

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

Everything that you need to know but
were afraid to ask

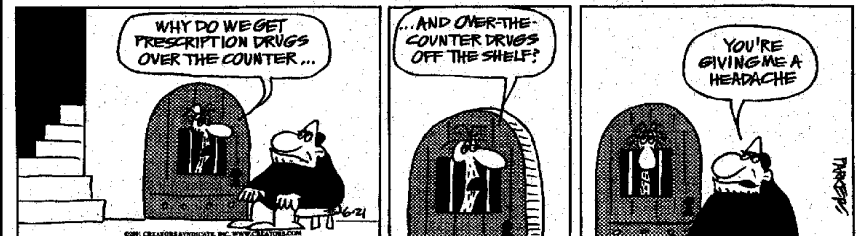
DEA Rules - Objectives

- × 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

Drug Classifications

- × Controlled Substances
- × Legend Drugs – Rx Only
- × Over the Counter drugs
- × Things that look like drugs
 - Herbals
 - Nutritional

WIZARD OF ID / Brant Parker and Johnny Hart



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 - Investigational?
- × 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.

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 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 advise 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

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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

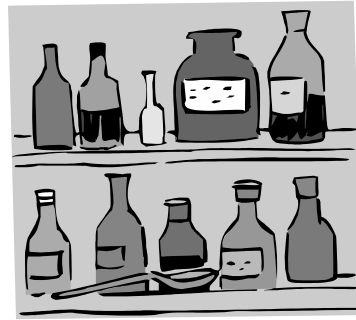


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Pharmacy Security

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

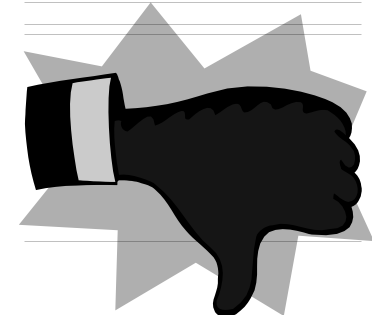


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Pharmacy Security, cont.

- × CS may NOT be stored in
- × Tackle boxes
- × Unlocked drawer
- × All CS's in one place



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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

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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.

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

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.

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

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.
- × DEA notification required.

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 12/31/03 you decide that you want to discard records back beyond 12/31/01 remember some Rx's filled from 7/1-12/31/01 may have been refilled during the early months of 2002 therefore must be kept.)

DEA Rule Change 3/97

- × NOTE: Formerly, certain CS prescriptions had to be identified with a 1" Red "C" stamp to differentiate between prescriptions in filing systems. This is NO longer required IF you have a computer system that can provide info that the DEA needs 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
- × Refilled CS Rx over 5 times in 6months
- × 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.

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!

Records Continued

- × 1998 Texas Cases
- × New Standard developed by Congress
- × Fine reduced from \$ 25,000 to \$ 10,000 per violation
- × 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.

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 time of inventory (beginning of business or end of business)
- × Must be signed by person taking inv.

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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!
 - (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.

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Order Forms Continued 1305

- × Apply for forms with initial registration
- × Order more PRN
- × ID Information remains the same
- × Based upon Orig. Registration
- × Only registrant 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 order 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"!!!!
- × If supply to anyone send 222 copy 2 to DEA.

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		
LINE NO	TO BE FILLED IN BY PURCHASER					
	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 10 mg		
	5	1	100	Demerol 50-mg Tablets		
	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		U.S. OFFICIAL ORDER FORMS — SCHEDULES I AND II DRUG ENFORCEMENT ADMINISTRATION DEA COPY 2		

DEA Form 222 (June 1983)

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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 FL 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

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Current Case 10/03

- × 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

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

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.

End Part 1 DEA Rules

Prescriptions 1306

- × KNOW THIS SECTION OF DEA RULES!
- × How do controlled substances get to patients?
 - Prescription
 - Direct administration by practitioner
 - Dispensing by practitioner
 - Hospital medication order

Prescriptions 1306 continued

- × Who may issue prescription?
 - DEA Registered Practitioner or exempt from registration AND authorized by State
 - Within course of TX AND scope of practice
- × Use of physician's agents
 - Nurse, clerk, etc. may COMMUNICATE Rx or refill authorization at the prescriber's request
 - MUST be FROM prescriber -Get name for the record.
 - Written Rx NOT valid if nurse signs doc's name & her initials.

