

# *Hot Topics in Retail Pharmacy Compliance*

## **HCCA Compliance Institute**

April 16, 2018

**Don Bell**

*Senior VP & General Counsel, National Ass'n of Chain Drug Stores*

**Daniel Fitzgerald**

*Commercial Litigation Department, Walgreen Co.*

**Selina Coleman**

*Norton Rose Fulbright*

## **Agenda**

- I. Pharmacy Enforcement Landscape
- II. Pharmacy Enforcement Risks
- III. Opioids and DEA Compliance

# I. PHARMACY ENFORCEMENT LANDSCAPE

## Enforcement Landscape

- ◆ General Enforcement / Scrutiny
  - Heightened levels of scrutiny and obligations
  - Government auditing of claims for reimbursement
  - Duty to return overpayments from federal payers
- ◆ “New Frontiers” for Whistleblowers
  - Record number of qui tam cases, including challenges to:
    - Gifts, coupons, and other potential inducements
    - Loyalty programs, price matching, and U&C pricing
- ◆ Consumer Class-Action Lawsuits
  - Effects of discount programs on U&C pricing reported to commercial payers

## Enforcement Landscape

**28%:** Percent of Medicare Part D spending on drugs with an annual per-user spend of \$10,000+ in 2015, which is:

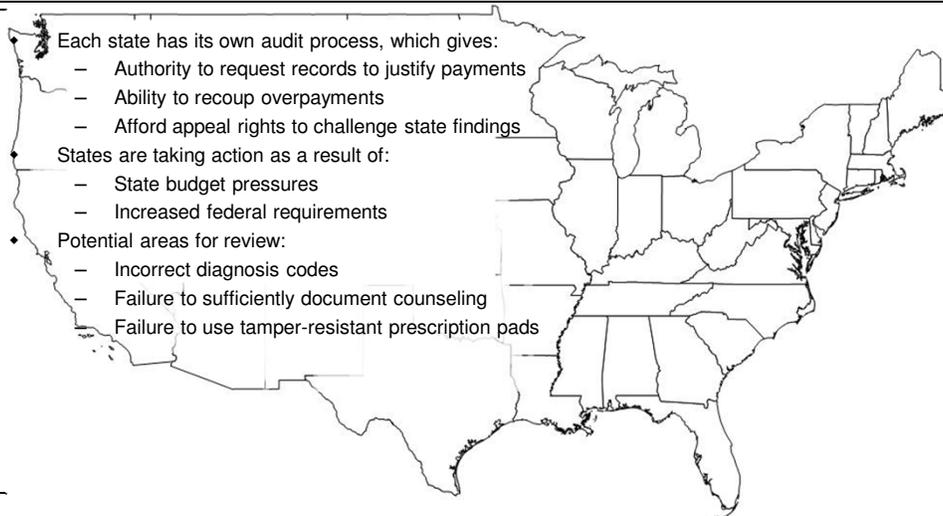
- \$37.9 billion in Medicare Part D program spending
- 6% increase from 2014
- 156% increase from 2006

**1,432:** Pharmacies with questionable billing of Medicare Part D per 2015 OIG Report

**134%:** Percent increase in OIG cases involving Part D between 2010 and 2015



## State Medicaid Audits



## Active OIG Workplan Items -- Pharmacy

- ◆ Opioids
  - Prescription Opioid Drug Abuse and Misuse Prevention - Prescription Drug Monitoring Programs
  - FDA Oversight of Risk Evaluation and Mitigation Strategies To Address
- ◆ Proper Billing
  - Documentation of Pharmacies' Prescription Drug Event Data
    - Are claims adequately supported by documentation?
    - Additional reviews of pharmacies with questionable billing
  - Duplicate Claims for Hospice
  - Invalid Prescriber Identifiers
  - Payments after Patient Death

## II. PHARMACY ENFORCEMENT RISKS

## **Pharmacy Enforcement Risks**

- Overpayments & Billing Errors
- Usual & Customary Pricing
- Improper Patient Referrals

9

## ***OVERPAYMENTS & BILLING ERRORS***

## Grounds for Overpayment

- ◆ Overpayment rule for Parts A & B in February 2016; guidance on Part D payments in May 2014
- ◆ Overpayments become “obligations” 60 days after they are “identified”
- ◆ Up to six months of “reasonable diligence” before the 60-day clock starts ticking
- ◆ Even after re, provider can still be liable for retaining the overpayment for more than 60 days after identifying it
- ◆ Effect of Escobar – new grounds for defense?

