Preparing for a DEA Audit –
Know What to Expect

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Why **You** should Pay Attention to this Presentation

- DEA is using every resource available to identify reckless practitioners, pharmacies, distributors and manufactures.
- Tools at their disposal include administrative, civil and criminal enforcement actions.
- DEA has added pharmacies to their inspection schedule.
- A mistake could result in a $15,040 fine per violation.
  - Can your business and livelihood survive such a fine?
Where do I as the Pharmacist fit in?

Control Substance Act of 1970

- Established a “closed system” that tracked and accounted for controlled substances from import or manufacture through wholesale distribution to the ultimate end-user.
- As the pharmacist, you are the last link in the chain before the CS is handed to the end-user.
- You are the last line of defense to prevent diversion.
The CSA’s Closed System of Distribution

- Scheduled Inspections/Audits
- Reporting Requirements
- Record-Keeping Requirements
- Security Requirements
- Established Schedules
- Registration
- Established Quotas
Valid Prescription

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.

21 C.F.R. § 1306.04(a)
Pharmacist’s Responsibility

• “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.”

21 C.F.R. § 1306.04(a)
What’s the Conflict about Corresponding Responsibility?

• The “corresponding responsibility” requirements with which the pharmacist must comply tend to be relatively unknown to many prescribers and contributes to the potential for conflict between prescribers and pharmacists.
What are Pharmacists’ Obligations

- A duty to “act in the usual course of his/her professional practice”;
- and “in good faith”;
- and “in accordance with generally accepted medical standards”.

The practice of medicine is easy since the Pharmacist does everything.
“Generally Accepted Medical Standards”? 

• Includes the 6 fundamentals of a doctor examination

✓ Medical history (personal and family)
✓ Physical Exam
✓ Appropriate tests conducted on patient to arrive at a diagnosis
✓ The diagnosis of the problem
✓ Course of Treatment
✓ Follow-up
Obligations continued...

- A duty to question a prescription of doubtful, questionable, or suspicious origin
- A duty to refuse to fill a prescription until the suspicion is resolved
- A duty to verify that the prescriber is properly licensed with the DEA and Medical Board to prescribe controlled substances
Obligations continued...

• A duty **NOT** to act with:
  • Willful Blindness, or
  • Deliberate Ignorance

• A duty to act like a reasonable pharmacist in recognizing various red flags which create a level of concern that might cause the pharmacist to either choose not to fill a prescription or take some other type of action.
“Red Flags”
Thou Shall Nots

• A circumstance that does or should raise a reasonable suspicion as to the validity of a prescription.
“Red Flags” typically have been interpreted to be more likely to reflect drug abuse, addiction, or diversion (i.e., criminal activity).

Various courts have determined that these red flags provide knowledge to pharmacists which cannot be deliberately ignored without violating the law.
Common Red Flags

- Drugs known for diversion/abuse
- High quantities or dose prescribed
- Patients seeking early refills
- Patients traveling long distances to doctor or pharmacy
- "Doctor shopping" or "pharmacy shopping"
- Patient behavior does not match their purported medical condition
- Patient admits to taking CS for invalid purpose or uses street talk regarding CS
Signs of Questionable Prescribing for Pain

- Acute and Sporadic Pain
  - Prescribing several different kinds of short-acting opioids at the same time
  - Long-term prescribing of opioids for a short-term problem without a diagnosis of chronic pain

- Chronic Pain
  - Routine prescribing and dispensing of drugs not recommended for chronic pain.
  - High volume practice.
  - Scanty notes.
  - Failure to document an appropriate reason for prescribing opioids (No treatment plan).
  - Prescribing many types of drugs with abuse potential for one patient.
  - Prescribing or dispensing to suspicious individuals.
  - Prescribing controlled substances to self or family members
Common Pharmacy Red Flags

• A high ratio of controlled vs non-controlled substances
• A high percentage of cash payments for CS
• Pharmacy’s rate of dispensing CS far exceeds that of other pharmacies in the immediate area
• Clear lack of individualized dosing of medication by certain practitioners
• “Cocktail” prescribing (i.e., opioid/benzo/soma, opioid/benzo, etc.)
• The RPh ignores reasonable warnings by other pharmacists regarding problems with a practitioner’s prescribing practices
Pharmacist Due Diligence – How to Protect Yourself

• The number one rule is the documentation of your due diligence efforts.
• If it’s not documented, it didn’t happen
• Checklist:
  ✓ Does the prescription appear to be valid and have all the required information
  ✓ Verify identification of patient
  ✓ Does the drug dosage amount, duration, and quantity seem to be in normally observed prescribing patterns
  ✓ Your assessment of the patient (ask questions if necessary)
Checklist continued…

✓ Do you believe that the 6 fundamentals of a doctor examination were conducted?

