

Opioids And DEA Compliance

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Agenda

The Opioid Abuse Crisis

Distinguishing Rx and non-Rx abuse

Solutions Involving Pharmacies

- Quantity limits, national PDMP, mandatory e-prescribing, drug take back, etc.
- Pharmacy implementation issues

DEA Enforcement Activities

Pharmacy actions and suspicious orders

Opioid Litigation

- State, local and tribal



Learning Objectives

Upon completion of the activity, participants should be better able to:

- 1. Understand and comply with recent laws and rules that affect prescribing and dispensing of opioids.
- 2. Describe DEA standards and activities associated with monitoring suspicious orders of controlled substances.
- 3. Summarize pharmacy issues associated with dispensing less than prescribed quantities of opioids.



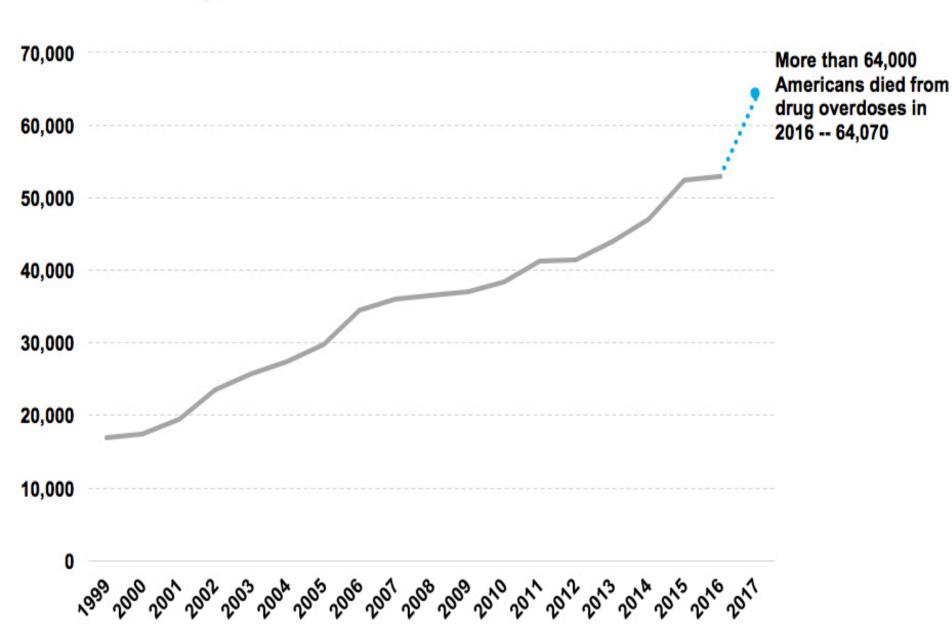
Disclosure

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Total U.S. Drug Deaths



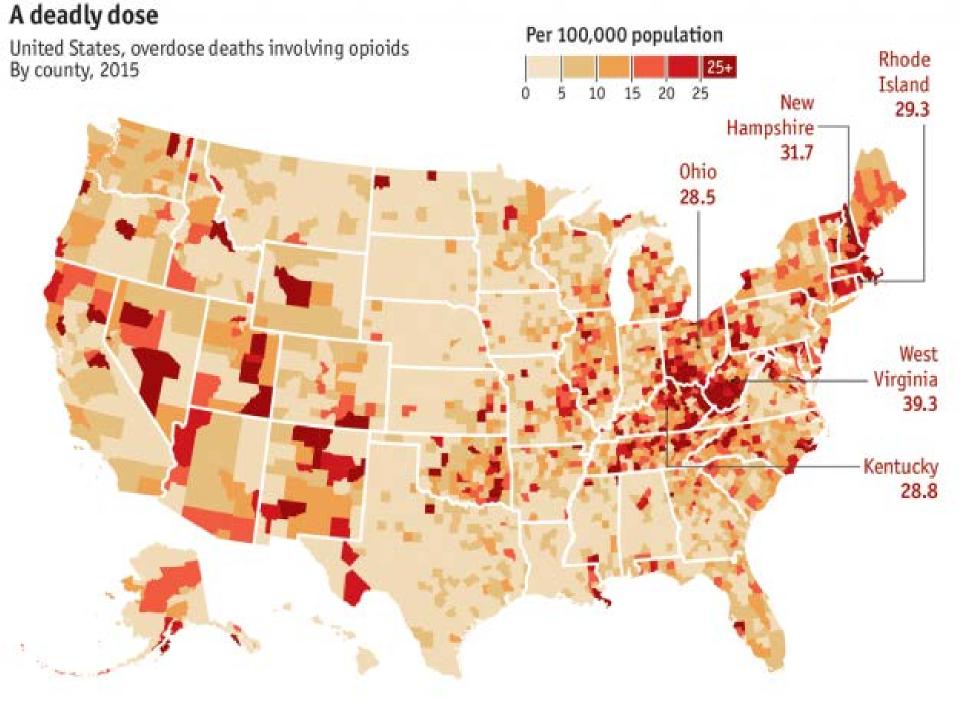


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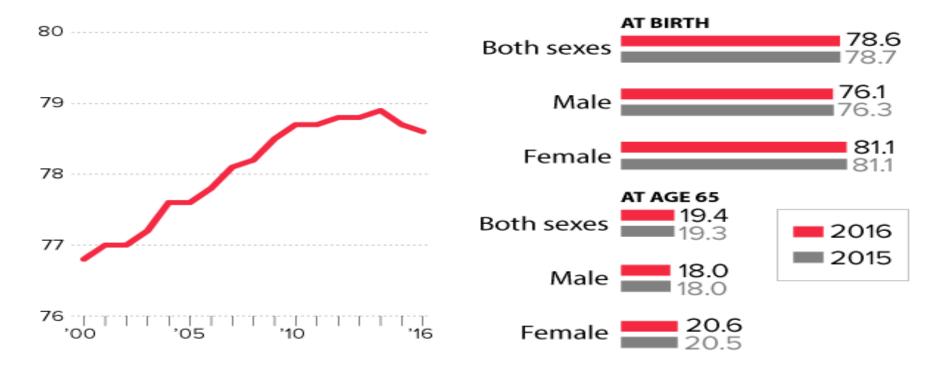
National Overdose Deaths

Number of Deaths Involving Opioid Drugs

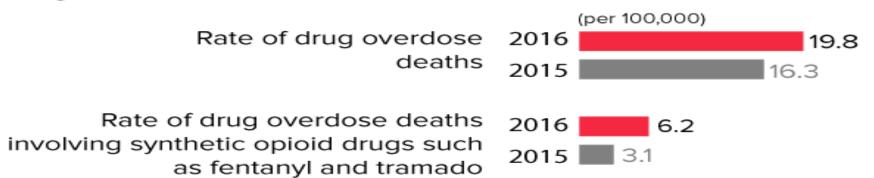




US life expectancy declining again



Drug overdose deaths increase 21% in 2016.

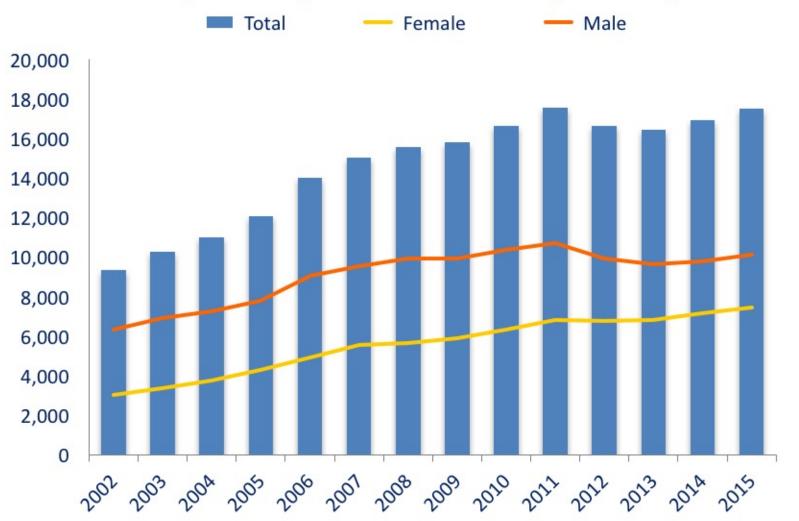


Source: Centers for Disease Control



National Overdose Deaths

Number of Deaths Involving Prescription Opioid Pain Relievers (excluding non-methadone synthetics)