## Common Causes of Pharmacy Overpayments

- ◆ Prescription Billing Errors Including:
  - Incorrect information submitted on the claim
  - Failing to reverse claims for services not provided
  - Failing to have adequate documentation to support claim (prior authorization, physician orders, purchasing records)
  - Double Billing / Coordination of Benefits

## Consequences of Billing Errors

- ♦ As noted in the OIG Workplan, an area of focus for 2018 includes review pharmacy prescription drug event data for billing accuracy
  - **Recoupment of Reimbursement**
    - Likely to increase as Prescription Drug Plan face more pressure to audit
    - Self disclosure if identified internally
  - **Overpayment Liability**
    - Medicare / Medicaid: Failure to report and return overpayments within 60 days could result in FCA violations / penalties
    - Commercial: Overpayments may violate a pharmacy's contractual obligations to the payor, which can result in allegations of fraud, legal action, or contract termination
  - **Qui Tam Relators** – Relators may identify billing mistakes and bring cases
  - **M&A Complications** – Proposed transactions may be delayed, cancelled, or face significant price concessions
  - **Monitorships** – Settlements may require CIA with HHS-OIG

## Examples of Prescription Billing Errors

- ♦ Omnicare (January 2017)
  - \$8 million to resolve allegations submitted False Claims to Medicare and Medicaid programs by billing for incorrect NDC codes causing it to submit claims for different generic drugs than were actually dispensed
- ♦ Nashville Pharmacy (January 2016)
  - \$7.8 million to resolve numerous billing errors including automatically refilling medication against contractual requirements, billing for medications after the date of the beneficiary's death, and billing for prescriptions from unlicensed prescribers
- ♦ Rhine Drug Company (June 2017)
  - \$2.175 million to resolve allegations that it violated the FCA by billing for medication not provided and failing to follow Controlled Substance Act requirements; resulted in a Corporate Integrity Agreement with the OIG
- ♦ Med-Fast (October 2017)
  - \$2.7 million to resolve allegations that improperly billed for recycled medication and failed to credit government health care programs for medication that returned or not delivered to patients; resulted in a Corporate Integrity Agreement with OIG

## ***Usual & Customary Pricing***

### **U&C Pricing & Discount Card Programs**

- ◆ Retail pharmacies often offer prescription club programs
- ◆ Members pay an enrollment fee to receive discounted prices on prescription drugs and other benefits
- ◆ According to some state Medicaid agencies, the discounted drug price should be used as the pharmacy's U&C price

## Usual & Customary Pricing - Overview

- ◆ Qui Tams Re: U&C Prices: Whistleblowers have recently brought FCA lawsuits against pharmacies alleging that these programs improperly inflate U&C prices, which result in higher reimbursements for pharmacies
  - Pharmacies charge regular cash prices to payers but may sell the drug at a lower cost to certain cash customers (e.g., club members)
- ◆ Many states define U&C prices differently
  - Some states have attempted to enact Most Favored Nation regulations that seek to ask the pharmacy submit the lowest price accepted as the U&C or variations on a similar requirement
- ◆ Transitioning to Member Class Actions

## Example: *U.S. ex rel. Garbe v. Kmart Corporation*

- ◆ **Overview**
  - Whistleblower case with allegations that Kmart misrepresented U&C prices of generic prescriptions; government declined
- ◆ **Allegations**
  - Kmart allegedly violated the FCA by misrepresenting the price of generics when reporting U&C prices to federal payers
    - e.g., whistleblower claimed Kmart charged a customer \$5 for a 30-day supply of Simvastatin, but billed Medicare for 'U&C price' of \$152.97
- ◆ **Outcome**
  - 7th Circuit upheld argument that "general public" includes customers who are members of discount card programs
  - Kmart will be paying \$59M in settlements (December 2017)

## **Example: *Corcoran et al. v. CVS Pharmacy***

- ♦ **Overview**
  - Class of members alleged they overpaid for copayments and coinsurance
- ♦ **Allegations**
  - CVS allegedly discounted prescription drug prices for discount program members
  - Class consisted of members that had insurance and did not have access to the discounted prices and as such allegedly paid inflated cost sharing
  - Claim the U&C price billed to their insurance should have been the discount program price
- ♦ **Outcome**
  - Dismissed on summary judgment; key PBMs issued declarations that discount programs did not affect U&C price
  - Case has been appealed

