MEDICAID AUDITS, DEPARTMENT OF HEALTH INSPECTIONS, AND DEA INVESTIGATIONS

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BEING PREPARED FOR MEDICAID AUDITS

GOALS

The learner should be able to:

- Identify Medicaid audit triggers
- Explain the difference between audits and investigations
- Recall the four main types of Medicaid audits
- Recall tips for responding to auditor's requests/questions
- Identify main areas of inspection during DOH inspections
- Summarize the post-inspection process for deficiencies found during DOH inspection
- List various areas of inspection during DEA inspections
- Identify differences between DEA inspections and investigations
- Understand the key issues when determining to consent or request administrative warrant
- Recall post-inspection process

MEDICAID AUDITS

This section does not apply to investigative audits conducted by the Medicaid Fraud Control Unit of the Department of Legal Affairs Sec. 465.188(3) F.S.

NOTICE

SEC. 465.188(1)

1. One (1) week notice
2. May not be conducted within the first five (5) days of the month
3. Allowed 10 days to produce documentation to address discrepancies
4. Audit report must be delivered within 90 days

WHO WILL CONDUCT MEDICAID AUDIT

1. Florida licensed pharmacist
2. AHCA investigators — Medicaid participating pharmacies

WHO/WHAT CAN BE AUDITED

1. Any person or business enrolled in Medicaid
2. "A Medicaid provider has an affirmative duty to supervise the provision of, and be responsible for, goods and services claimed to have been provided, to supervise and be responsible for preparation and submission of the claim that is true and accurate …"

AUDIT PERIOD

1. Audit period may not exceed one year.
2. Providers must retain records for five (5) years and make them available to state and federal agencies conducting investigations. Sec. 409.913(9) F.S.

