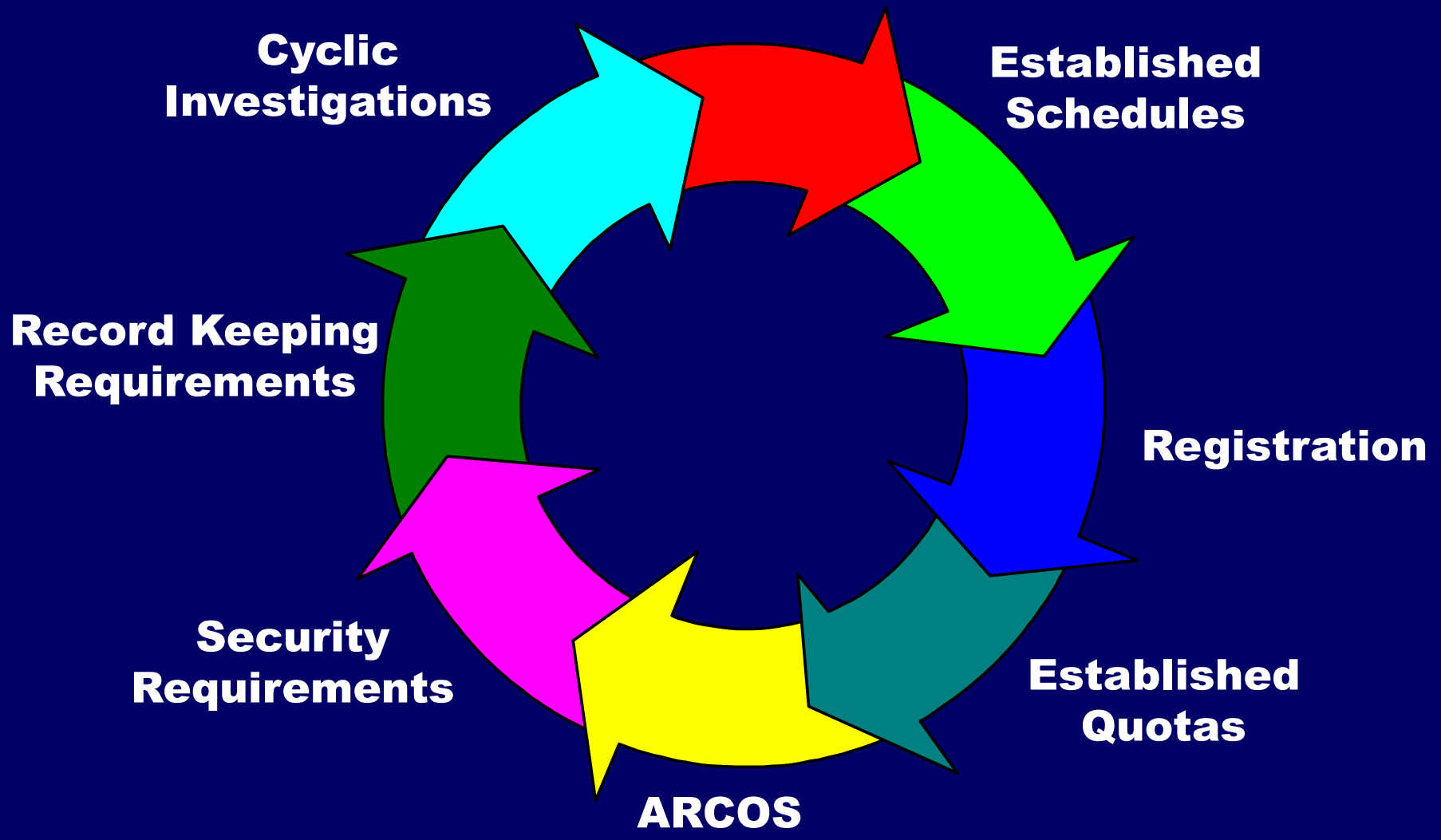
All persons who lawfully handle controlled substances must be registered with DEA or exempt from registration.

Ultimate users (patients) are not required to register with DEA to possess controlled substances.