• Medical history
• Physical Exam
• Appropriate tests conducted on patient to arrive at a diagnosis
• The diagnosis of the problem
• Course of Treatment
• Follow-up
Checklist continued…

✓ Check internal patient profile records and perform drug utilization review

✓ Check PMP database for frequency, type, quantity, and provider information

✓ Verify prescriber’s DEA registration and State license

✓ Speak with prescriber, if necessary, to obtain diagnosis code(s) and what the future treatment plan will be (how can you help?)

✓ Provide thorough patient education
Due Diligence continued…

- Consider the geographical distances between:
  - Pharmacy / Patient
  - Practitioner / Pharmacy
  - Patient / Practitioner

- Is the cash payment for controlled substances justified?
- Is the patient requesting early refills?
Due Diligence continued…

- Contacting DEA / Law Enforcement or other entity when appropriate
- Accurately maintaining required records
- Documentation, documentation, documentation…
Remember…

• The law does not require a pharmacist to dispense a prescription of doubtful, questionable, or suspicious origin.

• To the contrary, the pharmacist who deliberately ignores a questionable prescription when there is reason to believe it was not issued for a legitimate medical purpose may be prosecuted along with the practitioner for knowingly and intentionally distributing controlled substances.
Use Professional Judgement

• A pharmacist is required to exercise sound professional judgement when making a determination about the legitimacy of a controlled substance prescription.

• Such a determination is made BEFORE the prescription is dispensed.
DEA Recordkeeping Requirements

• Must maintain complete and accurate records on a current basis for each controlled substance purchased, received, stored, distributed, dispensed or otherwise disposed of.

• Maintained for two years for inspection and copying by DEA officials.
  ➢ State requirements may be longer

• Must be maintained separately from other pharmacy records or in such a form that they are readily retrievable.
Required Records

- All inventory records of controlled substances, including the initial and biennial inventories, dated as of beginning or close of business.
- Executed and unexecuted official order forms (DEA Form 222) or the electronic equivalent (No paper if using CSOS).
- Power of Attorney authorization to sign order forms/CSOS.
- Receipts and/or invoices for schedules III, IV, and V controlled substances.
- Records of controlled substances dispensed (i.e., prescriptions).
Records continued…

• Records of controlled substances distributed (i.e., sales to other registrants, returns to vendors, distributions to reverse distributors)

• *Reports of Theft or Significant Loss (DEA Form 106)*, if applicable

• *Inventory of Drugs Surrendered for Disposal (DEA Form 41)*, if applicable

• DEA registration certificate

• Self-certification certificate and logbook (or electronic equivalent) as required under the Combat Methamphetamine Epidemic Act of 2005
Power of Attorney for DEA Forms 222 and Electronic Orders

(Name of registrant) 

(Address of registrant) 

(DEA registration number) 

I, ______________________ (name of person granting power), the undersigned, who am authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or Controlled Substances Import and Export Act, have made, constituted, and appointed, and by these presents, do make, constitute, and appoint ______________________ (name of attorney-in-fact), my true and lawful attorney for me in my name, place, and stead, to execute applications for Forms 222 and to sign orders for Schedule I and II controlled substances, whether these orders be on Form 222 or electronic, in accordance with 21 U.S.C. 828 and Part 1305 of Title 21 of the Code of Federal Regulations. I hereby ratify and confirm all that said attorney must lawfully do or cause to be done by virtue hereof.

____________________ (Signature of person granting power)

I, ______________________ (name of attorney-in-fact), hereby affirm that I am the person named herein as attorney-in-fact and that the signature affixed hereon is my signature.

____________________ (Signature of attorney-in-fact)

Witnesses:

1. ______________________ (Signature of witness)

2. ______________________ (Signature of witness)

Signed and dated on ______________________ (current date).

Notice of Revocation – to be completed only when Power of Attorney is revoked.

The foregoing power of attorney is hereby revoked by the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or the Controlled Substances Import and Export Act. Written notice of this revocation has been given to the attorney-in-fact on this same day.

