

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

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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 by DEA & States



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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 benzodiazepines
 - Darvon, Talwin.
- Schedule V Some abuse potential
 - Some are Rx only Some are 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 Written or Verbal Rx OK refillable up to 5 times in 6 months from date of ISSUE
- 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 outside of official govt duties- 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 if they do not have a DEA number
- 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 DEA Administrator giveth, the DEA 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
- Only MD, ARNP, PA, RPh may dispense take home

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Practitioners Security

- Securely locked
- Substantially constructed cabinet



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Pharmacy Security

- May disperse among other prescription drugs.
- OR
- Store in 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. BUT...
 - 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 available on DEA website
- <http://www.deadiversion.usdoj.gov/>
- 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., when a 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 12/31/06 you decide that you want to discard records back beyond 12/31/04 remember some Rx's filled from July to 12/31/04 may have been refilled during the early months of 2005 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 (when rules became effective)
- Then every 2 years on the same date
- New Pharmacies take on Opening (even if zero)
- NOTE CHANGE (3/97) Previously there were very specific date requirements, now biennial inventories must be just 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 - usually hospitals & some nursing home phcys
 - 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

- Must be 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.) & # of commercial pkg (e.g., 110 tabs = 1.1 com. pkg)
- 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 drug 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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Order Forms Continued

- DEA has developed rules to allow electronic ordering of Schedule II drugs.
- Not too many pharmacies are taking advantage of these provisions. They are quite complex.
- IF you order electronically you have to go back to the website when the order comes in so that you can advise DEA of the receipt of the drugs.

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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			
TO BE FILLED IN BY PURCHASER			SUPPLIER'S DEA REGISTRATION No			
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--	Demerol-50-mg-Tablets			
6						
7						
8						
9						
10						
4		NO OF LINES COMPLETED	SIGNATURER 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				

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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
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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 a name from this list."
- RPh delivered drugs to MDs office
- RPh filled verbal schedule IIs
 - No emergency shown
 - No signed Rx received

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Recent Case 10/03

- The drugs were handed out to student athletes, family members, others
- No records were kept by the physician
- Physician's license was revoked
- Pharmacist was fired by the hospital that was unknowingly providing the drugs.
- Pharmacist had license suspended for 6 months

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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.

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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 they have no stock, or there were errors, erasures, etc. on the order form.
- 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

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