THE CSA'S CLOSED SYSTEM
EVERYONE IS REGISTERED
RECORDKEEPING FOR ALL CONTROLLED SUBSTANCES



DEA DIVERSION CONTROL PROGRAM
Includes



Types of Investigations & Examples

Types

- Administrative
- Civil
- Criminal

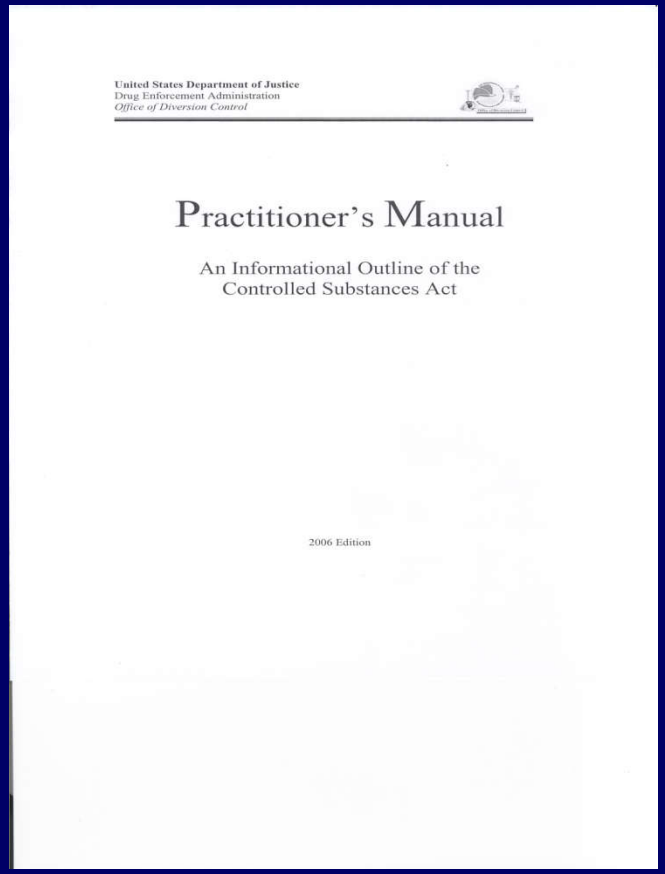
Examples

- Provider self-abuse
- Recordkeeping violations
  - Manufacturers
  - Dispensers
  - Handlers of CS's
  - Significant fines possible
- Pill Mills, Billing fraud & other

Online DEA Resources

Practitioner's Manual

https://www.deadiversion.usdoj.gov/


United States Department of Justice
Drug Enforcement Administration
Office of Diversion Control

Practitioner's Manual

An Informational Outline of the
Controlled Substances Act

2006 Edition

- https://www.deadiversion.usdoj.gov/pubs/manuals/pract/index.html
- Great source for CS recordkeeping requirements.

Controlled Substance Recordkeeping Requirements CFR 1300

(Similar to U.S. Banking System)

- Banks
- Money
- Recordkeeping
- Every dollar accounted for

- Manufacturers/Distributors/ Pharmacies/Providers who maintain controlled substances (CSs)
- CSs
- Recordkeeping
- Every CS accounted for

Required Records – Controlled Substances
CFR Part 1304

- POA's for II's
- Initial Inventory
- Biennial Inventory
- Closing Inventory
- Receiving Records, 222's or invoices – 2 year federal retention
- Distribution Records
- Theft and Loss – DEA Form 106 Report to LE
- Drug Destruction – DEA Form 41 – Reverse Distributors – Return to Manufacturer
- Prescriptions vs Dispensing (Must keep dispensing records)

The DEA Audit Process

- Two diversion investigators or more
- Two to four hour process
- Starts with a DEA form 82 “Notice of Inspection”
- You have right to refuse
- Administrative search warrant option
- Records need to be “readily retrievable”

The Key Records in a DEA Audit Process that Will be Checked

1. Executed and unexecuted official order forms (DEA Form 222) or the electronic equivalent
2. Power of Attorney authorization to sign order forms
3. Receipts and/or invoices for schedules III, IV, and V controlled substances
4. All inventory records of controlled substances, including the initial and biennial inventories, dated as of beginning or close of business
5. Records of controlled substances distributed (i.e., sales to other registrants, returns to vendors, distributions to reverse distributors)

The Key Records in a DEA Audit Process that Will be Checked

6. Records of controlled substances dispensed (i.e., prescriptions, schedule V logbook)
7. Reports of Theft or Significant Loss (DEA Form 106), if applicable
8. Inventory of Drugs Surrendered for Disposal (DEA Form 41), if applicable
9. Records of transfers of controlled substances between pharmacies
10. DEA registration certificate
11. Self-certification certificate and logbook (or electronic equivalent) as required under the Combat Methamphetamine Epidemic Act of 2005

Will also count and confirm several drug inventories

The DEA Audit Form

1	2	3	4	5	6	7	8	9
Names & Strength of Drugs	Initial Inventory as _____	Total Purchased (same time frame)	Total Accountable For (2 +3)	Closing Inventory as of _____	Total Dispensed	Total Can Account For (5+6)	Difference Over= Short = (7-4)	Percentage Difference (8/4 x100)

The Most Common DEA Recordkeeping Violations

- No Power of Attorney for 222s
- No initial or biennial inventories
- No separate inventories (Sch 2 vs Sch 3-5)
- Failing to report thefts and losses
- Failure to record transfers