U.S. prescriptions of opioid painkillers

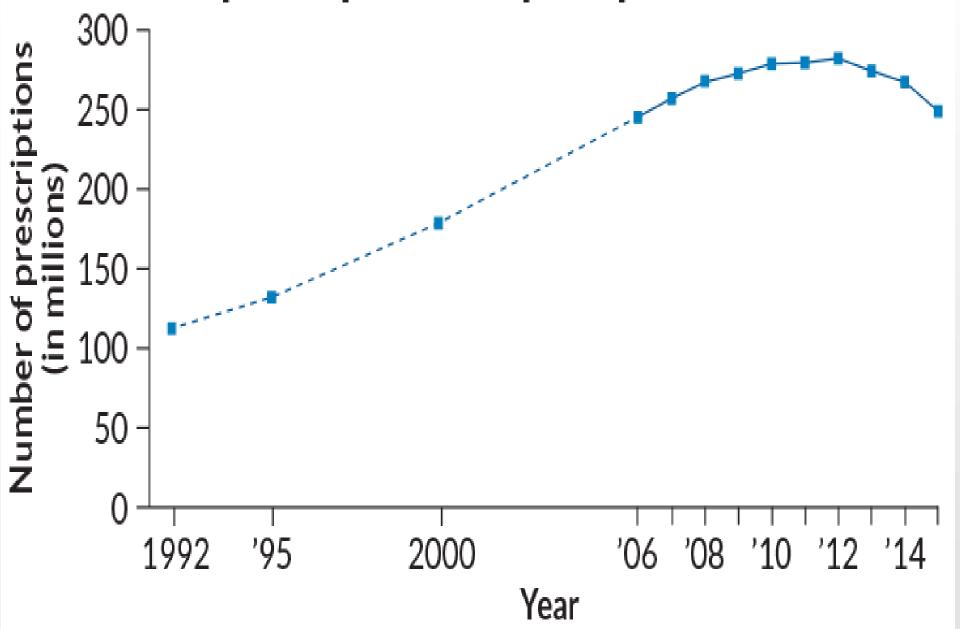
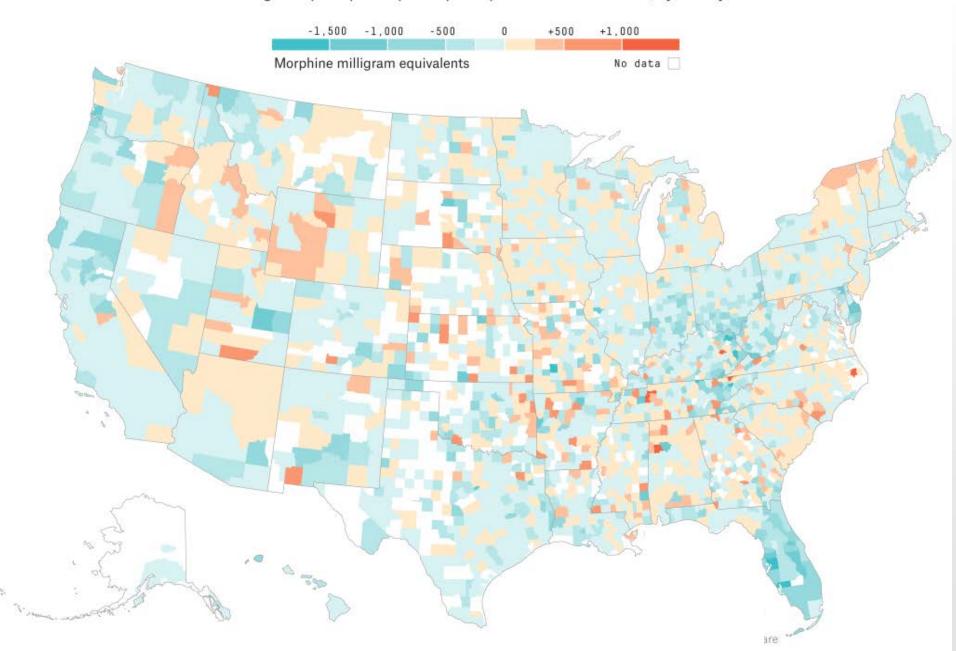


