

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

Everything that you need to know but were
afraid to ask

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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
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WIZARD OF ID / Brant Parker and Johnny Hart



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DEA Rules

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



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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

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Controlled substances

- Five schedules continued
- Schedule IV Less abuse potential
 - Librium, valium, other benzos
 - Darvon, Talwin.
- Schedule V Some abuse potential
 - Some Rx only Some OTC
 - Codeine cough syrups, Tylenol elixir with codeine, antidiarrheals

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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

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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.

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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

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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

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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

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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

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Security Standards 1301.71-.93

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

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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

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Practitioners Security

- Securely locked
- Substantially constructed cabinet



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Pharmacy Security

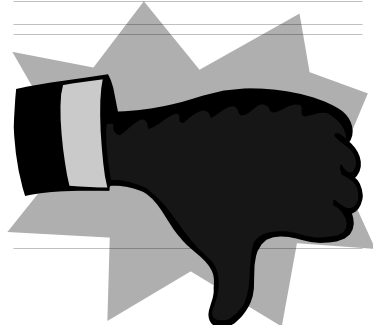
- May disperse among other prescription drugs.
- OR
- Securely locked substantially constructed cabinet



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Pharmacy Security, cont.

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



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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.

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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!

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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.

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Quotas 1303

- 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)

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Records 1304

- 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.

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Records 1304 Continued

- 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.

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Records 1304 Continued

- May keep some records at Central location (e.g., chain pharmacy headquarters)
- BUT NOT:
 - Prescriptions
 - Biennial Inventories
 - Executed Order forms (DEA 222'S)
 - These must remain at the pharmacy
- Central records must be made available in 2 days.
- Notify DEA that you want to keep centralized.

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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.)

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DEA Rule Change 3/97

- NOTE: Formerly, certain CS prescriptions had to be identified with a 1inch 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

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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 6months
- Paid \$ 40,000 fine
- Bought Rx Computer



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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.

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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!

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Records Continued

- 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.

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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.

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Inventories 1304.11-19

- 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:

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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"

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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

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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.)

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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

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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

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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

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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

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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.

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See Reverse of PURCHASER'S Copy for Instructions		No order form may be issued for Schedule I and II substances unless a completed application form has been received (21 CFR 305.04)		OMB APPROVAL No. 1117-0010		
To (Name of Supplier) Area Wholesale Drugs, Inc.			STREET ADDRESS 222 First Street			
CITY AND STATE Chicago, Illinois 60000		DATE Feb. 9, 1990		TO BE FILLED IN BY SUPPLIER SUPPLIER'S DEA REGISTRATION No.		
TO BE FILLED IN BY PURCHASER						
LINE No	No of Packages	Size of Package	Name of Item	National Drug Code	Packages Shipped	Date Shipped
1	10	25	Codeine Sulfate Tablets 60 mg			
2	10	25	Codeine Sulfate Tablets 30 mg			
3	5	50	Dexedrine Spansules 10 mg			
4	2	500	Dexedrine Spansules			
5	1	100	Demeral-50-mg-Tablets	cancelled		
6						
7						
8						
9						
10						
4 NO OF LINES COMPLETED		SIGNATURE OF PURCHASER OR HIS ATTORNEY OR AGENT <i>James Jones</i>				
Date Issued 4/20/89	DEA Registration No AP1234567	Name and Address of Registrant Prescription Drug Chain Inc. Store #10 110 Main Street Anytown, Ill. 66666				
Schedules 2, 2N, 3, 3N, 4, 5		Registered as a Pharmacy				
No of this Order Form B11108023						
DEA Form 222 (June 1983)		U.S. OFFICIAL ORDER FORMS — SCHEDULES I AND II DRUG ENFORCEMENT ADMINISTRATION DEA COPY 2				

ENDORSEMENT		
MAY BE MADE ONLY BY THE PERSON OR FIRM TO WHOM THIS ORDER IS ISSUED WHO MUST BE A MANUFACTURER OR DISTRIBUTOR REGISTERED IN SCHEDULE I OR II		
TO (ALTERNATE SUPPLIER) Local Drug Wholesale Inc.		
ADDRESS (NUMBER AND STREET) 1025 Highland Ave.		
(CITY, STATE AND ZIP CODE) Anytown, Illinois 12345		
PLEASE SEND MERCHANDISE REQUESTED ON THE REVERSE SIDE OF THIS SHEET ONLY TO PERSON OR FIRM DESIGNATED AND ONLY AT LOCATION SPECIFIED BY THE ADMINISTRATOR DRUG ENFORCEMENT ADMINISTRATION		
NAME OF PERSON OR FIRM IF NOT AN INDIVIDUAL Prescription Drug Chain, Inc. Store #10	SIGNATURE OF ENDORSER OR HIS ATTORNEY OR AGENT <i>James Jones</i>	DEA REGISTRATION OF ENDORSER PL 1234567
NUMBER AND STREET 110 Main Street		
CITY, STATE AND ZIP CODE Anytown, Illinois 12345		
THE PERSON SUPPLYING THE DRUGS OR PREPARATIONS ORDERED ON THIS FORM WILL RETAIN COPY 1 AND SEND COPY 2 OF THE FORM TO THE DEA DIVISION OFFICE FOR THE AREA IN WHICH THE SUPPLIER IS LOCATED PROMPTLY AT THE CLOSE OF THE MONTH DURING WHICH IT IS FILLED		
COMPLETE ALL PARTS		

- ### 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 IIs
 - 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

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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.

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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.

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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

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End of Part 1 Controlled Substances