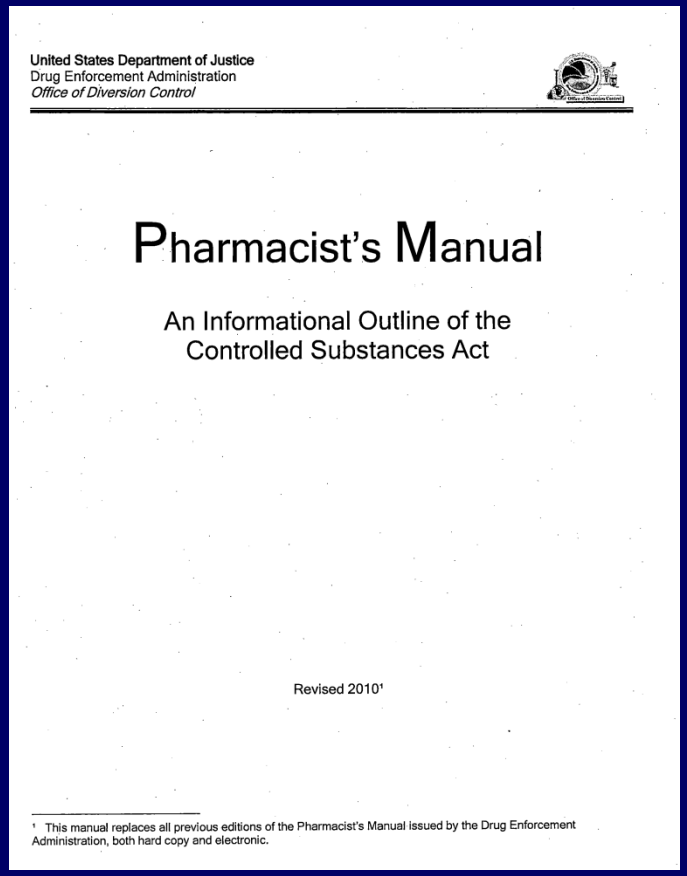
Security

- Controlled substances stored at the registered location should be in a “securely locked, substantially constructed cabinet or safe”
- If substantial quantity, recommend a safe and alarm system
- Access restricted

Online DEA Resources

Pharmacist's Manual

https://www.deadiversion.usdoj.gov/



United States Department of Justice
Drug Enforcement Administration
Office of Diversion Control

Pharmacist's Manual

An Informational Outline of the
Controlled Substances Act

Revised 2010[1]

[1] This manual replaces all previous editions of the Pharmacist's Manual issued by the Drug Enforcement Administration, both hard copy and electronic.

- https://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/index.html

Registration Assistance

- **HQ Registration Call Center**
  - (800) 882-9539
    8:30 am-5:50 pm EST

  DEA.Registration.Help@usdoj.gov

  - ELECTRONIC PRESCRIPTIONS FOR CONTROLLED SUBSTANCES

    EPCS@usdoj.gov

  - IINTERPRETATION AND GUIDANCE ON DEA POLICIES AND REGULATIONS

    ODLP@usdoj.gov

Registration Summary

- A separate registration is required for every principal place of business, unless a registrant is only prescribing at a second location.
- If a registrant maintains supplies of controlled substances, administers, or directly dispenses controlled substances at that second location, a separate registration must be obtained.

National Forensic Laboratory Information System
NFLIS

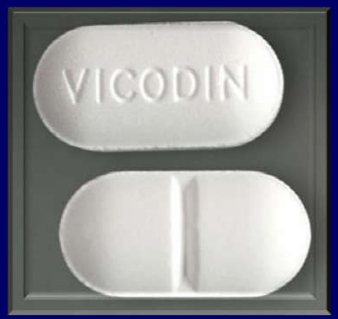
91% all evidence from 273 participating labs from 49 states

https://www.nflis.deadiversion.usdoj.gov

Most Commonly Abused Pharmaceutical Drugs

Top Four Narcotic Analgesics Submitted to Crime Laboratories

Fentanyl (illicit)	30.5%
Oxycodone	15.46%
Buprenorphine	10.33%
Hydrocodone	9.26%



Source: National Forensic Laboratory Information System – 2018

Top Three Benzodiazepines Submitted to Crime Laboratories

Alprazolam (Xanax)	59%
Clonazepam (Klonopin)	14%
Diazepam (Valium)	5%

www.nflis.deadiversion.usdoj.gov

The Holy Trinity

Prescription Drug Combination that Gives Heroin - Like - High

- Hydrocodone – Vicodin/Lortab/Norco
- Alprazolam - Xanax
- Soma - Carisprodol

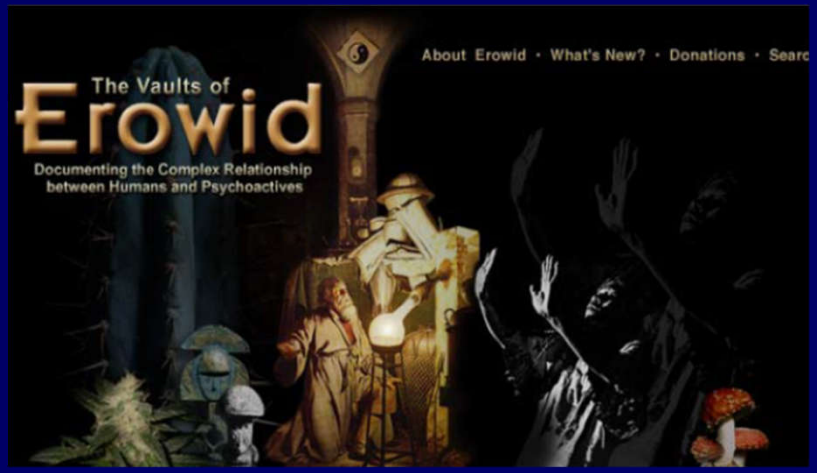
- No legitimate medical purpose

Other Common Drug Cocktails

- Soma + codeine = "Soma coma"
- Always changing
- Gabapentin abuse

Drug Blogs
(Research Tool)

- Erowid.org
- Bluelight.org
- Drugs-Forum.com
- Opiophile.org



Hospital Investigations
What do we commonly see?

