DEA Bootcamp 101 with Case Studies

October 29, 2019

Dennis Wichern
DEA Special Agent (Ret.)
PDC LLC

Who I Am

• Retired DEA Special Agent in Charge - Chicago.
• 30 years of experience.
• Worked through the Indiana “pill mill” crisis during 2005 through 2014.
• Have been partnering with medical community/prescribers for last 10 years through CS programs.
• Developer of CME and CLE prescription drug risk mitigation programs focusing on prescriber safeguards, DEA compliance, MAT, pain and drug destruction.
• I am not an attorney.
• Zero medical training.
Give Me an Example of a Typical DEA Investigation

Medical Office?
Medical Office?
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.
Provider Licensing

1. State Medical License
2. State Controlled Substance Registration
3. Federal Controlled Substance Registration (DEA) $731 fee for three years.
4. X-Number (DEA & HHS) License to treat substance users. Must have license from SAMHSA. No fee.
5. All federal licenses contingent on state licenses

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.

DEA has no medical doctors on staff.
The Latest Numbers

DEA Registrants

- 17,700 hospitals/clinics
- 72,000 Pharmacies
- Approximately 310,000 pharmacists
- 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 - CDC
970,090 active physicians
4,081 physicians disciplined

Surrendered 570
Revoked 264
Denied 97
Total 931

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.
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/

• 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)

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

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Names &amp; Strength of Drugs</td>
<td>Initial Inventory as _______</td>
<td>Total Purchased (same time frame)</td>
<td>Total Accountable For (2 + 3)</td>
<td>Closing Inventory as of _______</td>
<td>Total Dispensed</td>
<td>Total Can Account For (5+6)</td>
<td>Difference Over = Short = (7-4)</td>
<td>Percentage Difference [(8/4) x100]</td>
</tr>
</tbody>
</table>

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/

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

- INTERPRETATION 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 Narcotics Analgesics

<table>
<thead>
<tr>
<th>Narcotics Analgesics</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Fentanyl (illicit)</td>
<td>30.5%</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>15.46%</td>
</tr>
<tr>
<td>Buprenorphine</td>
<td>10.33%</td>
</tr>
<tr>
<td>Hydrocodone</td>
<td>9.26%</td>
</tr>
</tbody>
</table>

Source: National Forensic Laboratory Information System – 2018

Top Three Benzodiazepines Submitted to Crime Laboratories

<table>
<thead>
<tr>
<th>Benzodiazepines</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Alprazolam (Xanax)</td>
<td>59%</td>
</tr>
<tr>
<td>Clonazepam (Klonopin)</td>
<td>14%</td>
</tr>
<tr>
<td>Diazepam (Valium)</td>
<td>5%</td>
</tr>
</tbody>
</table>

www.nflis.deadiversion.usdoj.gov
The Holy Trinity
Prescription Drug Combination that Gives Heroin-Like-High

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

- 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
Headlines- Hospitals & Pharmacies

UM pays $4.3M to settle federal charges for stolen drugs, but criminal charges possible

Effingham Health System paying largest settlement ever for thousands of unaccounted Oxycodone tablets

Mass. General to pay $2.3 million over drug thefts

Walk me through the cases
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

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

University of Michigan Health System

- 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.

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

University of Michigan Health System

- Both medical personnel had injected liquid opioids meant for patients and found in bathrooms.
- Diversion of drugs went on for a long 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.

$2.3 Million Dollar Civil Penalty for Hospital Drug Diversion
September 28, 2015

Massachusetts General Hospital

- Self-reported
- Nurses stealing drugs – 14,000 oxycodone tablets from ADM (had been falling asleep at work)
- Had not been keeping ADM’s access up-to-date
- No supervisory review of ADM usage
- Multiple diversion of drugs by nurses with no discipline
- Loose control over CSs – some brought to lunch room & took home
- Overall lack of recordkeeping
Hepatitis Outbreak – Florida, Mayo Clinic
2010

• Radiology technician
• Employed at Mayo Clinic from 2004 to 2010
• Switched patients fentanyl syringes with saline solution infected with hepatitis C

Hepatitis Outbreak – Colorado
2009

• A surgical tech who infected at least 18 hospital patients with hepatitis C by stealing liquid painkillers and leaving behind her dirty syringes was sentenced to 30 years in prison.
• Stole laid out fentanyl and replaced with saline tainted with her blood.
Multi-state Hepatitis Outbreak

2011

- David Kwiatkowski
- A cardiac technologist in 18 hospitals in seven states before being hired at New Hampshire's Exeter Hospital in 2011.
- Had moved from job to job despite being fired at least four times over allegations of drug use and theft.
- Since his arrest last year, 46 people have been diagnosed with the same strain of hepatitis C he carries.
- Kwiatkowski admitted stealing the injectable painkiller Fentanyl and replacing them with saline-filled syringes tainted with his blood.
- Sentenced to 39 years in prison

What’s the solution?
$4.3 Million Dollar Civil Penalty for Hospital Drug Diversion
August 30, 2018

University of Michigan Health System

• Result
• 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
• Implement a drug prevention and diversion educational program