Prescriptions continued

- × CASES
- × U.S. v. Moore 423 US 122 (1975)
 - Methadone Rx's not in course of prof. practice
- × U.S. v. Hayes 595 F.2d 258 (5th Cir 1979)
 - Corresponding responsibility for pharmacist knew Rx's had false names, MD= alcoholic etc
- × U.S. v. Lawson 682 F2d 480 (4th Cir 1982)
 - 1 doc, 1 presenter, multiple "patients"

Prescriptions continued

- × CASES, cont.
- × Vermont & 110th Medical Arts Pharmacy 177 Cal Rptr 807
- × 10,000 Rx's in 45 days 748,000 doses!!!
- × Patients: Henry Ford, Edsel Ford, Glenn Ford, Fairlane Ford, Pearl Harbor, etc.

Prescriptions continued

- × 1306.05(a) Format - Issuance of Rx
- × Dated as of and signed on date of issue
- × Full name & address of Patient
- × Directions for use
- × Name, address, DEA number of prescriber
- × Manually signed by prescriber (like check)
- × Sched. II in ink, indelible pencil or typed
- × Can be prepared by clerk SIGNED by MD

Prescriptions, cont.

- × Electronic Prescriptions
 - Schedule II NOT currently authorized
 - DEA is working on complex rules to allow
 - Schedule III-V
 - » DEA considers these to be equal to phone orders
 - » WA law allows BUT must be issued through a Board of Pharmacy approved system

Prescriptions continued

- × Warning label on container:
- × “Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.” ** (In Washington “State or Federal....)
- × No federal limit on life of Rx except 6mo refill limit. (State Limit 12 months II's)
- × Can NOT write post-dated Rx (Ritalin)

Prescriptions continued

- × Can NOT write post-dated Rx
- × How do you handle if 30 day limit by insurance company but visits every 90 days?
 - Date 3 prescriptions with today's date
 - Write "Do not fill before ____"
 - Each Rx may then be filled at 30 day intervals.

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Prescriptions continued

- × Who may fill CS prescriptions?
- × Only a pharmacist or pharmacy intern in a registered location
- × (Pharmacy technicians may assist)
- × Nurses in ER's can not fill Rx's
- × See state rules (WAC 246-873-060(7))for rural hospitals

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Prescriptions - DEA Numbers

- × Consist of 2 letters and seven numbers
- × First letter A, B, or M(for midlevel)
- × Second letter = First letter of last name
- × Numbers may be verified by following formula:
Add 1st, 3rd, & 5th digits = x then add 2nd, 4th & 6th digits = y. When add x + 2 times y, the last digit should equal last digit of DEA Number

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Verification of DEA Numbers

- × Sample DEA # for Dr James Brown:
- × AB 1234563
- × Add $1+3+5=9$
- × Add $2+4+6=12 \times 2 = 24$
- × Add $9+24=33$

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Verification of DEA Numbers

- x Sample DEA # for Dr James Brown:
- x AB 123456**3**
- x Add 1+3+5=9
- x Add 2+4+6=12x2= 24
- x Add 9+24=33
- x Terminal digits (**3**) are the same therefore this number is valid

Prescriptions continued

- x Schedule II Emergency Oral Rx's
- x Emergency - defined 21CFR290.10
 - Immediate administration necessary
 - No alternative treatment available
 - Not reasonably possible for prescriber to get written Rx to dispenser
- x Cover emergency period ONLY
- x Get signed Rx in **7days** (Was 72 hours)
- x Must notify DEA if do not get signed Rx in 7 days

Prescriptions continued

- x Long Term Care, Hospice or Terminally Ill Patients
- x Partial dispensing Schedule II OK up to limit on Rx and within 60 days
- x Must record partial dispensing on back of Rx or some other uniform record
 - Quantity disp, quantity left, dispensing RPh
 - Record if LTCF or Terminally Ill patient

Prescriptions continued

- x Schedule III, IV & V
- x Partial dispensing
 - May partially dispense up to amount authorized on Rx and within 6 months.
 - (e.g., Rx for 30 tabs + 3 refills = 120 tablets)
 - Could dispense 30, 10,10,10,30, 20,10 = 120)
 - Must record # at each dispensing otherwise DEA thinks you dispensed 30, 30, 30, 30, 30, 30 & 30 = 210

Prescriptions - Faxing

- × OK to FAX Schedule II to any Pharmacy BUT RPh must receive and review Original signed Rx before dispensing. EXCEPT:
- × OK to FAX Schedule II to Home IV pharmacy may use as original Rx ONLY IV, IM, etc. (NO ORAL DRUGS) Also OK for LTC (incl. AFH, BH)
- × Eliminates need for most “emergency Rx”
- × NOTE: Faxed Rx must be a signed Rx not a transcribed telephone order