- Nurses/doctors self abusing liquid painkillers from patients
- From syringes or dispensing machines
- Do not see significant provider issue in hospitals due to management oversight, policies & peer review
- Controlled substance thefts and diversion – usual cause is poor oversight of drugs in pharmacies & lack of recordkeeping

University of Michigan Health System (UMHS)

$4.3 Million Dollar Civil Penalty for Hospital Drug Diversion
August 30, 2018

- Started in December of 2013 after nurse and anesthesiology overdosed on opioids with nurse dying.
- DEA goes in.
- UMHS did not have registration for 15 off-site ambulatory care locations, each of which received drugs from hospitals pharmacy
- UMHS failed to keep maintain required records, invoices, transfers, destruction, etc.
- UMHS failed to report thefts and losses of CS's.
- Entered into a three year MOA with DEA.

https://www.justice.gov/usao-edmi/pr/eastern-district-michigan-announces-record-setting-hospital-drug-diversion-civil
https://www.mlive.com/news/ann-arbor/index.ssf/2018/08/university_of_michigan_health_33.html

University of Michigan Health System (UMHS)

$4.3 Million Dollar Civil Penalty for Hospital Drug Diversion

August 30, 2018

- Both medical personnel had injected liquid opioids meant for patients and found in bathrooms.
- Diversion of drugs went on for a significant time and due to deficient recordkeeping.
- 16,000 hydrocodone pills stolen.
- Drugs were diverted from Omnicells dispensing machines.
- RN's diverted liquid opioids from Omnicells and replaced with saline solution.
- Key personnel were interviewed and lacked knowledge of controlled substance policies.

University of Michigan Health System (UMHS)

$4.3 Million Dollar Civil Penalty for Hospital Drug Diversion

August 30, 2018

- Results
- Formation of Executive –level CS Safety and Compliance oversight Committee
- Creation of Diversion Prevention Program tasked with preventing, detecting and responding to diversion.
- Unannounced quarterly audits
- Implement software called Controlled Substance Tool
- Implemented a drug prevention and diversion educational program

Provider Investigations
What did you see as a DEA Agent?

- Healthcare providers paid by # of patients seen & tied to CS prescriptions.
- Prescriptions sometimes tied to back injections
- Rural more than urban settings
- Almost always involves older male doctors, 45 yoa +
- Sex for drugs on some occasions
- Hospital MD's moonlighting in OUD treatment

Ambulance Service Investigations What do we see?

- EMT personnel self abusing liquid painkillers from kits.
- Poor accounting of CS's

Brick & Mortar Pharmacy Investigations
What Do We Commonly See?

- Controlled substance thefts and diversion by pharmacy techs.
- Generally, smaller non-chain pharmacies have more issues.
- Recordkeeping violations. (Keep perpetual inventory and limit transfers for simplicity.)

Case Studies

Civil Fine Pharmacy

Schnuck Markets Agree To Pay $65,000.00 Civil Penalty

June 12, 2015 Stephen R. Wigginton, United States Attorney for the Southern District of Illinois, announced today that Schnuck Markets, Inc. (Schnucks) has paid the United States of America sixty-five thousand dollars ($65,000.00) as part of a voluntary agreement settling allegations that Schnucks violated the Controlled Substances Act.

The United States alleged that Schnucks pharmacies filled prescriptions written by unauthorized practitioners. In particular, the allegations include that the pharmacies filled prescriptions written by mid-level practitioners not authorized to prescribe certain controlled substances and by practitioners who previously surrendered their prescribing privileges.

https://www.justice.gov/usao-sdil/pr/schnuck-markets-agree-pay-6500000-civil-penalty

Civil Fine Pharmacy

CVS to Pay $3.5 Million to Resolve Allegations that Pharmacists Filled Fake Prescriptions

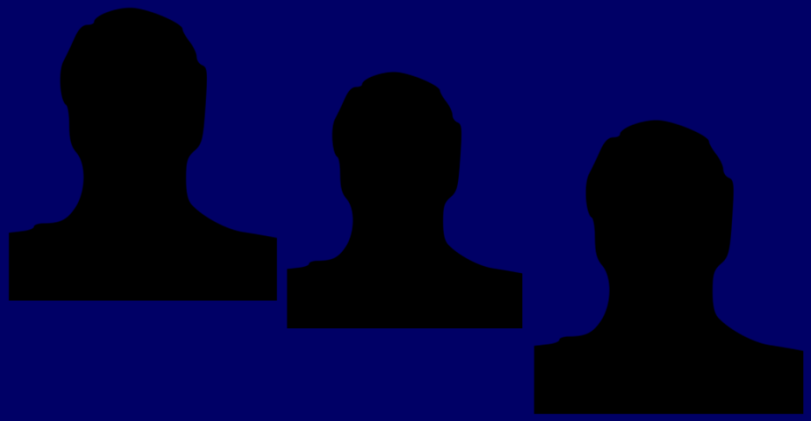
BOSTON June 30, 2016– In one of the largest settlements to date involving federal allegations of prescription drug diversion in Massachusetts, CVS Pharmacy, Inc., has agreed to pay $3.5 million to resolve allegations that 50 of its stores violated the Controlled Substances Act by filling forged prescriptions for controlled substances – mostly addictive painkillers – more than 500 times between 2011 and 2014.

