Prescription Audits:
When the DEA or AG Come Knocking
Anticipating and Responding to Heightened Investigations of Prescribing and Dispensing Practices

THURSDAY, NOVEMBER 21, 2013
1pm Eastern  |  12pm Central  |  11am Mountain  |  10am Pacific

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Prescription Audits: When the DEA or AG Come Knocking

November 21, 2013

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Current Topics and Trends

• Examples of DEA Actions
  • Individual Prescribers
  • Pharmacies
  • Wholesalers

• Constructive Delivery
Examples of DEA Actions
• Samples of Administrative Actions

  – Actions Against Individual Prescribers
    • Recordkeeping
    • Medical Needs

  – Actions Against Pharmacies
    • Valid Prescriptions
    • Conducting a Proper Inventory
    • Largest Controlled Substance Fine

  – Actions Against Wholesalers
    • Compliance Program – Monitoring
    • State Actions
Actions Against Individual Prescribers

Recordkeeping

• Sigrid Sanchez, M.D.
  • Application for registration denied due to violations of recordkeeping, physical security, employee oversight provisions of CSA/regulations by pharmacy respondent.
    • Responsible for prior actions of the original owner/operator who ceased employment and passed on responsibilities to the respondent.
  • The revocation was upheld despite arguments that the violations underlying the revocation may not have been initially perpetrated by the respondent (i.e. poor recordkeeping merely continued from prior operations as opposed to abrogation of adequate recordkeeping upon transfer).
Actions Against Individual Prescribers

Medical Need

• **Clair L. Pettinger, M.D.**
  • Registration revoked after DEA determined that the practitioner had issued 9 prescriptions for controlled substances absent legitimate medical need to undercover DEA agents.

• The revocation was upheld despite:
  • The practitioner’s introduction of evidence that the undercover agents may have deliberately induced diversionary prescription through symptomology deception;
  • Evidence that the practitioner had undertaken significant efforts to improve identification of legitimate versus non-legitimate medical need.
Actions Against Pharmacies

Valid Prescriptions

- **S&S Pharmacy (d/b/a Platinum Pharmacy & Compounding)**
  - Registration revoked and all controlled substances seized after informants made cash purchases of Schedule II narcotics (oxycodone) from pharmacy employees based on fraudulent prescriptions.
  
  - The informants provided fraudulent prescriptions for oxycodone to the pharmacy.
Actions Against Pharmacies

Conducting a Proper Inventory

• Top RX Pharmacy
  • Registration revoked for multiple CSA/regulatory violations, including:
    - Failure to conduct initial inventory
    - Providing false information to controlled substance distributors
    - Failure to maintain accurate and complete records and/or account for controlled substances
    - Diluting promethazine syrup before dispensing
    - Dispensing controlled substances under circumstances in which it knew or should have known that the drugs were being diverted from non-medical, illegitimate purposes.

• The pharmacy failed to conduct initial inventory or maintain accurate records of controlled substances received, which led to further investigations of the pharmacy’s dispensing practices.
Valid Prescriptions

The DEA alleged that between 2008 and 2011 two large retail pharmacies in Florida had purchased quantities of oxycodone that considerably surpassed the amount ordinarily purchased by retail pharmacies.

- Further, the DEA alleged that the pharmacies had dispensed controlled substances to customers under circumstances indicating that the drugs were illegally diverted and had failed to appropriately monitor dispensing habits.

- The pharmacies argued that the high volume of dispensing was due to the fact that the two locations, one of which was open 24 hours a day, were busy stores, and that both locations had made significant efforts to implement robust anti-diversion procedures.

The pharmacies implemented several programs, such as monitoring prescriber habits, to help ensure controlled substances were being used properly.
Actions Against Pharmacies

Largest Controlled Substance Fine

• On June 11, 2013, a large retail pharmacy chain agreed to pay $80 million in civil penalties to the DEA—the largest ever settlement involving allegations based on the Controlled Substances Act.