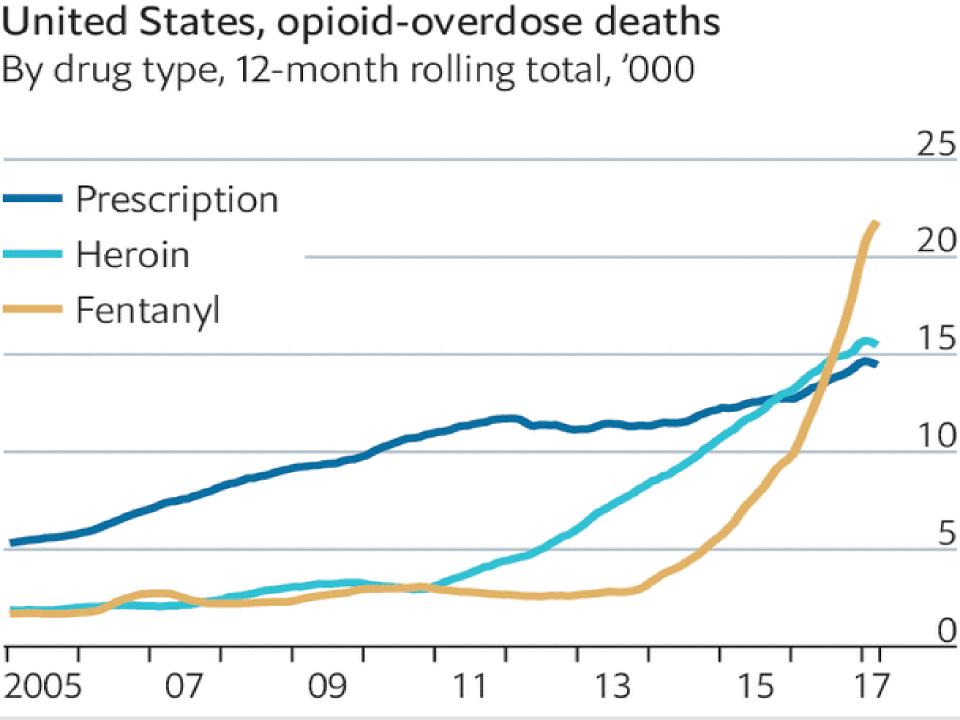
Table 1. Total number and rate of opioid prescriptions dispensed, United States, 2006–2016

Year	Total Number of Prescriptions	Prescribing Rate Per 100 Persons
2006	215,917,663	72.4
2007	228,543,773	75.9
2008	237,860,213	78.2
2009	243,738,090	79.5
2010	251,088,904	81.2
2011	252,167,963	80.9
2012	255,207,954	81.3
2013	247,090,443	78.1
2014	240,993,021	75.6
2015	226,819,924	70.6
2016	214,881,622	66.5

Opioid prescriptions are still rising in many U.S. counties

Change in opioid prescriptions per capita from 2010 to 2015, by county









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Response To Opioid Abuse

Federal

- Presidential emergency declaration
- Presidential opioid commission

State, County, City, Tribal

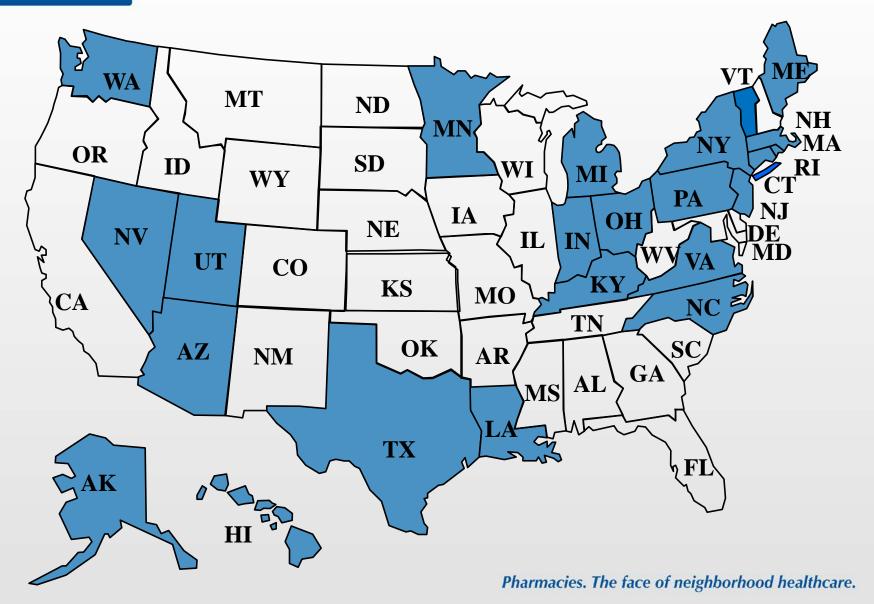
- Legislation, regulation and litigation