This settlement resolves two investigations of CVS stores initiated by the DEA after it received an increased number of calls reporting forged oxycodone prescriptions. The forged prescriptions traced back to just a few individuals. One of the forgers, P.R., signed a dentist's name on 56 of 59 oxycodone prescriptions that P.R. was then able to get filled at five CVS locations. CVS pharmacists filled these prescriptions even though CVS banned P.R. in 2011 and its computer system contained notes warning that P.R. had tried to fill forged prescriptions in the past.

Another forger, E.M., signed a dentist's name on 131 prescriptions for hydrocodone – another highly addictive opioid – and then had them filled at eight CVS stores. One of those stores, in South Dennis, Mass., filled 29 forged prescriptions for E.M. in just six months. Those 29 prescriptions totaled 1,290 pills of hydrocodone, or seven pills a day. At a different CVS store, E.M. was able to fill 28 prescriptions that she had forged for herself and three other alleged patients even though the prescriptions were identical except for the patient name and even though E.M. presented some of the prescriptions just days apart. CVS also filled 107 prescriptions that bore the dentist's Massachusetts address, even though, by then, the dentist had closed her Massachusetts practice and moved to Maine. CVS pharmacists could have discovered that the address on these prescriptions was no longer valid had they called the phone number on the prescriptions or checked the DEA's website.

https://www.justice.gov/usao-ma/pr/cvs-pay-35-million-resolve-allegations-pharmacists-filled-fake-prescriptions

Criminal Charges
Pharmacists & Doctor



- Doctors office inside pharmacy
- Two Pharmacists decided who saw Dr.
- Patient files kept in pharmacy area
- Pharmacists took cash for UDS's
- Pharmacists counseled patients how to pass UDSs
- Pharmacists signed scrips for doctor
- Patients who failed UDSs paid cash fines
- Doctor charged more for early refills
- All prescriptions had to filled at pharmacy
- No exams by doctor
- 90% of business relied on patients tied to doctor

https://www.justice.gov/file/984456/download

Criminal Charges

Pharmacist & Red Flags

Berea Pharmacist Found Guilty of Illegally Dispensing Hundreds of Thousands of Prescription Pills and Thousands of Boxes of Pseudoephedrine and Money Laundering

2/17/2017 LEXINGTON, Ky. – A Berea pharmacist, Lonnie Hubbard, age 41, has been convicted by a federal jury of 71 counts, including fifty-six drug counts, involving the illegal dispensing of controlled substances without a legitimate medical purpose and dispensing pseudoephedrine knowing it would be used to manufacture methamphetamine; maintaining a drug involved premises; twelve counts of money laundering; and two conspiracy charges.

According to evidence presented at trial, from 2010 until 2015, Hubbard, who owned RX Discount Pharmacy in Berea, sold prescription pain pills, without a legitimate medical purpose, and sold pseudoephedrine, knowing or having reason to believe that it was being used to manufacture methamphetamine. Many of the people Hubbard sold to were addicts and drug traffickers from Madison, Rockcastle, Laurel, Clay and other counties in central and eastern Kentucky.

The evidence further established that many of Hubbard's customers visited pain clinics in Florida, Ohio, Tennessee, and Georgia, to obtain illegitimate prescriptions from irreputable clinics. Hubbard would charge $600 to $1,000 to fill a cocktail of prescriptions, which included excessive amounts of oxycodone. According to trial testimony Hubbard also sold multiple boxes of pseudoephedrine at a time, at excessive prices, to drug addicts and traffickers. From 2013 to 2015, Hubbard's pharmacy was the number one independent pharmacy retailer of Pseudoephedrine in Kentucky.

Those who obtained drugs at Hubbard's pharmacy testified that RX Discount was one of the only places in Kentucky that would fill their out of state prescriptions for pain medication. More than twenty doctors from Florida, Georgia, and Tennessee, who wrote the illegal prescriptions related to this case, have either surrendered their medical license, been indicted, or are currently under investigation.

https://www.justice.gov/usao-edky/pr/berea-pharmacist-found-guilty-illegally-dispensing-hundreds-thousands-prescription