• The settlement resolves allegations that the pharmacy chain had an “unprecedented” number of record-keeping and dispensing violations under the CSA. Specifically, the DEA alleged that the pharmacy chain negligently allowed controlled substances, such as oxycodone, to be diverted for abuse and black market sale.
Actions Against Pharmacies

- Other recent allegations made by DEA against a large pharmacy chain:
  - A chain pharmacy knowingly filled prescriptions for controlled substances that were not issued for a legitimate medical purpose pursuant to a valid physician-patient relationship in Kentucky and in New York.
  - A pharmacy chain did not properly notify the DEA of significant theft and loss of controlled substances, which allowed the diversion of controlled substances to continue and undermining DEA’s ability to investigate such thefts and/or losses.
  - At pharmacies in California, Pennsylvania and Maryland, a pharmacy chain either failed to maintain or failed to furnish to the DEA upon request records that are required to be kept under the CSA.
Actions Against Pharmacies

• Other recent allegations made by DEA against a large pharmacy chain:
  - A pharmacy chain failed to properly execute DEA forms used to ensure that the amount of Schedule II drugs ordered by it were actually received.
  - The DEA also conducted accountability audits of controlled substances at a pharmacy chain to determine whether the chain could properly account for Schedule II and III controlled substances purchased and dispensed. The results of the audits revealed significant shortages or surpluses of the most highly abused drugs, including oxycodone and hydrocodone products, reflecting a pattern of non-compliance with the requirements of the CSA and federal regulations that led to the diversion of controlled substances.
Actions Involving Wholesalers

Compliance Program - Monitoring

• On May 15, 2012, a large wholesale distributor agreed to a two-year suspension of its license to ship controlled substances from its Florida center.

• The DEA suspended the wholesaler’s registration based on allegations that it knew or should have known that 4 of its customers, including two pharmacies in Sanford, Florida, were inappropriately filling prescriptions for oxycodone. Specifically, the DEA alleged that the wholesaler:
  - Failed to maintain effective controls against the diversion of controlled substances, including failing to conduct meaningful due diligence to ensure that controlled substances were not diverted; and
  - Failed to detect and report suspicious orders of controlled substances as required by the CSA, on or before May 14, 2012.
Actions Involving Wholesalers

State Actions

- The West Virginia Attorney General filed a lawsuit against 14 drug distributors alleging that the entities have benefited from the state’s prescription drug abuse problem and seeking damages and attempting to cut off the so-called “pill mill” process.

- The lawsuit alleges that the distributors provide a bridge between drug manufacturers and the nation's vast network of retail pharmacies. These entities have been targeted before for allegedly not doing enough to recognize and stop the flow of addictive pain pills.
Constructive Delivery
Constructive Delivery

• Congressional Intervention
  - Will we finally get to see new legislation?

• DEA policy is that the delivery must still be to the patient…even for injectable medication.
Prescription Audits

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Trends – Physician Dispensation

• 44 generally permissive states (6 restrictive states: MT, MA, NY, TX, UT, WY)
• Most active dispensation states: CA, FL, HI, IL, MD
• Limitations on dispensing Schedule II and III controlleds (FL 2011 “Pill Mill Law”)
• Workers compensation physician dispensation
  – Awareness of disproportionate share of drug costs
  – Reform of state laws to limit mark-ups (CA 2007, IL 2012)
• Popular practice areas for dispensation
  – urgent care
  – pain, weight loss, integrative medicine
Who’s subject to audit?

• CSA Definition of “Practitioner”
  – Physician, dentist, veterinarian, podiatrist, mid-level practitioner (e.g. PA, NP), scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by U.S. or the jurisdiction in which the practitioner practices or performs research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.
  – Every person or entity that handles controlled substances must be registered with DEA or be exempt by regulation from registration.
Registration

• Each separate location at which drugs are stored, prescribed or dispensed must be registered separately.

