REGISTRANT INSPECTIONS
Disclosure: Bobby Otero

I have no relevant personal/professional/financial relationship(s) to disclose
DEA’s Closed System of Distribution

- Importer
- Analytical Lab
- Manufacturer
- Exporter
- Distributor
- Reverse Distributor
- NTP
- MLP
- Teaching Institution
- K-9 Handler
- Hospital
- Pharmacy
- Practitioner
Closed System of Distribution

The DEA is responsible for:

- the **oversight** of the system
- the **integrity** of the system
- the **protection** of the public health and safety
Closed System of Distribution

- Established Schedules
- Registration
- Established Quotas
- ARCOS
- Security Requirements
- Recordkeeping
- Regulatory Investigations
Registrant Inspections
Registrant Inspections

Regulatory Inspection defined:

A periodic review of records, security, and business practice to determine if continued registration is in the best interests of the general public.
Registrant Inspections

Reasons for visiting and inspecting:

- Ensure compliance and responsible sales
- Identify potential areas of diversion
- Grievance complaint
- Local, state or federal referral
Registrant Inspections

Upon Arrival:

- Arrive unannounced

- Appointments afford opportunities to conceal crimes or complicate access

- Identify the decision maker
Registrant Inspections

Upon Arrival:

- Display credentials: seek cooperation
- Obtain informed consent (NOI)
- Obtain Administrative Inspection Warrant
Registrant Inspections

Investigators confirm:

- State authority/licensure
- List of owners/corporate officers
- List of responsible individuals (DOB/SSN)
- Physical security for drugs
- Recordkeeping compliance
- Understanding of federal regulations
Registrant Inspections

Conduct background checks:

- Identify the responsible individuals
- Identify the individuals with access to cage, vault, and cont sub
Registrant Inspections

Records review:

- Review records and record keeping system (purchases, sales, disposals, etc)

- Identify primary customers and their activity/volume for selected products
Registrant Inspections

Records review:

- Review overall purchase to sales consistency

- Identify suspicious transactions or trends (cash sales, excessive purchases, etc)
Registrant Inspections

For Audits:

- Immediately secure access to inventory, records, and computers
- Count inventory with management
- Get agreement on inventory count
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Overall safety review:
Registrant Inspections

Overall business procedure review:
Registrant Inspections

Overall security review:
Responsibility of Registrants

“For god’s sake Walters, wait until the patient is fully anesthetized before going through his wallet.”
Registrant Responsibility

Upon Receiving Controlled Substances:
Must take a complete physical inventory
(“Initial Inventory”)

Title 21, CFR 1304.11(b)
Registrant Responsibility

Must take a complete physical inventory every 2 years from date of Initial Inventory ("Biennial Inventory")

Title 21, CFR 1304.11(c)
Registrant Responsibility

Inventories:

- Think “Checkbook”!
Registrant Responsibility

2 + 2 Must Equal 4!

What do you mean you can't fill my prescription any more??? I've been writing these for years...

It was the blue crayon that finally put the END to Lucy's prescription fraud.
Total lost in production: 12,220 kgs!!!
Quimicos Mil Saldarriaga
Medellin, Colombia
Note lack of infrastructure
Registrant Responsibility

Maintain Complete and Accurate Records (Minimum 2 years)

- DEA-222 Order Forms
- Purchasing Invoices
- Inventories
- Any DEA-related correspondence

Title 21, CFR 1304.04(a)
Registrant Responsibility

Recordkeeping:

- Maintain records separate from all other records
- “Readily retrievable”

Title 21, CFR 1304.04 (f) and (g)
Registrant Responsibility

Recordkeeping:

- Must maintain complete and accurate records of receipt and distribution of controlled substances.

Title 21, CFR 1304.21(a)
Registrant Responsibility

Recordkeeping:

- Must complete DEA-222 order forms with the date and quantity received.

Title 21, CFR 1305.13(e)
Copy of DEA-222 Order Form

Must have date received and quantity received!!
Registrant Responsibility

Recordkeeping:

- Must provide effective controls against theft and diversion of controlled substances.

Title 21, CFR 1301.71
Registrant Responsibility

Must provide adequate security for controlled substances:

- Perpetual inventory (not required)
- Report thefts or loss
- Destruction/disposal
Registrant Responsibility

Must provide adequate security for controlled substances:

- Vault and/or Cage
- Store in a “…securely locked, substantially constructed cabinet”
- Disperse among the stock
- Limit access
Result of Inspection
Result of Inspection

Possible Measures:

- Verbal Warning
- Letter of Admonition (LOA)
- Memorandum of Agreement (MOA)
- Immediate Suspension Order (ISO)
- Order To Show Cause (OTSC)
Result of Inspection

Title 21, USC 842(a)(5):

- **Civil**: Provides a remedy of maximum $10,000 USD per violation.
Result of Inspection

Arrest and/or Criminal Fines

Title 21, United States Code (USC) 841

Title 21, USC 842

Title 21, USC 843

Provides a remedy for criminal violations
Registrant Inspections

COMPLIANCE, NOT NECESSARILY PERFECTION!

"All the other women in the office are suing you for sexual harassment. Since you haven't sexually harassed me, I'm suing you for discrimination."
Things to Consider
KNOW YOUR CUSTOMER!

THIS IS NOT WORKING. CAN I GO BACK ON THE VALIUM?
TRUST YOUR GUT INSTINCT - FIRST INSTINCT IS USUALLY THE BEST

lunchbreak by cta

The thieves broke into the pharmacy and stole all of the viagra!

Sounds like we should be on the look-out for hardened criminals...
Do Not Ignore the Red Flags!

How to tell when there's something fishy about your pharmacy:

What do you have for ear wax removal?

Oxycontin.

Dandruff?

Oxycontin.

Hemorrhoids?

Oxycontin.

Is there anything that isn't cured by Oxycontin??

For foot odor, we suggest Xanax.