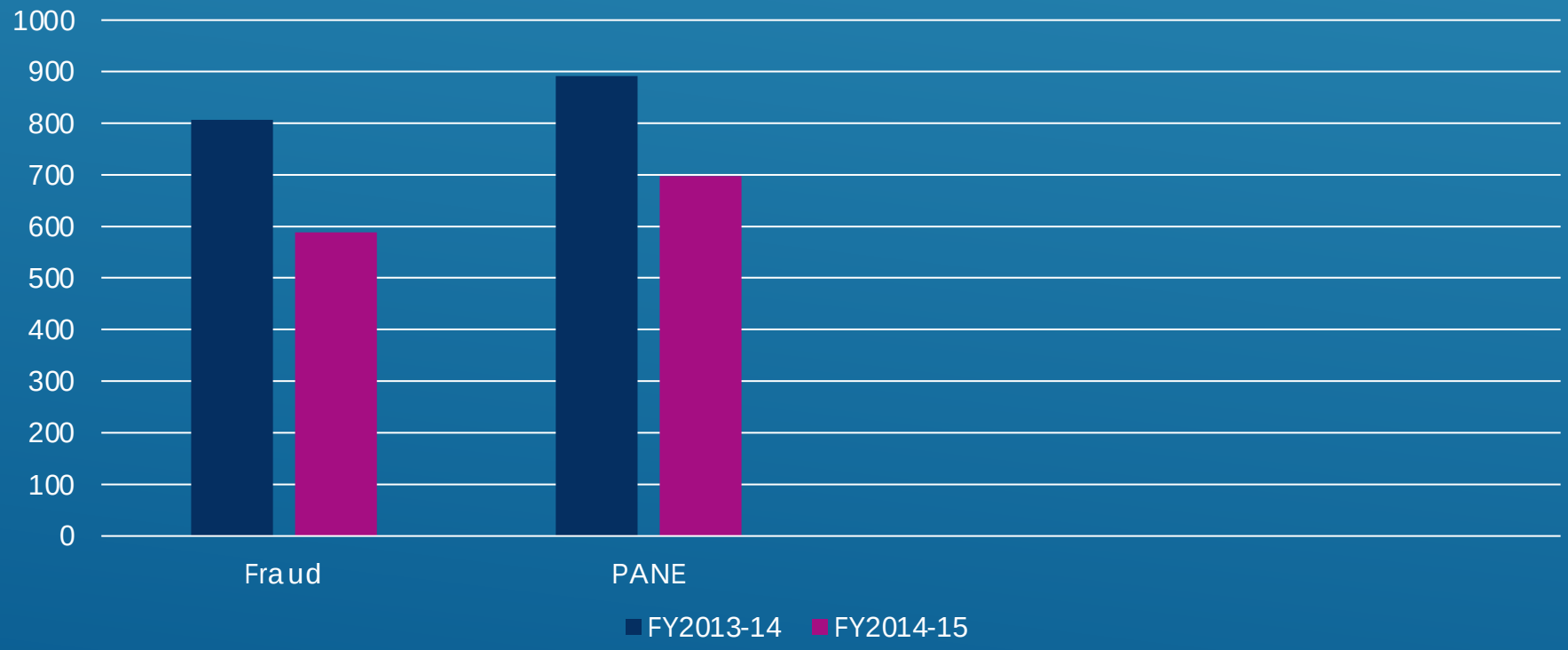
AUDIT VS. INVESTIGATION

1. Audit looks for overpayment and compliance
   - ▸ AHCA
2. Investigation looks for fraud
   - ➢ Medicaid Fraud Control Unit — Chapter 409 F.S.

AUDIT TRIGGERS

1. Complaints
2. Data
3. Random

MFCU COMPLAINTS



1. COMPLAINT SOURCES

1. Medicaid recipient, family member, provider, etc.
2. Whistleblower (Qui Tam action)
3. Medicaid plans

TOP FIVE MFCU PROVIDER COMPLAINTS

1. Physicians
2. Home- and Community-Based Services
3. Pharmaceutical Manufacturer
4. Medical Supplies/Durable Medical Equipment
5. Pharmacy

2. DATA SOURCES

1. Utilization Management Programs
   - Fee for service and health plans
2. Medicaid Management Information (MPI) detection unit, Sec. 409.913 F.S.
   - Shift from online complaints to detection via data assessment
   - Data mining on steroids — powerful analytical tools