• Exceptions:
  – Registered at one location and merely prescribing (without administration/dispensing/storage) at other location
  – Agents /employees of practitioner (other than mid-level practitioners if acting in normal course of business or employment unless otherwise required by state law)
  – Hospital/institutional agents/employees covered by the institutional registration

• Best practice: separate registrations of all practitioners in dispensing offices

• Shipments to registered locations only.
  – No transporting of medications
  – Challenges in mobile practice
Registration challenges in Mobile Practice

• Weak spot in regulatory oversight – mobile practices prohibited, leading to practitioner confusion, inconsistent enforcement

• Separate addresses for storage and administration?
  – Registration of home address- may be prohibited under state law

• No provision for lawful transportation

• Practices where location is not suitable for registration
Audit Preparedness-Prescribing

• Prescription for controlled substances not "effective" unless "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 CFR § 1306.04(a).

• Record requirements:
  – No general requirement to keep records of controlled substances
  – Exceptions:
    • Prescribing in the course of maintenance or detoxification treatment (21 CFR §1304.03 )
    • Electronic prescribing digitally signed record, internal audit trail and any auditable event (21 CFR § 1311.150)
    • Institutional practitioners must retain a record of identity proofing and issuance of the two-factor authentication credential, where applicable, as required by 21 CFR §1311.110 (21 CFR §1304.06)
Audit Preparedness—Prescribing

• Prescriptions must be issued for a legitimate medical purpose by a practitioner acting in the usual and lawful course of professional practice

• (1) All of the information required under §1304.22(c) and part 1306 of this chapter.
• (2) The digitally signed record of the prescription as received as required by §1311.210 of this chapter.

• (d) A registrant and application service provider must retain a copy of any security incident report filed with the Administration pursuant to §§1311.150 and 1311.215 of this chapter.
• (e) An electronic prescription or pharmacy application provider must retain third party audit or certification reports as required by §1311.300 of this chapter.
• (f) An application provider must retain a copy of any notification to the Administration regarding an adverse audit or certification report filed with the Administration on problems identified by the third-party audit or certification as required by §1311.300 of this chapter.
Audit preparedness
Dispensing Overview

- Records must be **readily retrievable** and kept available for inspection.
  - Produced in a reasonable time
  - Identifiably distinguished from other records
- Security requirements
  - Physical controls
  - Inventory monitoring
  - Workforce screening/oversight
- Recordkeeping requirements
  - Biennial Inventory
  - Dispensation logs
  - Invoice/Shipment records
  - Disposal records
Audit Preparedness-Security

• Security- Procedures and Controls to Guard against Theft/Diversion
  • Locked cabinets-securely locked, substantially constructed storage
  • Employee screening
  • Reports of lost or stolen medications

• Adequacy of “effective controls and procedures” assessed relative to location, type of building, type and qty of drugs, type of cabinet/safe/vault, monitoring (alarm), public access, police access

-21 CFR § 1301.71 et seq.
Recordkeeping

- Biennial inventory
  - New inventory every 2 yrs from initial inventory
  - Exact count on Schedule II substances
  - Estimated count for Schedule III, IV or V (unless container is >1000 tablets or capsules. (21 C.F.R. §1304.11.)
  - Inventory must be maintained in written form and must include the: (i) name of each substance; (ii) finished form; (iii) number of units; and (iv) number of commercial containers on hand at the time of the inventory.

