DEA Rules - Objectives

- The student will be able to discuss the manner in which the DEA regulates the distribution of C.S.
- The student will be able to describe the registration process, security, record keeping requirements, use of order forms, regulation of prescribing & dispensing and DEA inspection authority

DEA Rules

- Closed Drug Distribution System
- Everyone is registered
- Everybody keeps records
- Records available for review

D. E. A. Rules
21 C.F.R. 1300

Everything that you need to know but were afraid to ask
Controlled Substances

- Five schedules
  - Schedule I  No medical use
    - Heroin, Marijuana, LSD
  - Schedule II  Medical use high abuse potential
    - Morphine, codeine, OxyContin, Percodan, Percocet, Ritalin
  - Schedule III Less abuse potential
    - Codeine combo, hydrocodone combo, marinol

Controlled Substances

- Schedule I Not prescribed - (May Rx IF Investigational Drug)
- Schedule II Written Rx or emergency NO refills
- Schedule III Verbal Rx OK refillable 5/6
- Schedule IV ditto
- Schedule V Verbal Rx OK refill per MD up to 12 months; Some are OTC

Controlled Substances

- Schedule III & V
  - Note the quantities of controlled substances per dosage unit or per 100 mL that determine what schedule a product will be placed in (e.g., Codeine 200 mg/100mL = Schedule V Codeine 1800 mg/100mL or 90 mg per dosage unit equals Schedule III)
- NOTE: you may get exam questions on this.
Registration - 1301.

- Must register for ALL activities related to Controlled Substances (e.g., Mfg., Distrib., Dispensing, Prescribing, Research, etc.)
- Some Exempt from fee BUT must comply with law (e.g., State or U.S. Govt. Agencies)
- Separate registration for EACH location.
  - MD with 2 offices if Rx only = 1 registration if dispense/administer at both then 2 registrations

Registration 1301 Cont..

- Exemptions:
  - Agents/Employees
    - Hospital - use hospital DEA number + suffix
    - ONLY while treating hospital patients
    - Hospital keeps list of suffixes & makes available to other registrants & law enforcement
  - Moonlighting - need own registration

Registration 1301 Continued

- Military exemptions
  - Army, Navy, Public Health Service, etc.
- Must use Service ID No. (i.e., SSN) on Rx
- Ocean Vessels (Commercial)
  - May obtain C.S.
  - If MD, must register
  - If NO MD available, Captain may obtain C.S.
  - Pharmacy advises DEA then OK to sell

Registration 1301 Continued

- DEA will register IF state will authorize
- What the Administrator giveth, the Administrator may taketh away!
- Order to show cause
  - Hearing could be held
  - Applications = your burden of proof
  - Suspend/Revoke = DEA’s burden of proof
Security Standards 1301.71-.93

- Security requirements differ depending upon type of registrant
- Non-practitioners (Mfg., Whl., Research)
- Narcotic Treatment Programs
- Practitioners
- Pharmacies

Security Standards 1301 Cont.

- Non-Practitioners
- Vaults, Alarms, Perimeter security, limited access, etc.
- Narcotic Treatment Programs
- Drugs received by licensed person or designee NOT NTP Client!
- Administered by licensed person
- Clients must be separate from drugs

Practitioners Security

- Securely locked
- Substantially constructed cabinet

Pharmacy Security

- May disperse among other prescription drugs.
- OR
- Securely locked substantially constructed cabinet
Pharmacy Security, cont.

- CS may NOT be stored in
- Tackle boxes
- Unlocked drawer
- All CS’s in one place (unless locked)

Security 1301 Continued

- Other security controls
- Employer must have screening procedures
- May NOT employ person convicted of felony related to CS or if had DEA Registration denied, revoked, surrendered (for cause)
- NOTE: Waivers are available from DEA
  - Hard to get, take 6+ months, employer applies for the waiver NOT the prospective employee.