Mis-branding Drugs

Pikeville Doctor Admits To Conspiracy To Misbranding Prescription Drugs

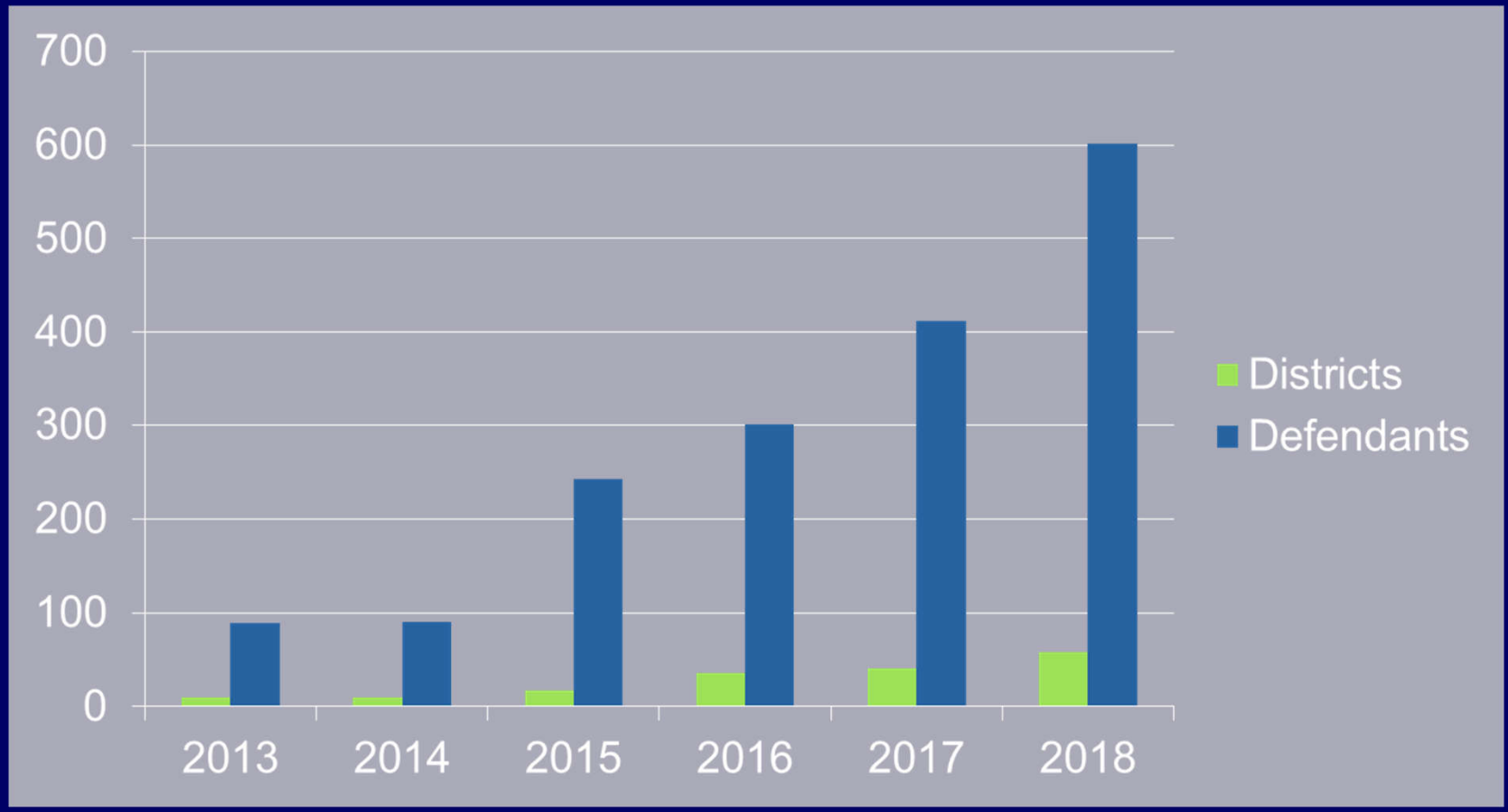
4/17/14 PIKEVILLE, KY - A Pikeville doctor admitted in federal court that he allowed a pharmacy access to his prescription drug samples that were supposed to go to his patients. Thad Manning, 48, pleaded guilty on Wednesday to conspiracy to misbranding drugs. Manning agreed to forfeit $250,000 which represents the proceeds he received as a result of the conspiracy. Manning will also enter into drug rehabilitation for an addiction to hydrocodone.

Manning admitted that over the course of several years he received numerous prescription drug samples from various pharmaceutical companies. In the written agreement between Manning and the pharmaceutical companies, Manning pledged to provide the samples to patients. Instead, Manning allowed Marrowbone Clinic Pharmacy (later known as Marrowbone Hometown Pharmacy) to take the prescription samples and co-mingle them with other prescription drugs already in stock bottles. These co-mingled drugs were ultimately dispensed to the pharmacy's customers.

Because the pharmacy removed the sample medications from their original packaging and mixed them with medications from stock bottles, the drug's identifying information and expiration information on the stock bottle became inaccurate and thus misbranded. This made it impossible for the consumer to know whether or not their particular medication had been recalled by the Food and Drug Administration or the pharmaceutical companies.

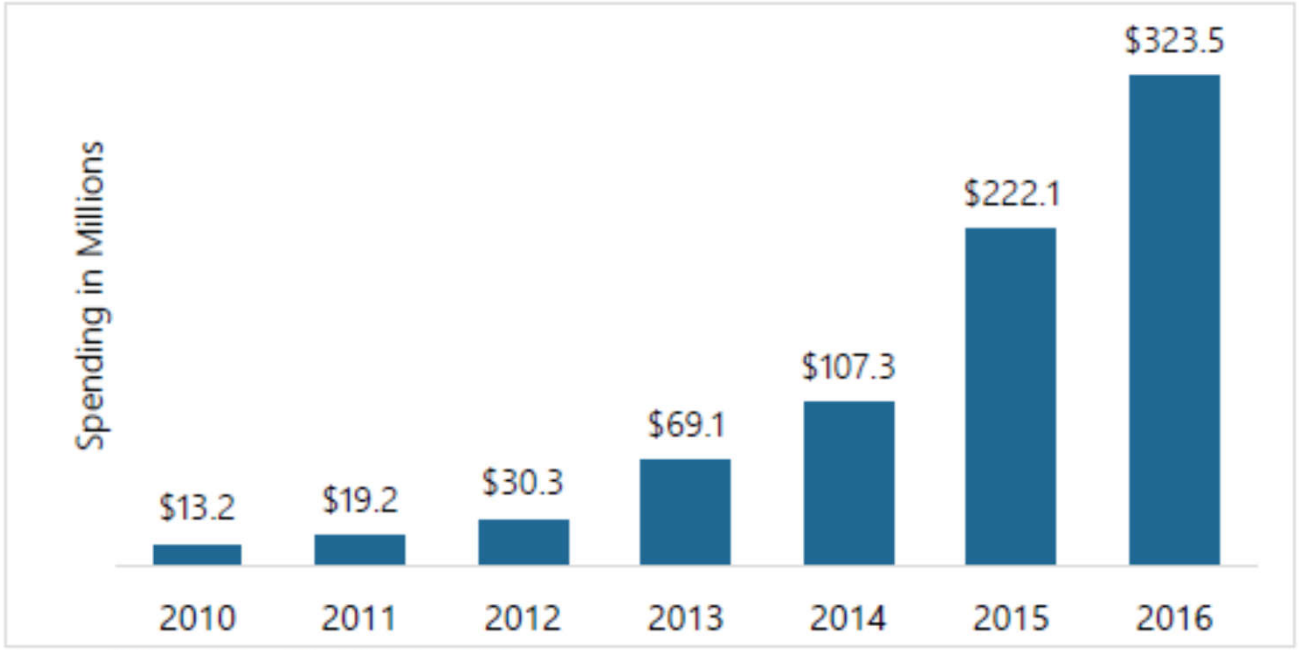
https://www.justice.gov/usao-edky/pr/pikeville-doctor-admits-conspiracy-misbranding-prescription-drugs