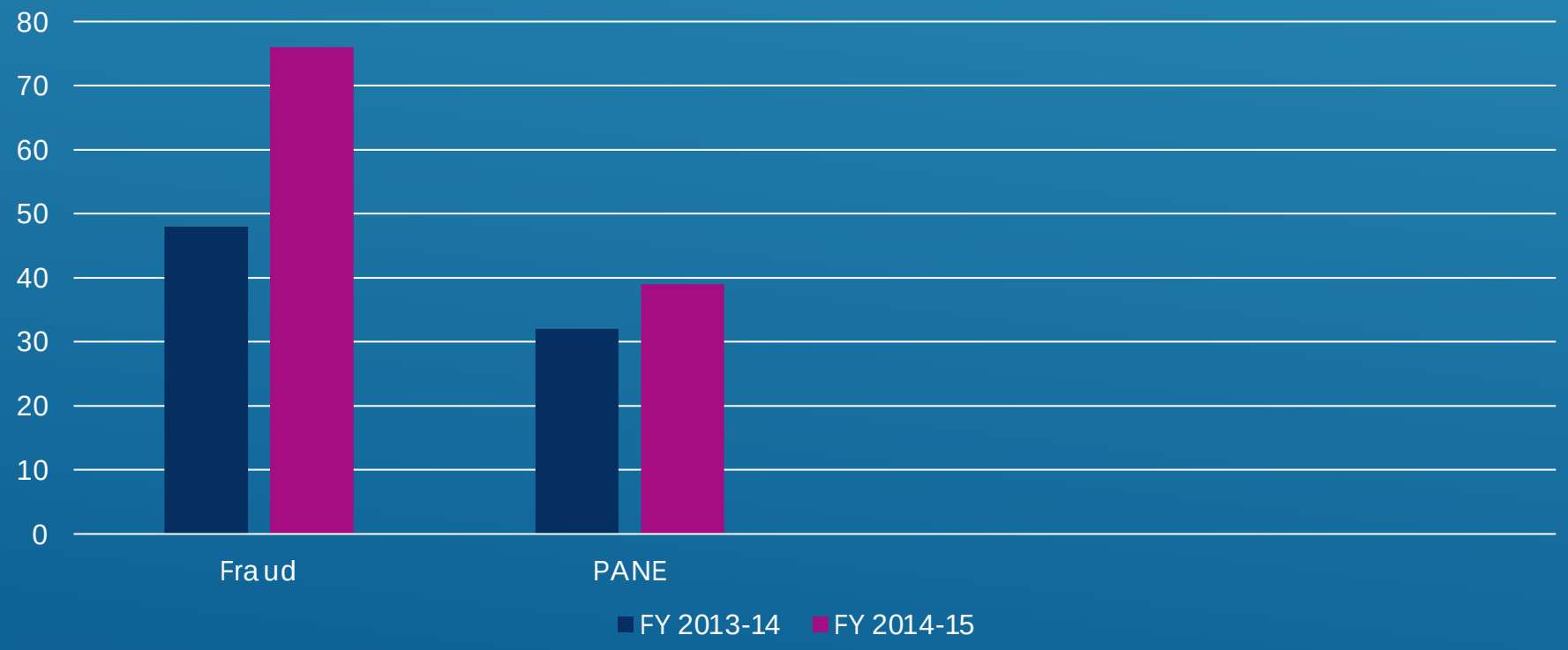
DATA MINING

1. The practice of sorting Medicaid claims through statistical models
2. Compares provider claims to peer group
3. Compares brand to generic drug fills
4. Examines geographic fill rates
5. Looks for compound drugs
6. Compound vs FDA approved

3. RANDOM

1. Bad Luck
2. Random
   - at least 5% are required to be random

REFERRALS FOR PROSECUTION



PRIMARY REVIEW AREAS

1. Abuse
2. Fraud
3. Overpayment
4. Compliance

ENTITIES CONDUCTING AUDITS/INVESTIGATIONS

1. Medicaid
   - MFCU
   - AHCA
2. Managed Care
3. Third Party
4. Law Enforcement
   - Federal: DEA, HEAT, DOJ, FBI, OIG
   - State

TYPES OF AUDITS

1. Inventory
2. Records
3. Invoices
4. Pre-enrollment site visit
5. Prepayment reviews

AUDIT METHODS

1. Desk Audit
   - Preceded by a records request for offsite audit
2. Onsite Audit

MEDICAID REQUEST FOR RECORDS

1. F.S. Sec. 409.907 & 409.913 gives AHCA and MFCU authority to examine all Medicaid-related records
   - Failure to provide records will result in sanctions (F.A.C. 59G-9.070)
   - Must send paper copies regardless of media format
   - Incomplete record(s) is a separate offense
   - Records retention is five (5) years

REQUIRED RECORDS

(NOT EXHAUSTIVE)

1. Business records
2. Medical related records
3. Itemized inventory
4. Prescription records
   - Written Rx
     - Controlled substance requirements
   - Oral Rx

- Patient Records F.A.C. 64B16-27.800

BUSINESS RECORDS

1. Invoices, claims forms, and supporting documents
2. Authorizations, assignment, contract
3. Provider enrollment documentation, personnel records
4. Accounting ledgers, financial records,
5. Permit(s), DEA registration
6. Purchasing documentation

ITEMIZED INVENTORY

- Inventory must support billing during audit period
- Inventory must be supported by written or electronic records

PRESCRIPTION RECORDS

- Written Rx: Name, registration and signature prescriber, strength, quantity, directions for use, duration (if PRN estimate duration), date and day of issue, counterfeit proof prescription pad (F.S. 456.42)
- Controlled Substance: Full name and address of person for which drug is dispensed, full name and address of prescriber, DEA registration, name, strength, quantity, directions for use, # of scripts according to pharmacy records, initial of pharmacist and date filled. F.S 893.04(c)
- Oral: Schedule III-IV OK if reduced to writing; II in emergency F.S. 893.04(f)