Security 1301 Continued

- Must notify DEA (and Board of Pharmacy) of any theft or “significant loss” of CS.
- Use form DEA 106
- Employees MUST report drug diversion by other employees!

Labeling & Packaging 1302

- Must include symbol for schedule on label e.g., C-I, C-II, C-III, C-IV or C-V
- Must be prominently located
- All packages must be sealed.
The DEA sets quotas annually for the amount of certain controlled substances which may be manufactured. Sometimes, this interferes with availability of product. Companies don’t like to share “their” quota with new competitors (e.g., new generic comes on the market).

Everyone who handles CS must keep records of receipt & disposition. Types of records vary by Registrant. Records must be “Readily Retrievable” — Able to separate CS info. from other info.

Pharmacies must maintain ALL records of receipt and disposition. (Invoices, 222’s, Rx, Returns, Loss Reports, Sales Invoices)

Physicians must keep these records IF
- Dispense C.S. to patients for use at home
- Regularly dispense or administer AND
  - Charge fee for CS or
  - Charge Higher office fee if get C.S.

No records if ONLY administer

NOTE: WA law requires records to be kept.

May keep some records at Central location (e.g., chain pharmacy headquarters)

BUT NOT:
- Prescriptions
- Biennial Inventories
- Executed Order forms (DEA 222’S)

Central records must be made available in 2 days.

Notify DEA that you want to keep centralized.
Records 1304 Continued

☐ Must keep records for 2 years
☐ Although must keep files to account for refills of Rx’s issued before the 2 years.
☐ (e.g., on 12/31/05 you decide that you want to discard records back beyond 12/31/03 remember some Rx’s filled from July to 12/31/03 may have been refilled during the early months of 2004 therefore must keep those records for 30 months.)

DEA Rule Change 3/97

☐ NOTE: Formerly, certain CS prescriptions had to be identified with a 1-inch Red “C” stamp to differentiate between prescriptions in filing systems. This is NO longer required IF you have a computer system that can print out info that the DEA needs sorting by doctor, by drug, etc.
☐ ALL WA pharmacies now have computers

The last holdout pharmacy without a computer

☐ Got reported by insurance company
☐ Could not account for refills on DEA audit
☐ Refilled CS Rx over 5 times in 6 months
☐ Paid $40,000 fine
☐ Bought Rx Computer

Records 1304 Continued

☐ Schedule I & II Records separate from all others (incl. inventories, Rx, invoices)
☐ Also must complete DEA 222 form by inserting number of packages received in the appropriate box on form.
Records Continued

- US v. Green Drugs 905 F.2d 694 3cir1990
- Pharmacy short 4798 Percodan, 1902 Percocet, 2753 Preludin
- Court found “inadvertent mistake” (sloppy)
- Appeals court applied “Strict Liability Sdt.”
- Law requires complete and accurate records
- Lesson: Be careful, thorough and accurate!

1998 Texas Cases

- New Standard developed by Congress
- Fine reduced from $25,000 to $10,000 per violation
- New negligence standard – RPh knew or should have known of violation.

Inventories 1304.11-19

- Originally taken on 5/1/71
- Then every 2 years
- New Pharmacies on Opening (even if zero)
- NOTE CHANGE (3/97) Previously there were very specific date requirements, now biennial inventories must be taken within two years of previous inventory.

Perpetual Inventories:
- Some pharmacies maintain a perpetual inventory of all CS
- Some have perpetual inventory for II’s only
- These do NOT meet the requirement for a biennial inventory.
- You could make a copy of a perpetual inventory for a particular day and make sure it is accurate and has ALL of the data on the following slide:
### Inventories Continued
- Written, typewritten, or printed form
- Must include ALL CS under control of registrant
  - Hospital - Phcy, clinic & nursing unit stock
  - LTC Pharmacy - Phcy & NH emergency kits
- Must show date & time of inventory (beginning of business or end of business) & DEA #
- Drug strength, quantity, & form (tab, cap, etc.)
- Must be signed by person taking inv.
- Must identify as, “Biennial Inventory”