____________________ (Signature of person revoking power)

Witnesses:

1. ______________________ (Signature of witness)

2. ______________________ (Signature of witness)

Signed and dated on ______________________ (current date).
Preparing for a DEA Audit

DEA Record Keeping

1. Is the DEA Biennial Inventory on file? (21 CFR 1304.11(b))
   - Yes
   - No

2. Are Beginning of Business (BOB) or Close of Business (COB) indicated? (21 CFR 1304.11(p))
   - Yes
   - No

3. Is a Material Inventory and a Fehler Inventory separate into Schedule II and Schedule III (21 CFR 1304.40(d)(1)-(4)(B))
   - Yes
   - No

4. Are Schedule II CSO reports submitted quarterly with quantity and date received in compliance? (21 CFR 1305.23(j))
   - Yes
   - No

5. Are DEA 222 forms for secure mailable & ship quantities & date included? (21 CFR 1305.53(b)(1)-(4))
   - Yes
   - No

6. Are Schedule II invoices/crushed retabletable (preliminary forms) (21 CFR 1304.07(c)(1))
   - Yes
   - No

7. Are Schedule II invoices separately filed with dates and quantity received? (21 CFR 1304.07(h)(1)-(d)(j))
   - Yes
   - No

8. Are Schedule II prescriptions retabletable (preliminary forms) (21 CFR 1304.07(d)(1))
   - Yes
   - No

9. Are Schedule II prescriptions retabletable (21 CFR 1304.07(d)(1)
   - Yes
   - No

10. Is NPI familiar with procedures for theft and lost Investigating (Reporting)? (21 CFR 1301.70(e))
    - Yes
    - No

11. Has pharmacy received a CED training and printout from DEA website? (21 CFR 1314.2(b)(3)(d)(b), 1314.22)
    - Yes
    - No

12. Does the pharmacy have a signed Power of Attorney on file? (21 CFR 1304.06(d)(2))
    - Yes
    - No

13. Have signed/or a copy of the current application for registration? (21 CFR 1304.06(b))
    - Yes
    - No

14. Does the pharmacy have CSOS Substation Agreement(s) on file? (21 CFR 1304.06(b)(2))
    - Yes
    - No

15. In the CSOS certificate holder knowing that you are not a holder password? (21 CFR 1311.38)
    - Yes
    - No

Need assistance or would like a full DEA "mock" audit performed?
Contact IPC at compliance-services@ipcx.com

www.ipcx.com | 800.274.5525
DEA Biennial Inventory

• Is the DEA Biennial Inventory on file?
  ➢ (21 CFR 1304.11(c))

• Are Beginning of Business (BOB) or Close of Business (COB) indicated?
  ➢ (21 CFR 1304.11(a))

• Is Biennial Inventory and all other inventories separated into Schedule II and Schedule III-V inventories?
  ➢ (21 CFR 1304.04(h)(1)+(h)(3))
Inventory Records

• An Inventory is a complete and accurate list of all stocks and forms of CS’s in the possession of the pharmacy.
• Determined by an actual physical count for Schedule II’s and an estimated count or measure of III-V’s.
• If the container holds more than 1000 tabs or caps, an exact count must be made.
• Schedule II inventories kept separate.
• Inventory records must be readily retrievable.
Inventory Types

- **Initial Inventory**
  - When issued a DEA registration
  - Count should be zero

- **Biennial Inventory**
  - Taken every two years
  - Ensure labeled “Biennial Inventory”
Schedule II CSOS Receipts / DEA 222 Forms

• Are Schedule II CSOS receipts annotated with quantity and date received in computer?
  ➢ (21 CFR 1305.22(g))

• Are DEA 222 forms for returns readily retrievable & ship quantity & date filled in?
  ➢ Report loss or stolen blank forms to DEA
  ➢ (21 CFR 1305.13(b)(c)(d)+1305.17(b)(c))
Schedule II Invoices

• Are Schedule II invoices readily retrievable (separately filed)?
  ➢ (21 CFR 1304.04(h)(1))
Schedule III-V Invoices

- Are Schedule III-V invoices separately filed with dates and quantity received?
  - Invoice or packing slip is official record of receipt
  - All records must be readily retrievable. Do not mix in with non-controlled invoices
  - (21 CFR 1304.04(h)(3)+1304.21(d))
Schedule II Prescriptions

• Are Schedule II prescriptions readily retrievable (separately filed)?
  ➢ (21 CFR 1304.04(h)(2))
Schedule III-V Prescriptions

• Are Schedule III-V prescriptions readily retrievable?
  ➢ (21 CFR 1304.04(h)(4))
Prescription Records

• Option 1:
  - A file for Schedule II’s
  - A file for Schedule III-V’s
  - A file for all Non-controlled

• Option 2:
  - A file for all Schedule II’s
  - A file for all other drugs but III-V’s must be readily retrievable (i.e., 1” or higher red “C” stamp in lower right corner or electronically filed)
Theft and Significant Loss Reporting

• Is RPh familiar with procedures for theft and loss investigating & reporting?
  ➢ Theft
  ➢ Significant loss
  ➢ (21 CFR 1301.76(b))

• Notify DEA within 1 business day in writing
• Notify State regulatory authorities
• Notify local PD
• Following investigation, file DEA Form 106 (Theft or Loss Report) on the DEA website (www.deadiversion.usdoj.gov)
In-Transit Loss

• When shipment fails to reach your destination, the supplier is responsible for reporting the loss to DEA.