Prescriptions - Faxing, Continued

- × Schedules III-IV
- × May FAX to any pharmacy and may use as the original IF signed by prescriber.
- × May FAX order to hospital for administration

Prescriptions Schedule II

- × What may a pharmacist change on a Schedule II?
- × Almost anything!!!
- × EXCEPT
 - The Drug
 - The patient name
 - The prescriber’s Signature

Prescriptions Schedule II

- × If Rx unsigned must send back to doctor
- × If Wrote John Smith but meant Jim Smith must return for new Rx
- × If order strength not in stock
 - OK to change and change directions & quantity.
 - Must document changes

Prescription labeling

- × Date of filling
- × Pharmacy name and address
- × Serial number
- × Patient name
- × Prescriber name
- × Directions for use
- × Transfer “caution” label

End of part 2

Prescription labeling continued

- × THINGS NOT NEEDED ON Rx LABELS
- × Pharmacy DEA number
- × Prescriber DEA number
- × Patient address
- × Prescriber address

Prescriptions Computer Records

- × Must use EITHER manual or computer may NOT use mixed system
- × Computerized system MUST provide:
- × All information about the Rx
- × On-line retrieval of refill history of Rx including dates/quantities of refills, ID of RPh filling/refilling

Prescriptions Computer Records

- × Must document that RPh verified accuracy of data entered into computer system
- × If daily hard copy printout is provided, it must be verified, dated, & signed by RPh(s)
- × If no daily printout **MUST** use bound book or separate file- Must be verified as correct by RPh(s)

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Prescriptions Computer Records

- × Must be able to provide printout of any refill data.
- × Detailed Audit Trail - Any drug, generic and brand, strength, dosage form, quantity dispensed, RPh, Patient, Practitioner
- × Backup system required for computer failure. Enter data when system is up.

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Prescriptions - Institutional Label

- × Usual label information **NOT** required in hospitals, nursing homes, etc IF
- × 1. Not more than 7 days supply of II's
- × 2. Not more than 34 day supply or 100 doses of Sched. III or IV is supplied
- × 3. Drugs not in possession of patient
- × 4. Institution provides control/records
- × 5. System ID's Phcy, Patient, Drug
- × 6. May return in hospitals **NOT** from NH's

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Prescription Transfer (1306.25)

- × No transfer of Schedule II
- × III-V Transfer once only **UNLESS** common database (3/97)
- × (Non-CS OK to transfer more than once)
- × Communicate information between 2 RPh's
 - Intern OK
 - (See BOP FAX transfer guidelines)

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Prescription Transfer of Information

- × **Transferor** Pharmacist
- × Write “VOID” on Rx
- × Write name, address, DEA # of receiving pharmacy on reverse of Rx
- × Record name of receiving RPh
- × Record name of transferor RPh
- × Date of Transfer

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Prescription Transfer of Information Continued

- × **Receiving** Pharmacist
- × Write “Transfer” on Rx
- × Record Patient, MD, drug, etc (1306.05) like information on verbal Rx from MD
- × Record orig. date prescribed, date dispensed No. of refills, remaining refills, **date & location(s) of ALL refills (3/97).**
- × Information on Transferor RPh

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Prescriptions Transfer of Info.

- × IF have common electronic database
- × **May transfer more than once (3/97)**
- × Must satisfy all information requirements of manual system
- × Must be able to audit
 - Where were refills done?
 - Can’t exceed refill or time limits

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Schedule V OTC Sales – DEA 1306.26

- × Quantity limits
 - Opium products 240 ml or 48 dosage units
 - Other CS 120 ml or 24 dosage units
- × Only RPh or Intern may dispense (clerk may complete the sale, take \$ etc.)
- × One sale per 48 hours, Age 18 or over
- × Record details in Bound book.

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Schedule V OTC Sales - WA

- × Sell only for labeled “medical” purpose
- × 120 ml for cough, 240 ml for Antidiarrheal
- × NO solid dosage forms
- × C-V’s Not accessible to public
- × Show purchaser copy of rule re: Purchases
- × Purchaser (Age 21or>) must sign C-V book
- × 1 sale/96 hrs then 60 days

Schedule V OTC Sales WA cont.