- Dispensation logs
  - dates of dispensation
  - patient name, gender, address,
  - all details of the medication, quantity prescribed or dispensed must be maintained

- Purchasing/Delivery records

- Additional requirements for treatment (maintenance, detox, narcotic treatment) programs

-21 CFR Part 1304
# Biennial Inventory (21 CFR § 1304.11)

**Clinic Name:**

**MD Name:**

**Address:**

**Med. License #:** __________

**DEA #:** _________________

**Initial Inventory Date:**

**Last Inventory Date:**

<table>
<thead>
<tr>
<th>Date</th>
<th>Name of Substance</th>
<th>Finished Form</th>
<th>Number of Units or Volume of Each Finished Form in Each Container</th>
<th>Number of Commercial Containers on Hand at Time of Inventory</th>
<th>Total Units</th>
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<tbody>
<tr>
<td>9.15.13</td>
<td>Hydrocodone APAP</td>
<td>100-mg tablet</td>
<td>100 tablets per bottle</td>
<td>4 100-tablet bottles</td>
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</tr>
<tr>
<td>9.15.13</td>
<td>Lorazepam</td>
<td>3-ml vial</td>
<td>1</td>
<td>6 3-ml. vials</td>
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- Schedule II inventory – separate from other schedules
- Failure to maintain inventory – prima facie evidence of violation
Dispensation Log (21 CFR § 1304.22)

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<thead>
<tr>
<th>Clinic Name:</th>
<th>MD Name:</th>
<th>Address:</th>
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</thead>
<tbody>
<tr>
<td>MD License #:</td>
<td>DEA#:</td>
<td></td>
</tr>
<tr>
<td>Medication:</td>
<td>Carry Over:</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Date</th>
<th>Pt First Name</th>
<th>Pt. Last Name</th>
<th>Ordering Provider</th>
<th>Drug</th>
<th>Dose</th>
<th>Qty</th>
<th>Finished Form</th>
<th>Lot#</th>
<th>Given By</th>
<th>MD Signature</th>
<th>Count</th>
<th>Signature</th>
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<table>
<thead>
<tr>
<th>Pt Address/Phone</th>
<th>M/F</th>
<th>NDC#</th>
<th>ICD-9</th>
<th>Refill #</th>
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<tbody>
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Carryover Total

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DEA Form 106: Report of Theft or Loss of Controlled Substances

• Discrepancies must be investigated promptly to account for variances in controlled substance inventories.

• If theft or loss is determined to be the cause of the variance, Form 106 report must be submitted at time of discovery to DEA (and in some instances to police)
Disposal of Controlled Substances

• Request assistance from local SAIC via DEA Form 41 (surrender)
  – SAIC “shall authorize and instruct” on disposal via:
    • transfer to another authorized person (Reverse Distributor)
    • delivery to DEA agent or office
    • destruction in presence of DEA
    • “[b]y such other means as the [SAIC] may determine to assure that the substance does not become available to unauthorized persons” (including regular process with records and periodic reporting)

• Pending new regulations to implement the Secure and Responsible Drug Disposal Act of 2010 (“Take Back” collection events)-published Dec. 21, 2012
DEA Form 222

• Triplicate order form for DEA Schedule II controlled substances-issued by local DEA office

• Also needed for transfer/disposal (e.g. Reverse Distributors)

• Also maintain all invoices, shipping records, and packing slips
Recommended Policies and procedures

• Personnel
  – Employee screening/background checks
  – Exclude any person convicted of drug-related crimes or who has had DEA registration denied, revoked, surrendered
  – Biological fluid testing?

• Security Safeguards
  – Secured prescription access
  – Writing actual amounts not just numbers on Rx
  – No advance signed prescriptions
  – Report suspicion activity to DEA

• Records/Training / Enforcement / Self-auditing
Practical Recommendations

– Keep DEA Binder (or electronic equivalent) up to date for “ready retrievability”—in addition to required records, also keep licenses, registrations, certificates
– Rotate responsibilities among more than one person
– Keep tight control on keys, access
– Calendar next biennial inventory date
– Periodically self-test: Reconcile the inventory starting point, subsequent additional purchases, dispensation log, and hard count -- with any discrepancy accounted for. (21 C.F.R. § 21.)
Risk Issues

Growing attention on prescription drug abuse- opioid dependence/addiction, recreational abuse, overmedication as public health risks.

Single biggest enforcement focus: preventing diversion (i.e. diversion of prescription drugs from lawful medication purpose for illicit use, sale, and abuse

— “Bar[ring] doctors from peddling to patients who crave the drugs for those prohibited uses.”