National Healthcare Fraud Takedowns



2018 OIG/HHS Report on Compounded Topical Drugs in Medicare Part D

Exhibit 1: Part D spending for compounded topical drugs grew exponentially from 2010 to 2016.



Source: OIG analysis of Part D data, 2017.

2018 OIG/HHS Report on Compounded Topical Drugs in Medicare Part D

- Independent pharmacies were about seven times more likely than chain pharmacies to have questionable billing for compounded topical drugs.
- Of the 547 pharmacies with questionable billing for compounded topical drugs, 154 were located in the New York, Houston, Detroit, and Los Angeles metropolitan areas.

What Else is New?

Patient Drug Disposal "Ultimate Users"

Secure and Responsible Drug Disposal Act of 2010 - CFR part 1317

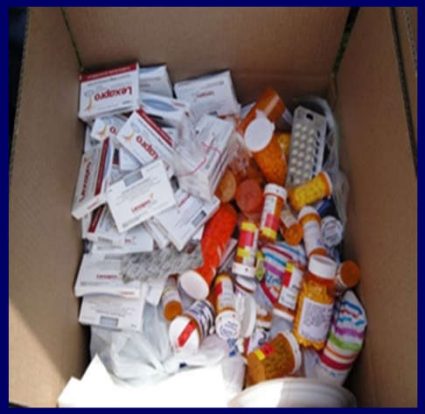
Drug Take-back Options- For Patients – "Ultimate Users"

This rule provides three voluntary options for ultimate user disposal:

(1) Take-back events, (law enforcement only)

(2) Mail-back programs, and (pharmacy linked)

(3) Collection receptacles. (pharmacy linked)



Federal Register /Vol. 79, No. 174 /Tuesday, September 9, 2014

Collection Receptacles Options

- Pharmacies
- Long-term Care Facilities
- Hospitals/clinics
- Opioid Treatment Programs
- Police Departments

Drug Disposal Options
Website Links

National Drug Take Back Day - every April and September

NABP www.awarerx.com

DEA
https://apps.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e1s1

Walgreens (multiple locations)
https://www.walgreens.com/storelistings/storesbystate.jsp?requestType=locator

CVS (multiple locations)
https://www.cvs.com/content/safer-communities-locate

Drug Destruction Options Pharmacies (Registrants)

1. Return drugs to manufacturer for credit & destruction.
2. Transfer to “Reverse Distributor” for destruction.
3. Destroy yourself.

(Remember to document and record transfer & destruction.)

Comprehensive Addiction and Recovery Act (CARA) Highlights

- In effect since July 22, 2016
- Qualifying physicians can treat up to 30, 100 or 275 patients (Board Certification for those treating 275)
- Qualifying NP's and PA's can treat up to 30 or 100 – had been for five year period but now forever. (States can raise limits)
- Revised SAMHSA guidelines TIP 63 published February 15, 2018.
- When in doubt – email SAMHSA.

Data Waived Physicians as of 8/2019 - SAMHSA	
30 patient limit	53,868
100 patient limit	12,882
275 patient limit	5,118
Total	71,868