REQUIREMENTS FOR PATIENT RECORDS

- 1. New or refill prescriptions
- 2. Electronic or hard copy
- 3. First and last name, address, date of birth, gender, Medicaid ID #
- 4. All scripts filled within past 12 months from most recent service:
  - A. Name of drug
  - B. Quantity
  - C. Date received
  - D. Prescriber's full name, address, and state license #

RECORDS CONT'D

- 5. Allergies, drug interactions, chronic conditions or diseases, etc.
- 6. Any related health information provided by provider
- 7. Pharmacist notes
- 8. If patient requests counseling, must document

HOW TO RESPOND TO REQUEST FOR RECORDS

1. Provide complete, well-organized records
2. If possible, conduct self-audit prior to delivering records
3. Keep originals
4. Explain abbreviations
5. Use physician records to support if necessary (F.S. 465.188(d))

WHAT AUDITORS LOOK FOR

1. Was correct quantity delivered to recipient?
2. Does quantity dispensed correlate with peers?
3. Were additional amounts billed to recipient, excluding co-pays, co-insurance, deductibles?
4. Were Medicaid, DEA, BOP rules complied with?
5. Do documents support medical necessity?

COMMON DEFICIENCIES

1. Insufficient records to support claim
2. Dispensing higher quantity than allowed by Medicaid rules
3. Unauthorized or early refill
4. Overbilled quantity
5. Compound of commercially available drugs (FDA approved)
6. Overpayment

ADDITIONAL REFILLS

- The authorization of additional refills or an existing prescription must be noted by either creating a new original prescription or prescriber's order by noting at least the date of the authorization, number of additional refills, and the prescriber or prescriber's agent authorizing refills.

Chapters 465 and 893 F.S. and Chapter 64B-16 FL. Admin. Code

CIVIL & CRIMINAL ACTIONS

1. False Claim, 31 U.S.C. Sec. 3729-3733
   - $10,700- $21,562 per claim
   - Treble damages
2. Anti-Kickback
   - Five (5) years in prison
3. Florida Patient Brokering Act
   Sec. 817.505 F.S.
4. Conspiracy

PENALTIES

1. BOP fines $1,000 - $10,000
2. Termination from Medicaid program
3. License revocation
4. Corporate Integrity Agreement (CIA)
5. Criminal penalties
   - Fines
   - Treble damages
   - Prison

TRUE OR FALSE

- 1. Medicaid Audits can only be conducted within the first 10 days of the month?
- 2. Pharmacies must retain patient records for at least 6 years?
- 3. Audit periods may not exceed 2 years?
- 4. Audits look for fraud and overpayments?
- 5. Pharmacies are within the top 5 providers for Medicaid Fraud complaints?

MULTIPLE CHOICE

Failure to provide Medicaid records to the MFCU may result in:

a. 2 years in prison

b. Administrative sanctions

c. Civil lawsuit

d. None of the above

C

MULTIPLE CHOICE

Prior to conducting an audit, Medicaid needs to:

a. Provide a 30-day notice

b. Show up unannounced

c. Provide 1-week notice

d. None of the above

DEPARTMENT OF HEALTH INSPECTIONS

TYPES OF INSPECTIONS

1. Initial inspection prior to permitting
   - Inspection is prerequisite to: initial pharmacy permit; permit for changes in ownership; and permit for change in location
2. Routine inspections
   - Determine if compliant with rules; obtain samples of drugs; or secure evidence to prosecute
     - Inspection may appear to be routine to ensure compliance but may be an investigation in response to complaint
     - Routine inspection can become an investigation
3. Investigations
   - Investigate suspected violation and secure evidence for prosecution
   - Triggers

WHO AND WHEN THEY INSPECT

- Pain Management Clinics
- Pharmacies
- Dispensing Practitioners

WHAT THEY INSPECT

1. Records

   "The records must be maintained for 4 years after the creation or receipt of the record, whichever is later." 465.022(12)(b)

   - General records
   - Inventory

2. Labeling Requirements

   - Proper labeling

3. Facility

   - Hours of operation
   - Adequate security
   - Proper signs, workplace, requirements, etc.