• The pharmacy is responsible for reporting loss after he/she has signed for or taken custody of the shipment.

• If delivered and pharmacy does not take custody (i.e. bottles missing) and shipment is returned to supplier, then supplier must report the loss.
Combat Methamphetamine Epidemic Act of 2005

• Has pharmacy conducted CMEA training and printed certificate from DEA website?
  - Must train employees and certify to DEA that it occurred (www.deadiversion.usdoj.gov)
  - (21 CFR 1314.35, 1314.40, 1314.42)

• Applies to the retail sales of OTC products containing ephedrine/pseudoephedrine which can be used to produce methamphetamine.

• Products placed behind counter.
CMEA continued…

• Must check the I.D. of purchasers and maintain a log of each sale that includes purchasers name and address, signature, product, quantity, date and time.

• Can only sell 3.6 grams to an individual in 1 day.

• Individual purchases are limited to 9 grams in a 30-day period.
Power of Attorney (POA)

• Does the pharmacy have current Powers of Attorney on file for CSOS/DEA-222’s?
  ➢ Separate digital certificate must be obtained for each person granted a POA
  ➢ (21 CFR 1305.05)

• Are the Powers of Attorney executed by the signer of the current application for registration (or Corporate Officer)?
  ➢ (21 CFR 1305.05)
CSOS Subscriber Agreement / Password

• Does the pharmacy have CSOS Subscriber Agreement(s) on file?
  ➢ (21 CFR 1311.60(c))

• Is the CSOS certificate holder ensuring that no one else uses his/her password?
  - (21 CFR 1311.30)
Other DEA Regulatory Requirements
Security – Minimum Storage Requirements

• Controlled substances must be stored in a securely locked cabinet of “substantial construction” or dispersed throughout their stock of non-controlled substances.

• Even though the Federal regulations do not specifically define locked cabinet construction, the intent of the law is that controlled substances must be adequately safeguarded. Therefore, depending on other security measures, a wooden cabinet may or may not be considered adequate.
Security continued…

• Some of the factors considered when evaluating a practitioner's controlled substances security include:
  • The number of employees, customers and/or patients who have access to the controlled substances.
  • The location of the registrant (high or low crime area).
  • Use of an effective alarm system.
  • Quantity of controlled substances to be kept on hand.
  • Prior history of theft or diversion.
Security – Employment Waivers

• A Pharmacy must not employ in a position which allows access to CS’s any person who has been:
  • Convicted of a felony relating to CS’s.
  • Has had an application for DEA registration denied, revoked or surrendered for cause.

• Owner/RPh can request a waiver to this requirement per Title 21 CFR 1307.03 and Pharmacist’s Manual.
Five Percent Rule

- Pharmacy may dispense CS’s to another pharmacy or a practitioner without being registered as a distributor.

- Must document transfer on a DEA Form 222 or invoice for III-V’s.

- The total number of du’s of all CS’s distributed by the pharmacy may not exceed 5% of all CS’s dispensed by the pharmacy during a calendar year.
DEA Inspections

- DEA has added pharmacies to their inspection schedule.
- Full blown accountability audit will be conducted.
- Audit must balance.
- If any discrepancies with drug accountability or record-keeping, administrative/civil actions could be imposed on pharmacy.
Types of Written Notices Used by DEA to Inspect Controlled Premises

- Notice of Inspection
- Administrative Inspection Warrant
- Search Warrant
Notice of Inspection
Administrative Inspection Warrant

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

IN THE MATTER OF THE ADMINISTRATIVE INSPECTION OF

DBA:

CALIFORNIA 90210

Magistrate’s Docket No. 09MJ 1897

WARRANT FOR INSPECTION

TO: Diversion Investigator Spencer Shelton and any other duly authorized investigator or agent of the Drug Enforcement Administration of the United States Department of Justice.