## ***Improper Patient Referrals***

## Improper Patient Referrals - Overview

- ◆ The Anti-Kickback Statute and Civil Monetary Penalties Law prohibit the referral of patients in exchange for anything of value to healthcare providers
- ◆ Could support False Claims Act lawsuits, including treble damages and per-claim penalties
- ◆ OIG has warned pharmacies about directly linking payments to patient referrals
- ◆ Pharmacies are scrutinized by the government and whistleblowers for improper patient referrals

## Examples of Potentially Improper Patient Referrals

### Patient Kickbacks

- ◆ Manufacturer Copay Coupons
- ◆ Pharmacy Marketing Programs
  - Discount / Reward Programs

### Third Party Kickbacks

- ◆ Marketing Companies
- ◆ Physicians
- ◆ Relationships with Manufacturers

## Examples of Alleged Improper Patient Referrals

- ◆ Florida Pharmacy Solutions (Owner/employee convicted in Sept. 2017)
  - Alleged to have provided a marketing firm over \$12 million dollars to steer TRICARE beneficiaries to the pharmacy resulting in over \$30 million in TRICARE reimbursement in 6 months (up from about \$4 million annually)
  - Many similar cases have been pursued in Florida against compounding pharmacies
- ◆ NY Pharmacy Inc. (Still pending – indictment in Nov. 2017 )
  - Alleged to have provided kickbacks to patients to fill their HIV prescriptions and then used an auto-refill program to continue to bill for those prescriptions, even when they medication was not delivered

## Expanded Protections AKS Safe-Harbors and CMP Exceptions

- ◆ In December 2016, HHS-OIG published a Final Rule Amending the AKS Safe Harbors and the exceptions to the CMP rule, some of these changes can impact pharmacies:
  - AKS Safe-Harbors
    - Pharmacy cost-sharing waivers for Medicare Part D beneficiaries with financial need
    - Manufacturer discounts for drugs available through the Medicare Coverage Gap Discount Program
  - CMP Exceptions
    - Certain Remuneration That Poses a Low Risk of Harm and Promotes Access to Care
    - Retailer Rewards
    - Remuneration to Financially Needy Individuals
    - Copayment Waivers for the First Fill of Generic Drugs

## CMP “Retailer” Exception

1. A “**retailer**”... (defined term)
2. May offer “**coupons, rebates, or other rewards**”
3. To government program beneficiaries...
4. If offered on “**equal terms**” to the “**general public**” regardless of health insurance status... and
5. Not “**tied**” to the provision of other covered items or services (*no sole / preferential accumulation based on purchases of federally reimbursable items, such as prescription transfers*)  
No corresponding protection under Anti-Kickback Statute

## Expanded Approach to CMP Protection

- ◆ Codified ACA’s “retailer rewards” exception:
  - Key definitions provided: e.g., limitations of who is a “retailer,” and broad scope of “other rewards”
  - No sole or preferential accumulation of rewards based only on purchases of federally reimbursable items (impermissibly “tied”)
    - Prescription transfers vs. coupon for general store spending, including redemption as copayment
    - More relaxed approach to “tying,” but will require close analysis to ensure compliance

## Pharmacy Marketing – Rewards Programs

- ◆ Many pharmacies have implemented programs offering patients discounts or rewards
- ◆ Highest risk programs have included gift cards for patients to transfer prescriptions
- ◆ Historically, these programs have excluded government beneficiaries and claims paid by government health care programs. But under the new Final Rule, depending on the structure of the program, these exclusions may no longer be necessary
- ◆ **OIG Advisory Opinion No. 17-05** (September 7, 2017)
  - Ruled that a retail pharmacy's Benefit Program satisfied the requirements of the exception to the definition of remuneration related to retailer rewards for the purposes of the Beneficiary Inducement CMP and had low risk of fraud and abuse under AKS
    - Discounts only available on out-of-pocket services
    - Program applied to a broad range of products and services (not just pharmacy)
    - Rebates could not be used to purchase prescription drugs
    - Doesn't offer any extra bonus or other reward for transferring prescriptions, nor offer greater rewards for dollars spent on copays than on general grocery items