4. Staff

   - Proper supervision of pharmacy staff
   - Proper identification, documentation, background screens

TYPES OF RECORDS

1. Patient Records
   - Contains medical history, allergy information, contact information, etc.
   - Documentation of consultation offered
   - HIPAA compliance
   - Immediately accessible to pharmacist
2. Prescription Records
   - Prescriptions with date dispensed, and initials of dispensing pharmacist (6, F.S., 64B16-28.140(3)(b), F.A.C.)
   - Controlled substances prescription records
   - Prescriptions not filled in excess
   - Prescripts can be retained in writing or electronic, so long as they can be printed when requested
3. Drug Records
   - Daily printout of dispensing records or certified log book attesting to fact that information electronic dispensing records have been reviewed by him/pharmacists (64B16-28.140, F.A.C.)
   - Fraudulent prescriptions reported to law enforcement
   - The pharmacy maintains an audit trail for all drugs from receipt of acquisition to sale or disposition
   - Additional requirements for controlled substance
   - Compound records (if applicable)

HOW TO RESPOND TO INVESTIGATORS' QUESTIONS

- Pros and cons of employees working with investigators
- Photographs

COMMON DEFICIENCIES

- Pharmacy closed without reporting closure to BOP
- No prescription department manager supervising pharmacy
- Failure to supervise technicians
- Records not properly maintained or immediately accessible during inspection
- Failure to properly label
- Inventory issues
- Failure to comply with PDM reporting requirements

ACTION

- Issue an inspection report to the Department's attorney for possible disciplinary action
- If disciplinary action is taken, DOH will issue administrative complaint
- Opportunity to request formal or informal hearing
- Hearing (BOP or ALJ)
- Recommendation
- File objections
- Final order issued by BOP
- Appeal district court
- NPDB reporting and reporting to other states you hold licensure

INSPECTION FORM

- “I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.”
- Legal Issues

POSSIBLE SANCTIONS INCLUDE:

- Suspension
- Revocation
- Correct deficiencies
- Fines
- Reimbursement of prosecution costs
- Sister state action
- Negative NPDB entry
- Probation/monitoring (requiring additional inspections)
- Require additional continuing education

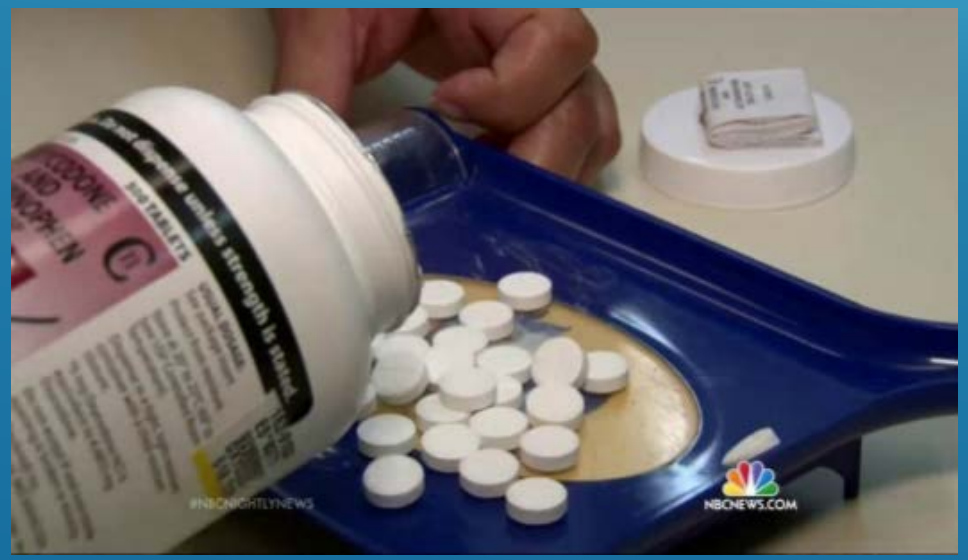
DEA INVESTIGATIONS

GOALS

- DEA Enforcement Actions
- Preparing for a DEA Inspection
- Surviving a DEA Inspection
- Post Inspection Procedures
- Corresponding Responsibility