Application having been made and probable cause as defined by 21 U.S.C. § 880(d)(1) having been shown by the Affidavit For Administrative Inspection Warrant by Diversion Investigator Spencer Shelton of the Drug Enforcement Administration for an inspection of the controlled premise of the

California 90210, and based on the lack of any prior inspection pursuant to 21 CFR 1316.09(a)(4)(i) and physician self-prescribing prescriptions maintained at AMC the requested administrative inspection is
United States District Court
NORTHERN DISTRICT OF GEORGIA

In the Matter of the Search of

A brick, single story building located at
2202 Virginia Ave., Atlanta, Georgia 30317,
with a plaque affixed to the building reading,
"H. A. Smith Company"

CASE NUMBER: 05-CR-770

TO: Diversion Investigator Amata M. Jones of the Drug Enforcement Administration, and any Authorized Officer of the United States

Affidavit having been made before me by Amata M. Jones who has reason to believe that on the property or premises known as:

Georgia 30117

in the Northern District of Georgia there is now concealed a certain person or property, namely

See Exhibit A attached hereto

I am satisfied that the information and any recorded testimony establish probable cause to believe that the person or property so described is now concealed on the premises described and establish grounds for the issuance of this warrant.

YOU ARE HEREBY COMMANDED to search on or before

July 8, 2007

(Dates shall exceed 10 days) the person or place named above for the person or property specified, serving this warrant and making the search IN THE DAYTIME - 8:00 A.M. - 10:00 P.M. - and if the person or property is found hereinafore seized, leaving a copy of this warrant and receipt for the person or property taken, and prepare a written inventory of the person or property seized and promptly return this warrant to LINDA T. WALKER as required by law.

June 29, 2007
Date and Time Issued
1:50 p.m.
at Atlanta, Georgia
City and State

LINDA T. WALKER
United States Magistrate Judge
Name and Title of Judicial Officer

/Signature:

LINDA T. WALKER
United States Magistrate Judge
Name and Title of Judicial Officer

/Signature:

LINDA T. WALKER
United States Magistrate Judge
Name and Title of Judicial Officer

/Signature:
### Sample Computation Chart
#### DEA Inspections-Audit Procedures

**Audit Period:** January 1, 2014 to March 31, 2014  
**Opening Inventory Date:** January 1, 2014  
**Closing Inventory Date:** March 31, 2014

<table>
<thead>
<tr>
<th>Drug Name, Strength, Form (Dosage Units)</th>
<th>Opening Inventory (BOB/COB)</th>
<th>Purchases</th>
<th>Total = Accountable For</th>
<th>Closing Inventory (COB)</th>
<th>Dosage Units Dispensed +</th>
<th>Supplier Returns +</th>
<th>Losses/Destruction +</th>
<th>Total = Accounted For</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxycodone 30mg Tab 100 Actavis</td>
<td>1200</td>
<td>2400</td>
<td>3600</td>
<td>2400</td>
<td>1200</td>
<td>0</td>
<td>0</td>
<td>3600</td>
</tr>
<tr>
<td>Hydrocodone 10/325 Tab 500 Mall</td>
<td>0</td>
<td>12000</td>
<td>12000</td>
<td>500</td>
<td>11000</td>
<td>500</td>
<td>0</td>
<td>12000</td>
</tr>
<tr>
<td>Clonazepam 1mg Tab 500 Actavis</td>
<td>2000</td>
<td>0</td>
<td>2000</td>
<td>500</td>
<td>1000</td>
<td>0</td>
<td>0</td>
<td>1500</td>
</tr>
</tbody>
</table>

* If the “Total Accounted For” is larger than the “Total Accountable For” then the “Total Difference/% Difference” will be an overage (+). If the “Total Accounted For” is less than the “Total Accountable For” then the “Total Difference/% Difference” will be a shortage (-).  
  e.g., Clonazepam shows 1500 (in red), indicating a shortage of 500 dosage units.
DEA ACTIONS

• Criminal action through USAO or State.
• Civil action through USAO.
• Immediate Suspension of DEA registration.
• Revocation of DEA registration – (Hearing).
• Restrictions on registration – Memorandum of Agreement (MOA).
• Letter of Admonition.
• Referral to State agency/board.
Criminal

- United States Code, Title 21 Section 841 (a)(1).
  - The illegal distribution/dispensing of a controlled substance.
Civil

• United States Code, Title 21 Section 842 (a)(5)/(a)(10).
  – It shall be unlawful for any person to refuse or negligently fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required.
  – Negligently to fail to keep a record or make a report (List 1 chemicals).
Thank You

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