$2.3 Million Dollar Civil Penalty for Hospital Drug Diversion
September 28, 2015

Massachusetts General Hospital

• Result
• Settlement Agreement – Great road map
• Establish FT Drug Diversion (DD) Compliance Officer
• Establish DD Team – CO, pharmacy, nursery & police/security
• Annual training
• Instituted ADM software
• Limited access to drug vault & server to pharmacists and techs
• Ceased drug carts 7 replaced with ADM’s
• Instituted daily and weekly reviews and audits of drug usage
• Hired outside auditors for review
Key Takeaways

Hospital & Pharmacy
- Create drug diversion team
- Must have PIC (Pharmacist in Charge)
- Review usage of drugs by medical personnel.
- Maintain strong oversight of ADM’s. ***
- Anticipate that liquid opioids will diverted and plan accordingly. Spot check pain level on patients. ***
- Use rule of two for drug wasting.
- Act when someone is caught replacing with saline.
- Limit locations where drugs are kept and track drugs from beginning to end. Maintain strong pharmacy oversight of drugs.

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.
Most Common Medical Office Risk

Case Example #1

• Office provider dispensing CS’s without maintaining required records.
• Office maintaining CSs without proper security and recordkeeping.
• DEA made aware after some triggering issue.

Other Healthcare Risk?

What do we see?

• Healthcare practitioners 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
Other Healthcare Risk?

- What is your complaint process? (Larry Nassar – small office & little oversight?)
- Importance of “rule of two”
- Providers contracting with others - while employed by you

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.


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Civil Fine Pharmacy

CVS to Pay $3.5 Million to Resolve Allegations that Pharmacists Filed 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 1,280 pills of hydrocodone, or seven pills a day. At a different CVS store, E.M. was able to fill 26 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-3-5-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

Appalachian Regional Prescription Opioid (ARPO) Strike Force Takedown Results in Charges Against 60 Individuals, Including 53 Medical Professionals
April 17, 2019

In the Western District of Kentucky, a doctor was charged with controlled substance and health care fraud counts in connection with providing pre-signed, blank prescriptions to office staff who then used them to prescribe controlled substances when he was out of the office, and for directing staff at the clinic, including individuals not licensed to practice medicine, to perform medical services on patients.

Appalachian Regional Prescription Opioid (ARPO) Strike Force Takedown Results in Charges Against 60 Individuals, Including 53 Medical Professionals
April 17, 2019

In the Eastern District of Kentucky, a doctor was charged for allegedly prescribing opioids to Facebook friends who would come to his home to pick up prescriptions, and for signing prescriptions for other persons based on messenger requests to his office manager, who then allegedly delivered the signed prescriptions in exchange for cash.


Appalachian Regional Prescription Opioid (ARPO) Strike Force Takedown Results in Charges Against 60 Individuals, Including 53 Medical Professionals
April 17, 2019

In the Western District of Tennessee, 15 individuals were charged, involving eight doctors and several other medical professionals. In one case, a nurse practitioner who branded himself the “Rock Doc,” allegedly prescribed powerful and dangerous combinations of opioids and benzodiazepines, sometimes in exchange for sexual favors; over approximately three years, the doctor allegedly prescribed approximately 500,000 hydrocodone pills, 300,000 oxycodone pills, 1,500 fentanyl patches, and more than 600,000 benzodiazepine pills.

Appalachian Regional Prescription Opioid (ARPO) Strike Force Takedown Results in Charges Against 60 Individuals, Including 53 Medical Professionals

April 17, 2019

In the Eastern District of Louisiana, a neurologist at an alleged pill mill was charged with conspiracy to dispense controlled substances and conspiracy to commit health care fraud. The defendant allegedly pre-signed prescriptions for controlled substances, including oxycodone, for patients whom he did not personally examine to determine medical necessity for the prescriptions, and pre-signed prescriptions for controlled substances while he was travelling internationally.

https://www.justice.gov/opa/pr/appalachian‐regional‐prescription‐opioid‐arpo‐strike‐force‐takedown‐results‐charges‐against

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.

**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.

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 should I know?

Patient Drug Takeback
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.

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<thead>
<tr>
<th>Data Waived Physicians as of 8/2019 - SAMHSA</th>
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<tr>
<td>30 patient limit</td>
</tr>
<tr>
<td>100 patient limit</td>
</tr>
<tr>
<td>275 patient limit</td>
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<tr>
<td>Total</td>
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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

 Prescription Drug Consulting LLC         Protecting Healthcare Organizations and Providers Nationwide

75

76
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


FDA’s View on CBD

• New approved drug for epilepsy – Epidiolex
• Schedule V
• Yearly cost is $32,500
• Contains less than 0.1% THC
• FDA’s view and laws – supersede 2018 hemp law & CBD
DEA's View on CBD - Hemp CBD is not a Controlled Substance
DEA Press Release
August 26, 2019

• “This notice also announces that, as the result of a recent amendment to federal law, certain forms of cannabis no longer require DEA registration to grow or manufacture. The Agriculture Improvement Act of 2018, which was signed into law on Dec. 20, 2018, changed the definition of marijuana to exclude “hemp”—plant material that contains 0.3 percent or less delta-9 THC on a dry weight basis. Accordingly, hemp, including hemp plants and cannabidiol (CBD) preparations at or below the 0.3 percent delta-9 THC threshold, is not a controlled substance, and a DEA registration is not required to grow or research it.”


What Will The Future Hold?

• 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)
• Surgical Trends: 3-7 days of opioids & increase of drug takeback receptacles
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
- 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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