ENFORCEMENT ACTIONS

- Letter of Admonition
- Civil Monetary Penalties:
  $10,000 each violation
- DEA Revocation/Suspension
- Criminal Prosecution for *Intentional* Violations
  - Controlled Substance Act
    21 U.S.C. 801 et. seq.
  - Health Care Fraud
    18 U.S.C. 1347
- Forfeiture of Proceeds Derived from Violations



PREPARING FOR A DEA INSPECTION

- Documentation is in order
- Policies and procedures
- Compliance plan
- Appropriate personnel and notification procedures
- Pre-inspection procedures

PREPARING: DOCUMENTS

- State C/S License and DEA Certificate of Registration (Form 223)
- Authorized personnel log, with screening statements
- Policy and procedure manual
- Most recent inventory (e.g. initial, biennial)
- Current and general usage logs
- Disposal records (or reverse distributor)
- Purchasing Records (i.e., invoices, packing slips, DEA Form 222s), with Schedule II separated from III-V
- Breakage-spillage reports, if applicable (DEA Form 41)
- Theft/significant loss reports, if applicable (DEA Form 106)

PREPARING: COMPLIANCE PLAN

Goal: Identify risks and mitigation strategies

- Specific Areas
  - Code of Conduct
  - Identifying compliance personnel
  - Compliance with corresponding duty
  - Cash purchases
  - “Do not fill” instructions
  - Documentation requirements
  - Screening of personnel and re-credentialing
  - PDMP review for controlled substances

TRUE OR FALSE

When filling a script, it is OK to call the physician and ask him/her to specify “dispense as written” so you can sell a more profitable drug.

SURVIVING AN INSPECTION

- First: Determine Type Of Inspection
  - Search Warrant = Criminal Action
  - DEA Form 82 = Request for Voluntary Inspection
  - Administrative Inspection Warrant = Administrative Action
  - DEA Agent vs. Diversion Investigator
- DEA Form 82: Seek Advice of Counsel
  - Informed Consent Required for DEA to Proceed
  - Only owner/operator/agent in charge can provide consent
  - Anything of incriminating nature can be used against you
  - May withdraw consent

TRUE OR FALSE

The DEA always has immediate access to search the pharmacy whenever they want.

SURVIVING: SHOULD I SIGN A DEA-82?

- You CAN refuse to sign DEA Form 82
  - Investigators will return the next day with an inspection warrant
  - Need only provide a court “legitimate purpose” — very low standard, 21 C.F.R. §1316.09
  - May also give “limited consent”
- Why Refuse?
  - You know you are non-compliant
  - Buy time to rectify procedural issues
  - Avoid office disruption
  - Secure counsel’s appearance

TRUE, FALSE, OR IT DEPENDS

When confronted by the DEA, I should do everything they ask and I will have a better chance of not getting in trouble.

SURVIVING: SEARCH WARRANT

- How Can I Tell If a Search Warrant is Being Executed?
  - Multi-agency operation
  - Agents will provide a copy of the warrant
- Can I Refuse?
  - No
- What Should I Do?
  - Remain silent
  - Contact counsel
  - Obtain counsel for the corporation and its employees so that they can make an informed decision on whether or not to cooperate

SURVIVING: LIMITS OF INSPECTION

- List of items allowed is contained in 21 C.F.R. 1316.03
  - Inspect/copy/verify records required by CSA
  - Only records required by the CSA!
- Not allowed
  - Generally depends on stated “purpose of inspection”
  - Inspect financial data
  - Sales data
  - Pricing data
  - Personnel files