### Inventories Continued
- Newly controlled substances (e.g., Ketamine, Midrin)
- Must inventory on day that it is controlled by DEA
- Must keep inventory at location for 2 yrs
- How do inventories help DEA?
  - Provides a reference point for audit

### Inventories Continued
- Exact count or measure for Schedule I & II
- Estimated count for III, IV & V EXCEPT for bottles over 1000 then Exact count!
  - (DEA apparently assumes that you can estimate an open bottle of 1000 but not 5000.)

### Order Forms 1305
- DEA Order forms (222’s) required for all transfers of Schedule I & II substances
- (some exceptions including samples taken by law enforcement, board, also procurement by ocean vessels)
- Only registrants may obtain.
- Person with Power of Attorney may sign.
- Keep Powers of Attorney with II records
Order Forms Continued 1305

☐ Apply for forms with initial registration
☐ Order more as needed
☐ ID Information remains the same
☐ Based upon Original Registration
☐ Only the registrant, who signed original application or person with power of attorney may request more forms

Execution of Order Forms

☐ Use computer, typewriter, pen or indelible pencil
☐ One item per numbered line
☐ One drug, size, strength per line
☐ Name, strength, dosage form, quantity, No.
☐ (Name of CS if a compound)
☐ One supplier per form
☐ Catalog Number or NDC optional

Order Forms Continued

☐ Person who signed most recent application for registration must sign order forms OR
☐ May grant Power of Attorney to anyone else (See 1305.07 for format)
☐ Must keep on file with executed order forms
☐ Do NOT need to send to supplier unless requested

Order Forms Continued

☐ Uses of triplicate 222 order forms
☐ Order Schedule II CS
☐ Return these drugs
☐ Sell to physicians, clinics, other phcys, etc.
☐ NEVER EVER EVER sell to physician on a "Prescription for office use"!!!!
☐ Always use an invoice & file with CS records.
☐ If supply to anyone send 222 copy 2 to DEA.
Recent Case 10/03

- WA Physician requested CS for dispensing
- Wrote Rx in clinic’s name
- RPh said, “I need a patient name on Rx.”
- Dr. said, “Here just use one from this list.”
- RPh delivered drugs to MDs office
- Filled verbal schedule IIIs
  - No emergency shown
  - No signed Rx received

Order forms Continued

- Use of triplicate 222 order forms, cont.
- Send copy 1 and 2 to supplier
- Keep copy 3
- If supplier can’t fill completely may supply remainder in 60 days but NOT beyond
- Supplier keeps copy 1 sends # 2 to DEA
- Recipient MUST record date & quantity received on copy 3.
Order Forms Continued

☐ No erasures or alterations permitted
☐ Forms may be endorsed by supplier to another supplier (e.g........., to Mfr for drop ship) see reverse of form

Order Forms Continued

☐ Supplier may return order form unfilled if no stock, errors, erasures, etc.
☐ Must include statement why returned
☐ Pharmacy keep form & statement with copy No. 3 in CS records
☐ Pharmacy may supply NEW order form to reorder.

Order forms continued

☐ Lost or stolen forms
☐ If lost in transit to supplier:
  ■ Issue New form
  ■ Attach statement that form was lost
  ■ File statement with copy 3
  ■ If found should be returned by supplier and filed with copy 3.

Order Forms Continued

☐ Lost order forms continued (Used or New)
☐ If lost or stolen OTHER than in transit
☐ Report loss including serial numbers to: Local DEA office (Change 3/97)
☐ If don’t know serial numbers give approximate date(s) forms were received.
☐ May sell CS to practitioner
☐ May NOT exceed 5% of total dosage UNITS
☐ (If>5% must be wholesaler)
☐ May return CS to supplier
End of Part 1 Controlled Substances