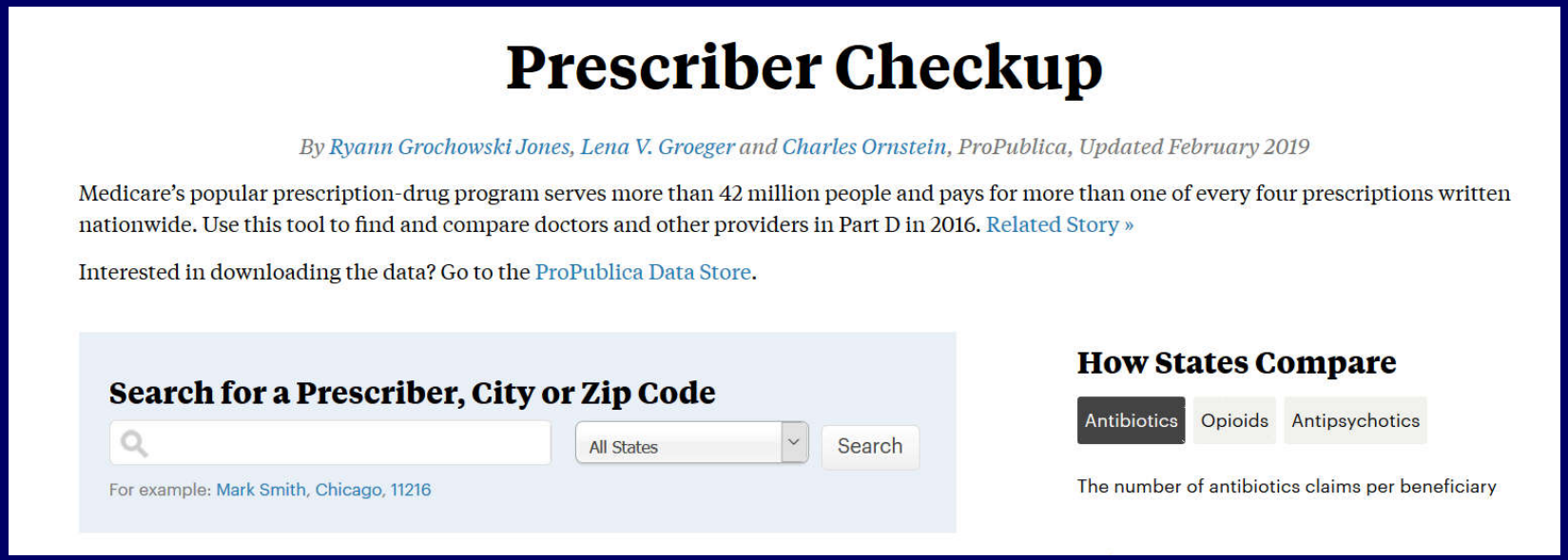
https://www.samhsa.gov/medication-assisted-treatment/training-materials-resources/practitioner-program-data

Telemedicine - 21 USC 802 (54)

- Ryan Haight Act - Federal
  - Background
  - Allows for telemedicine after a in-person evaluation
  - Provider must be licensed in states which it occurs
  - Patient must be in the physical presence of a doctor sitting in medical office
  - New exception regulation by DEA forthcoming

- Risk mitigation
  - Evolving medicine & law
  - Risk increases with CS's
  - Equal state & fed?
  - Ensure oversight & guideline adherence
  - Stay current

Use of ProPublica Prescriber Lookup to Minimize Risk?



Prescriber Checkup

By Ryann Grochowski Jones, Lena V. Groeger and Charles Ornstein, ProPublica, Updated February 2019

Medicare's popular prescription-drug program serves more than 42 million people and pays for more than one of every four prescriptions written nationwide. Use this tool to find and compare doctors and other providers in Part D in 2016. Related Story »

Interested in downloading the data? Go to the ProPublica Data Store.

Search for a Prescriber, City or Zip Code

All States | Search

For example: Mark Smith, Chicago, 11216

How States Compare

Antibiotics | Opioids | Antipsychotics

The number of antibiotics claims per beneficiary

https://projects.propublica.org/checkup/

Prescriber Notification Initiative for Opioids

- ATLANTA – The U.S. Attorney's Office for the Northern District of Georgia has identified approximately 30 medical professionals who are prescribing opioids in significantly higher quantities or doses than their peers or to patients who may pose a high risk of abuse or diversion. The U.S. Attorney will provide these prescribers with specific information about their prescription patterns and will refer them to educational materials, such as the Centers for Disease Control and Prevention (CDC) Guidelines for Prescribing Opioids for Chronic Pain, related to safe opioid prescription practices.

- The Department of Justice has made no determination, at this time, that prescribers who receive these letters have violated the law. We have a duty, however, to protect the lives and safety of our citizens, and making information available to prescribers within the District has the potential to save lives.

https://www.justice.gov/usao-ndga/pr/prescriber-notification-initiative-opioids

Coroner sent letters to doctors whose patients died of opioid overdoses. Doctors habits quickly changed

Los Angeles Times, August 9, 2018

- Started in San Diego
- Letters sent to doctor when a patient overdosed and died.
- Offered five prescribing tips.
- Study published in the Journal of Science
- Saw prescribing change
- CA Medical Board Prescriber Action

http://www.latimes.com/science/sciencenow/la-sci-sn-opioid-overdose-letter-20180809-story.html

The Future?

- Continued focus on provider and pharmacy operations linked to opioids
- Possible focus on ASC's (maybe just a matter of time)
- What will Telemedicine do? (History has not been kind when linked to opioids)
- Use ProPublica "Prescriber Lookup" to judge your risk?

Key Takeaways to Minimize Risk

- Maintain robust security and recordkeeping for CS's
- Limit the locations where CS's are kept
- Prescribe rather than dispense whenever possible
- Continue to police yourself through "peer review"
- Use the "rule of two" in high risk situations – patients & CS's
- Follow national and state guidelines whenever possible
- Practice due diligence & have a complaint process
- 99.9% of all providers & pharmacists have zero interaction with Boards or DEA.

Questions

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