- × Name & address of pharmacy on bottle
- × Initials of RPh or Intern, date of sale on label at time of sale
- × Bound book 8 1/2” x 11”, consecutively numbered pages.
- × Send NCR copy to board
 - End of page OR End of month if ANY sales during that month

Schedule V OTC Sales - The Washington Experience

- × 1982
- × 14,000 x 120 ml bottles/month
- × 7,000 from 25 of 1000 pharmacies
- × The 25 ranged from 100 up to 1000 per month from one pharmacy
- × One sold only on Wednesdays
- × 1995 - 2000/month for 1200 pharmacies

Miscellaneous 1307

- × May sell CS to practitioner
- × May NOT exceed 5% of total dosage UNITS
- × (If>5% must be wholesaler)
- × May return CS to supplier

Misc. 1307

- × Discontinuance or Transfer of Business
- × Registration and Unused 222's to DEA in Washington DC
- × CS's transferred to new owner OR disposed (see 1307.21)
- × Transfer - Notify DEA 14 days in advance provide details, including date of transfer
- × Inventory - both retain copies- Keep record

Misc. 1307 Disposal of CS

- × Transfer to another registrant
- × Return outdates to supplier
- × Use Reverse Distribution Companies
- × Advise DEA of plans to destroy so that they can send an observer. Specific date/time. Blanket approval available from DEA.
- × NOTE: Dept of Ecology concerns Re: disposal
- × OK to destroy (waste) small quantities during administration.

Misc. 1307

- × Peyote Exemption
- × OK for use by Native American Church for bona fide religious activities

Narcotic Treatment Issues

- × Only registered NTP may use narcotics to detox or maintain narcotic addicts
- × Only use Methadone or LAMM
- × Must administer onsite or "take home"
- × May NOT prescribe for addiction
- × Methadone may be prescribed for PAIN
- × OK to continue Methadone for NT in Hospital NOT in nursing home

Narcotic Treatment

- × 2003 Changes
- × Physician office treatment
 - » Buprenorphine SL (Suboxone)
 - » Buprenorphine SL with Naloxone (Subutex)
 - » 30 patient limit per practice
 - » MD must be Qualified & Notify DHHS/DEA
 - » May prescribe or dispense – Pharmacy may fill Rx
- Branch office of NTP
- Mobile NTP Van

Misc. Issues

- × Some CS are exempt from control
- × Fiorocet (Fiorinal is controlled)
- × Phenobarbital combos (TEP,etc)
- × Laboratory Reagents
- × Steroid-Estrogen combos
- × Steroids for Vet implants

DEA CS Schedules 1308.01 - .15

- × See also RCW 69.50.203-212
- × See also WAC 246-887
 - Should be the most current

Domestic Chemical Diversion and Control Act

- × Controls distribution of essential chemicals and precursors used to make illicit drugs. Also tableting or encapsulating machines
- × If deal in Ephedrine must report BUT pharmacy records will suffice if have info. (See 1310.06(d))
- × Also see State law and rules

Washington State Precursor Law

- × See 69.43 RCW/WAC 246-889-050(revised 2003)
- × Pseudoephedrine, ephedrine, PPA
- × 3 Gm limit per package
- × 3 package limit per sale
- × Persons may possess up to 15 grams (household)
- × No Limit on prescriptions
- × No limit on pediatric drugs < 15 mg/dose
- × Signs posted or other controls implemented

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Washington State Precursor Law cont.

- × Pseudoephedrine, ephedrine, PPA 2003
- × Suspicious Transactions Reports
 - 4,800 Shopkeepers
 - 383 mini-marts received 3.6 million doses in 2 months from 10 wholesalers
 - 137 mini-marts each received over 10,000 doses

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CSA Administrative

- × DEA Inspections
- × State purpose of inspection
- × Show credentials
- × Provide written notice of inspection
- × Receive informed consent
- × OR use Administrative Inspection Warrant

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CSA Administrative

- × Administrative Inspection Warrant
- × Name & Address of premises
- × Statutory authority
- × Nature of inspection
- × Establishment
 - not previously inspected or
 - last inspected on (date)

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CSA Administrative

- × Administrative Inspection Warrants
- × Regular business hours
- × Reasonable manner (don't Toss the place)
- × Refusal = Arrest & Inspection continues
- × Frequency
 - Manufacturer or Distributor - Annually
 - Pharmacy /Practitioner every 3 years

DEA Rules -Summary

- × We discussed the manner in which the DEA regulates the distribution of C.S.
- × We described the registration process, security, record keeping requirements, use of order forms, regulation of prescribing & dispensing and DEA inspection authority

Additional Resources

- × DEA website
- × www.deadiversion.usdoj.gov
- × Board of Pharmacy website
- × <https://fortress.wa.gov/doh/hpqa1/HPS4/Pharmacy/default.htm>