

# The Intersection of DEA, Pain and Opioids

Dennis Wichern

June 6, 2019



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## 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.

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## Disclosure Statement

This is to confirm that we do not have any personal financial or commercial affiliation to this subject matter.

This is not a promotional talk for any pharmaceutical company.

I do not intend to discuss off-label/investigative use of any commercial product.

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**Give Me a Example of a Typical  
DEA Investigation**

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**Medical Office?**



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**Medical Office?**



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## Medical Office?



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## Medical Office?



Source: Miami Herald  
[http://media.miamiherald.com/static/media/projects/2014/innocents\\_bot\\_images\\_pill\\_mill/](http://media.miamiherald.com/static/media/projects/2014/innocents_bot_images_pill_mill/)

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## What are the Laws on Prescribing?

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## 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.

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## 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.

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## Federal Law – Definition of a Legitimate Prescription

Title 21 Code of Federal Regulations (CFR) 1306.04

### Section 1306.04 Purpose of issue of prescription.

- (a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

### Section 1306.05 Manner of issuance of prescriptions.

- (a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner.

Source: [www.deadiversion.usdoj.gov/21cfr/cfr/1306\\_04.htm](http://www.deadiversion.usdoj.gov/21cfr/cfr/1306_04.htm)  
[www.deadiversion.usdoj.gov/21cfr/cfr/1306\\_05.htm](http://www.deadiversion.usdoj.gov/21cfr/cfr/1306_05.htm)

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## Other Important Law Facts

- Practicing medical providers are hired as experts during provider investigations to opine and testify to the standard of care – not DEA agents.

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## 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

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## 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.

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## Provider Investigations Common Denominators

- 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 +
- Small practices & solo providers
- Sex for drugs on some occasions

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## How About Some Examples?

**Appalachian states targeted as doctors are charged with prescribing painkillers for cash, sex**

SARI HORWITZ AND SCOTT HIGHAM  
The Washington Post

APR 17, 2019 12:35 PM

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## **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.

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

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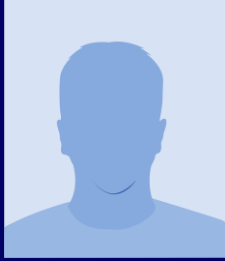
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## Dr. X's Indictment



- Doctor's office inside pharmacy
- 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
- More

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

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## 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.

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

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## Dr. H



- One provider pain clinic
- Cash only
- Cell phone appointment
- Other patient referral only
- Psychiatrist
- In 50's
- Major city

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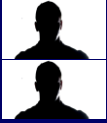
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**Med 1<sup>st</sup>**  
***Chiropractors and Doctor***



- One family practice provider
- Several NP's
- Two chiropractors - managers
- Medicaid patient focused
- All 50 plus
- Large city
- Focused on back injections



[http://www.michigan.gov/waiverandlicensing/chiropractors.html#http://www.michigan.gov/waiverandlicensing/chiropractors.html](http://www.michigan.gov/waiverandlicensing/chiropractors.html#http://www.michigan.gov/waiverandlicensing/chiropractors.html#http://www.michigan.gov/waiverandlicensing/chiropractors.html)

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***PAIN MEDICINE***

***Physicians Charged with Opioid Analgesic-Prescribing Offenses  
Volume 9, Number 6, 2008***

- Study undertaken by Center for Bioethics in partnership with the National Association of Attorneys General and the Federation of State Medical Boards
- Case review period, 1998 - 2006
- 725 doctors representing 0.1%

Source: [https://michigan.gov/documents/mlch/Pain\\_Medicine\\_StudySept08\\_270281\\_7.pdf](https://michigan.gov/documents/mlch/Pain_Medicine_StudySept08_270281_7.pdf)

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***Specialty of Physicians Involved in Criminal and Administrative Cases***

Specialty	%
General Practice	39.3
Physical medicine	2.7
Pain medicine	3.5
Psychiatry	8.1
Internal medicine	23.7
Anesthesiology	7.5
Emergency medicine	5.3
General Surgery	5.1
Obstetrician/Gynecologist	3.2
Pediatrics	2.9

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**Physicians Involved in Criminal and Administrative Cases**

Gender	%
Male	89.4
Female	10.6

Age Range	%
35 & under	3
35 - 44	18.1
45-54	39.5
55-64	24
65 +	15.5

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**Case Outcomes**

	%
Plead Guilty or No Contest	79.5
Plead Not Guilty	20.5

Plead Not Guilty	%
Found guilty or susequently plead	90.6

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**PAIN MEDICINE**

- Conclusions “Criminal or administrative charges and sanctions for prescribing opioid analgesics are rare. In addition, there appears to be little objective basis for concern that pain specialists have been “singled out” for prosecution or administrative sanctioning for such offenses.

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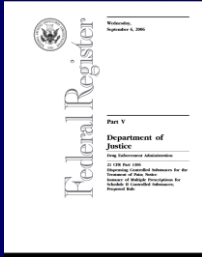
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**Dispensing Controlled Substances for  
the Treatment of Pain**  
September 6, 2006



[https://www.deadiversion.usdoj.gov/fed\\_regs/notices/2006/fr09062.htm](https://www.deadiversion.usdoj.gov/fed_regs/notices/2006/fr09062.htm) 28

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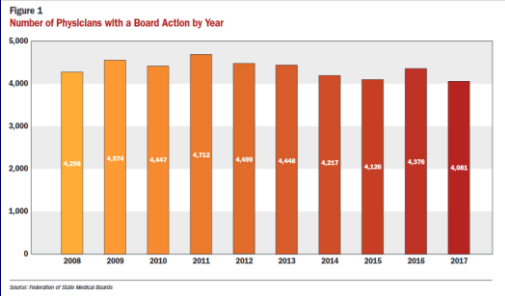
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**Federation of States Medical Boards**



<https://www.fsmb.org/siteassets/advocacy/publications/us-medical-regulatory-trends-actions.pdf> 29

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**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

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## **Safeguards & Suggestions for Providers**

- Treat your prescription pad like your checkbook & secure other pads
- Never sign prescription blanks in advance
- Practice due diligence
- Use PMP's more - than less
- Follow national/state/best practice guidelines whenever possible
- Be extremely careful when prescribing methadone for pain
- 99.9% of all providers & pharmacists have zero interaction with Boards or DEA

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***DEA's Focus is Primarily on Cartels, Gangs, and Criminal Organizations Trafficking, Heroin, Fentanyl, Cocaine and Methamphetamine - Not Against Medical Providers & Pharmacists***

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## ***Questions***

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