ARCOS system tracks flow of controlleds from manufacture to distribution to dispensing/retail level – (hospitals, pharmacies, practitioners, mid-level practitioners).

Risky Prescribing

• Large quantities relative to other practitioners (note: avoid ordering for multiple practitioners under one registration)
• No physical exam
• Questionable prescriptions
• Questionable circumstances
Most Common Diversion Risks

– Drug-seeking/doctor-shopping patients
– Illegal distribution (MD’s who sell or permit associates to abuse)
– Sloppy/Falsified Recordkeeping
– Self-abuse
– Employee pilferage from inventory
– Burglary (Break-ins)
– In Transit Loss (Hijacking)
– Forged / fraudulent / altered prescriptions
Recurrent Story: The “Hidden” Addict

- Physician spouse or employee
- Develops underlying health issue, *e.g.* injury, illness or procedure
- Legitimate prescription leads to dependency on narcotic opioids
- Hints of dependency are missed or attributed to problems (*e.g.* fatigue due to workload)
- Access to distributor account enables spouse/employee to bypass prescribing safeguards
- Order quantities increase, attracting DEA audit
- DEA uncovers major discrepancy in inventory
PRESRIPTION AUDITS: AUDIT PROCESS

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Audit Process

• Shorthand rule – the inspectors have broad authority to ask for documents and ask questions

• The “scope” of the audit will be up to the inspectors

• Employees should recognize this and try to be as cooperative as possible
Audit Process

- DEA

- State Authorities
  - Typically from the Pharmacy Board (or similar)
  - Or from State Attorney General’s Office
Audit Process

• California:

  – All stock of any dangerous drug or dangerous device . . . shall be at all times during business hours, open to inspection by authorized officers of the law.

  • Business & Professions Code § 4080
• California:
  – All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making.
    – Business & Professions Code § 4081(a)
• California:

  – A current inventory shall be kept by every . . . Pharmacy . . . who maintains a stock of dangerous drugs or dangerous devices.

  • Business & Professions Code § 4081(a).
• California

– When called upon by an inspector, the owner or manager of any entity licensed by the board . . . shall furnish the inspector with the names of the owner or owners, manager or managers, and employees together with a brief statement of the capacity in which these persons are employed on the premises.
  • Business & Professions Code § 4082
Audit Process

• Federal – DEA
  – Audit process
  – Two year record requirement
  – DEA Forms
    • 222 (sched. II drugs)
    • 106 (significant loss of controlled substance)
  – Logbook – pseudoephedrine
    • Combat Methamphetamine Epidemic Act of 2005
Audit Process

• DEA may ask for:
  – Registration certificate
  – Powers of attorney
  – Unused DEA 222’s; stored properly?
  – Executed DEA 222’s
    • Readily retrievable?
    • Any missing?
  – Supplier invoices
  – Distribution records
• DEA – Continued
  – Controlled substance prescriptions
  – Refill records
  – Computer dispensing printouts
  – Inventory records
  – Substances stored properly?
Cause for Heartburn

• The audit can be a “conversation” rather than a mere “inspection”

• The pharmacy is only as good as its weakest link, i.e., its weakest employee
Example

• In re Pacifica Pharmacy Corp.
  – Precedential Decision No. 2013-01 (available at Cal. Pharm. Board’s web site)

• Obviously egregious facts – pharmacist filled thousands of opiate prescriptions for out-of-area patients.

• License was revoked.
• In re Pacifica Pharmacy – Lesson

– It was a holistic inspection:

• Inspectors reviewed the CURES reports before coming

• Inspectors conducted inspections PLUS extensive interviews

• Inspectors found some violations BUT biggest problem was the overall impression the inspectors obtained, i.e., that this was a pharmacy that wasn’t properly complying with its “corresponding responsibility” to ensure prescriptions were proper