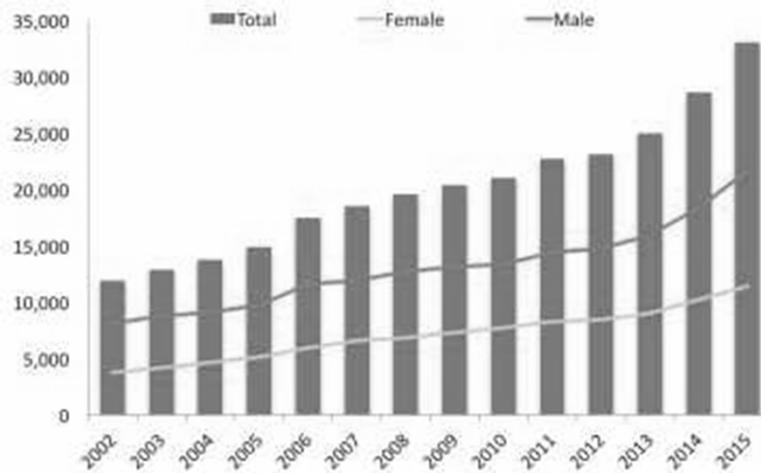
## Manufacturer Copay Coupons - Overview

- ◆ Drug manufacturers offer copay coupons to reduce patients' out-of-pocket costs and encourage purchase of specific items (often for brand drugs)
- ◆ Federal anti-kickback statute prohibits pharmacies from accepting copay coupons on claims paid by federal health care programs
  - Often difficult to identify federal program beneficiaries
- ◆ **OIG Advisory Opinion No. 16-07** from June 2016 allowed for coupons be offered to Medicare Part D beneficiaries
  - Claims could not be billed to Medicare Part D if coupon used
  - Additional responsibility on pharmacies that accept coupons

### III. OPIOIDS AND DEA COMPLIANCE

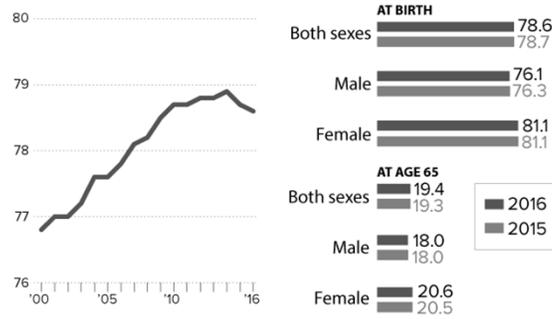


#### National Overdose Deaths Number of Deaths Involving Opioid Drugs

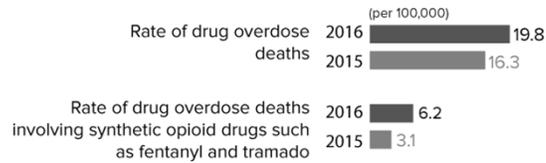


Source: National Center for Health Statistics, CDC Wonder

### US life expectancy declining again



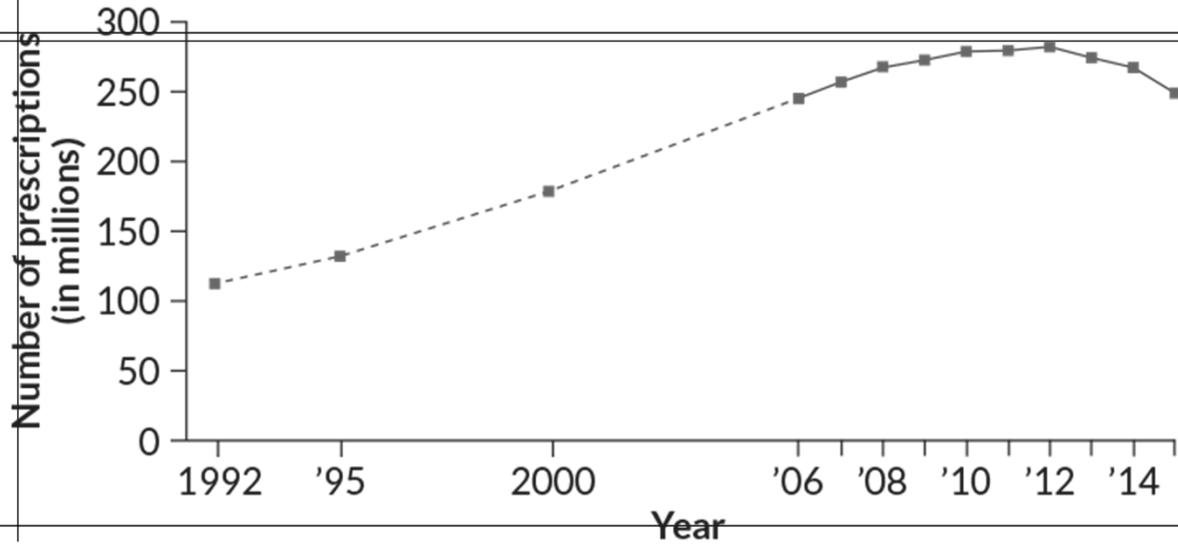
### Drug overdose deaths increase 21% in 2016.