Industry

- Pharmacies have stepped up
- Plans / PBMs changing coverage
- Manufacturers and wholesalers take action



Opioid Quantity Limits





Opioid Quantity Limits

Many New State Laws

- Apply to opioids; sometimes other meds
- Limit days supply and/or daily dosage
 - Limited to 3, 5 or 7 day supply of initial prescriptions for acute pain
 - Limit daily Morphine Mg Equivalents (MMEs)
- Exceptions for surgery, cancer, palliative care, substance abuse treatment, etc.
- Will pharmacies be required to police prescriber compliance?
- Drafted New Federal Legislation
- New Plan Designs Limit Coverage

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Opioid "Partial Fill" Issues

Dispensing Less Than Prescribed Quantities Of Opioids

- Some states limit pharmacist discretion
- CARA: partial fill if requested
- DEA rule: partial fill if "unable" to fully fill

How Should Pharmacies Respond...

- If pharmacist believes prescribed quantity is excessive? Corresponding responsibility rule
- If plan only covers 7-days but patient wants full prescription? Two Rx numbers needed?

Seeking DEA Clarification



PDMPs

Prescription Drug Monitoring Programs

- Controlled substance prescribing and dispensing databases
- Operated by states across the country

Prescriber And Pharmacy Obligations

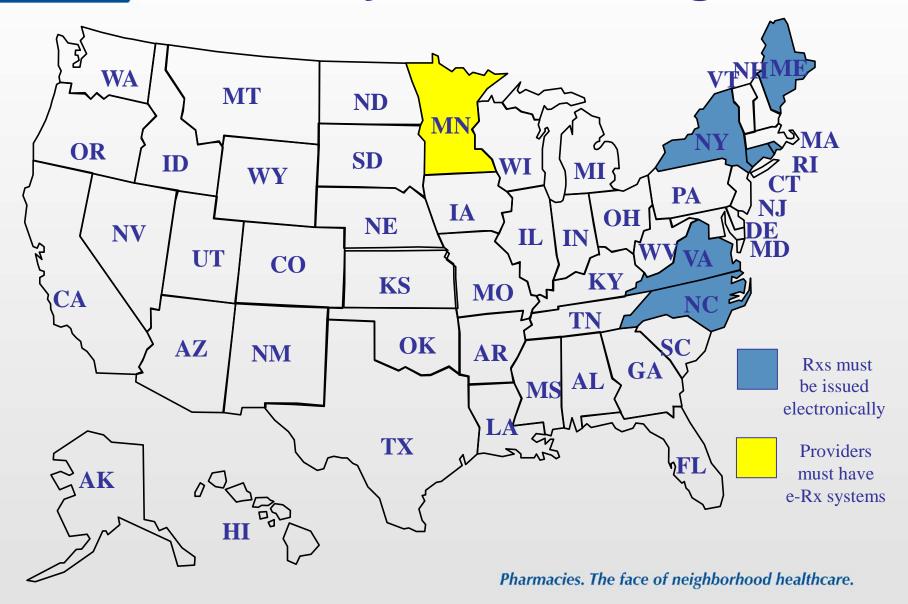
- Pharmacy workflow challenges

Building A National PDMP Database

- NABP InterConnect
- NCPDP proposal
- Potential federal legislation



Mandatory E-Prescribing





State Mandatory E-Rx Laws

6 States Mandate E-Prescribing + MN

 Effective 2016 (NY), 2017 (ME), 2018 (CT) and 2020 (NC, RI, VA)

Mandates Apply To...