SURVIVING: INSPECTION PROCEDURES

- Create a Policy to Inform Employees What to Do
- Inform owner or pharmacist in charge immediately
- Check credentials of investigators/contact Information
- Contact counsel prior to signing DEA Form 82
- Provide access to facility and documents listed in policies and procedures (see previous slide)
- Assist inspectors when required
- Take detailed notes during the process

POST INSPECTION

- Get a receipt for any records taken off site (DEA Form 12)
- Ensure you understand their findings
- Address any corrections required in the notice of deficiency
- Order to Show Cause
  - Procedure required before disciplining a registrant
  - You have the opportunity to offer a Corrective Action Plan within 30 days of Order to Show Cause

MULTIPLE CHOICE

If the DEA agent sits down and tells me that if I surrender my registration, they will stop their investigation, I should:

a. Agree because the DEA is always honest
b. Call my attorney
c. If I cannot reach my attorney, sign the form
d. Never sign a surrender form

SURVIVING: VOLUNTARY SURRENDER

- What If the DEA Asks Me to "Voluntarily Surrender" (DEA-104)?
  - Signing your career away with the stroke of a pen
  - Immediately seek the advice of counsel who is knowledgeable in DEA matters
  - License is effectively revoked upon signing form and handing to investigator/agent
- What Happens If I Don't Sign?
  - Administrative action
  - Potential criminal action
  - Potential state licensing issues
  - … but defending these issues is often better than signing your career away.

YES OR NO

If the physician writes the prescription, that's enough evidence of medical necessity.

CORRESPONDING DUTY

- CAS Corresponding Duty 21 C.F.R. 1306.04(a)
  - A pharmacist is prohibited from knowingly filling an order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research.
- Under Florida Law, Fla. Bd. of Pharm. Rule 64B16-27.810(1)
  - Must determine that the "order is valid"
  - Must review patient record and prescription and identify:
    - Overutilization or underutilization, therapeutic duplication, drug-drug interactions, clinical abuse/misuse
  - Where there is any doubt, must consult with prescriber Rule 64B16-27.810(2)

CORRESPONDING DUTY CONT'D

- "Red Flags"
  - Proximity to physician
  - Proximity to residence
  - Medication combinations (cocktail)
  - Cash purchases
  - Unusually high dosage
  - "Pattern prescribing" (i.e., same drugs, same diagnosis from physician)
  - Dx outside area of specialty
  - Prescriber with prior licensure discipline
  - Groups of patients
- What If I See a "Red Flag"?
  - Verify Dx with prescriber
  - Document medical necessity in notes
  - Only fill if your suspicions are resolved in favor of filling

11TH CIRCUIT INTERPRETATION

- That regulation imposes a responsibility on the prescriber to ensure prescriptions comply with the law and also a corresponding responsibility on the pharmacist who fills the prescription to ensure that the prescription is valid. § 1306.04(a). A pharmacist who knowingly fills a prescription not issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice is subject to penalties under the CSA. §1306.04(a). *Pharmacy Doctors Enterprises v DEA*, 789 F App'x 724 (CA 11, 2019)
- Jones believed that it was the prescribing physician's responsibility to issue medically legitimate prescriptions. That may be true, but as a pharmacist registered with the DEA, Jones had a "corresponding responsibility" not to fill prescriptions that were not issued for a medically legitimate purpose. 21 C.F.R. § 1306.04(a). The "corresponding responsibility" rule is not new, see *United States v. Hayes*, 595 F.2d 258, 261 & n.6 (5th Cir. 1979) (holding that pharmacists have an obligation "not to fill an order that purports to be a prescription but is not a prescription within the meaning of the statute"), nor is it unreasonable for the DEA to expect a pharmacist entrusted with dispensing highly regulated, addictive, and potentially destructive substances to fully understand her obligations under the law, regardless of prior work experience. *Jones Total Health Care Pharmacy, LLC v DEA*, 881 F3d 823 (CA 11, 2018)

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