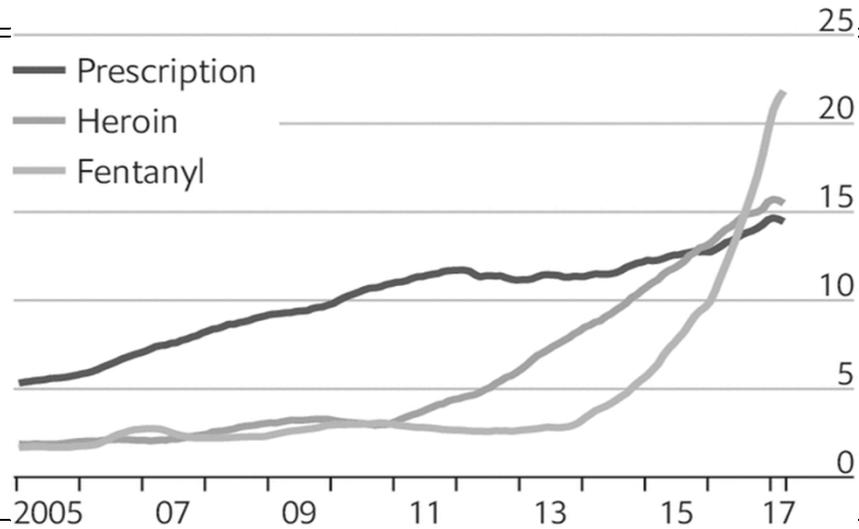
Source: Centers for Disease Control



### U.S. prescriptions of opioid painkillers



**United States, opioid-overdose deaths**  
By drug type, 12-month rolling total, '000



## Opioid Litigation

- ◆ State Attorneys General
  - 40+ AGs investigating industry participants
  - Dozen AG lawsuits primarily target manufacturers and distributors
  - Delaware lawsuit targets pharmacies
- ◆ Hundreds Of City And County Lawsuits
  - Many combined in massive proceeding
  - AGs joining settlement discussions
- ◆ Tribal Lawsuits
  - Jurisdictional issues

## Pharmacy Allegations

- ◆ Distributing Excessive Opioids
  - Suspicious orders monitoring duties
- ◆ Filling Suspicious Prescriptions
  - Dispensed despite “red flags” and other suspicious circumstances
- ◆ Inadequate Training
  - To stop employee diversion
  - To stop suspicious Rx's
- ◆ Improper Compensation
  - Reward filling opioid Rx's

## Recent Pharmacy Enforcement

- ◆ Filling Rx's 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 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.
- ◆ Medicare Part D Proposal
- ◆ Proposed Federal Legislation
- ◆ New Plan Designs Limit Coverage

## 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

## **Drug Take-Back / Disposal**

- ◆ Variety Of Programs
  - Kiosks ... mail back envelopes ... destruction packets ... take-back days, etc.
- ◆ Manufacturer-Funded Take Back Laws
  - Cities and counties mandating
  - Many states considering (NACDS model bill)
  - Federal proposals

## 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

**Thank you!**

## **Appendix: Pharmacy DEA Compliance Review**

### **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

## 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 Flag



- ◆ 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 Flag



- ◆ 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

## Pharmacy Red Flag



- ◆ 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

## Inventory

- ◆ 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

## 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
- ◆ **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
    - 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