- Opioids: ME, VA
- Controlled substances: CT, RI
- "Targeted" controlled substances: NC
- Controlled & non-controlled: NY

Many Exceptions That Vary By State

- Adverse impact on patient care
- Same facility prescribing and dispensing
- Waivers based on hardship, tech issues, etc.

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Federal E-Prescribing Bill

- Every Prescription Conveyed Securely Act
 - H.R. 3528
- Would Mandate E-Prescribing Of Controlled Substances
 - Schedules II-V
- Limited To Medicare Part D
- Exceptions Similar To State Laws
 - Pharmacies not required to verify whether exceptions apply



Drug Take-Back / Disposal

Variety Of Programs

Kiosks ... mail back envelopes ...
destruction packets ... take-back days, etc.

Kiosks: Opportunities And Challenges

- Expense, destruction or reverse distribution, security, theft, etc.
- GAO study critical of utilization

Manufacturer-Funded Take Back Laws

- Cities and counties mandating
- Many states considering (NACDS model bill)
- Federal proposals



Other Solutions

Education And Counseling

- Prescribers, pharmacists and patients

Improve Access To Treatment

- Access to naloxone at pharmacies
- Greater coverage of treatment for abuse

Prevent Improper Sales

Shut down illegal internet "pharmacies" and rogue pain clinics





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DEA Enforcement

DEA Response: Increased Enforcement

- Rx drug abuse is a "top priority"
- Increased enforcement against manufacturers, wholesalers, prescribers, pharmacies, users
- Pharmacies: "last line of defense"

DEA Enforcement Options

- Letter of admonition
- Civil fines of \$10,000 per violation
- Forfeit up to 2x gross profits
- Immediate suspension or show cause order
- Criminal prosecution





Suspicious Order Monitoring

- DEA Requires Systems To Detect And Report Suspicious Orders Of Controlled Substances
 - Orders of unusual size, frequency or pattern
- DEA Has Ramped Up Enforcement
 - Huge recent settlements + Masters decision
- Pharmacy Impact
 - Investigate and report orders
 - Justification of orders
 - Limits on quantities



Recent Pharmacy Enforcement

Filling Rxs With Invalid DEA Numbers

- \$11.75M settlement (1/17)
- \$834k settlement (7/17)

Store Level Diversion

- \$3M settlement (3/17)
- \$3.5M settlement (6/17)

Recordkeeping Violations

- \$5M settlement (7/17)



Opioid Litigation

State Attorneys General

- 40+ AGs investigating industry participants
- Dozen AG lawsuits primarily target manufacturers and distributors
- New Delaware lawsuit targets pharmacies
- NACDS AG outreach initiative

Hundreds Of City And County Lawsuits

- Many combined in massive proceeding
- AGs joining settlement discussions

Tribal Lawsuits

Lack jurisdiction?





Corresponding Responsibility

DEA Rule Says Controlled Substance Rx...

- Must be "for a legitimate medical purpose"
- Must be issued by a prescriber "acting in the usual course of his professional practice"

- Prescribers Are Responsible

- "but a corresponding responsibility rests with the pharmacist who fills the prescription"
- Pharmacist must not dispense if Rx not written for a legitimate medical purpose in the usual course of the prescriber's medical practice

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DEA Red Flags

- Pharmacists Must Investigate And Resolve All Red Flags
 - Otherwise cannot dispense controlled substance despite prescription
- DEA Won't List All Red Flags
 - DEA expects you to know them when you see them
 - DEA identifies new red flags





Patient Red Flags



- Has insurance but pays cash
- Seeks early refills
- Doctor shopping: Patient gets Rxs from multiple doctors
- Travels long distance to doctor or pharmacy
- Has Rxs for several CS drugs that treat same condition
- Uses street names for drugs or requests specific brand
- Group arrives at pharmacy with similar Rxs from same doctor
- Customers from same address have similar Rxs from same doctor
- "Runner" submits Rx and collects drugs for someone else
- Exhibits "drugged" behavior



Prescriber Red Flags



- Prescribes "drug cocktail"
 - Oxycodone, hydrocodone, alprazolam, etc.
- Prescribes large number or % of controlled substance Rxs
 - Compared with other prescribers
- Prescribes large quantities and large doses
 - Especially if may cause medical complications
- Prescribes depressants and stimulants for same patient
- Lack of individualized dosing: Pattern of prescribing same dose of same drug to different patients
- Drug not consistent with prescriber's practice
 - Fentanyl prescribed by dentist; vet prescribes for person
- State board or law enforcement investigating doctor
- No DEA registration



Prescription Red Flags

DEA Pharmacist's Manual:

- "Prescription looks 'too good"
 - "Prescriber's handwriting is too legible"
 - "Directions are written in full with no abbreviations"
 - "Prescription appears to be textbook presentations"
- "Quantities, directions or doses differ from usual medical usage"
- "Appears to be photocopied"
- "Written in different color inks or different handwriting"
- Apparent alteration or erasure marks
- Signature or callback number differs from previous Rx Pharmacies. The face of neighborhood healthcare.





Pharmacy Red Flags



- Dispenses refills too early
- Fails to question and counsel patients
- Fails to follow documentation requirements
- Located too close to pain clinic ... or too far away
- Relies solely on prescriber's assurance that Rx is legitimate
- Fails to contact other pharmacists to inquire why they refused to fill Rx



Security

- "Closed System Of Distribution"
 - Security, inventory, recordkeeping and reporting requirements
- "Effective Controls To Guard Against Theft And Diversion"
 - Rules do not require specific security measures
 - DEA evaluates security systems based on several factors, including:
 - Adequacy of electric detection and alarm systems and key control and/or combination lock systems
 - Supervision of anyone with access to storage area



Security

Controlled Substance Storage

- Schedule II-V: Locked in substantially constructed cabinet or dispersed among non-controlled drugs
- But beware of individual state requirements

Employees With CS Access

- No employees convicted of CS felonies
- No denied or revoked DEA registration

Diversion

- Report theft or significant loss to DEA
- Repeated thefts or failure to timely detect can suggest system deficiencies





Theft

Pharmacy Robbery & Burglary Increasing

Before

- Alarm and security systems; change locks
- Sufficient lighting and staffing

During

- Calm cooperation for safety of staff and customers
- Make mental notes of identifying features, etc.

After

- Activate alarm and contact law enforcement
- Seek witnesses and protect crime scene
- Report CS theft to DEA



<u>Inventory</u>

Initial And Biennial Inventory Must:

- Contain complete/accurate record of all controlled substances on day of inventory
- Indicate time of inventory
- Identify each CS
 - Name
 - Finished form
 - Units (or volume) per commercial container
 - Number of commercial containers
- Be maintained at the registered location
 - Schedule II inventory separate from other records



Recordkeeping

Maintain Complete And Accurate Records

- For each CS purchased, received, stored, distributed, dispersed, or disposed of
- Accountability of all CS throughout closed system

Maintained 2+ Years For DEA Inspection

Schedule II Records

Must be maintained separately from other records

Schedules III-V Records

Maintain separately, or readily retrievable from the ordinary business records

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Required Records Include...

- DEA registration certificate
- Official CS order forms (DEA Form 222)
- Power of Attorney to sign order forms
- Receipts/ invoices for Schedules III-V
- CS inventory records
- Records of CS distributed or dispensed
- Reports of theft or significant loss (DEA Form 106)
- Inventory of drugs surrendered for disposal (DEA Form 41)
- Records of CS transfers between pharmacies
- Self-certification certificate and logbook (or electronic equivalent) required by Combat Meth Act





Paper Prescription Records

Option #1: 3 Files

- Schedule II CS dispensed
- Schedule III-V CS dispensed
- All non-controlled drugs dispensed

Table 1 9ra 100 7ac

Option #2: 2 Files

- Schedule II CS dispensed
- All other drugs dispensed
 - Non-controlled and Schedule III-V
 - Use red "C" stamp (1+" high) to readily retrieve
 - o Red "C" waived for robust e-records system



E-Rx Recordkeeping

- For Rxs Created, Signed, Transmitted And Received Electronically
 - Rx records must be retained electronically
- Must Be Easily Readable
 - Or rendered into easily read format
- Records May Be Maintained At Another Location
 - But must be readily retrievable
- System Able To Print Or Transferring Records
 - In format readily understandable to law enforcement
- Records must be sortable
 - By prescriber name, patient name, drug dispensed and date filled



Thank You!

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