

D. E. A. Part 1

21 C.F.R. 1300

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1

DEA Law and Rules

Subjects to be covered:

- Scheduling
- Registration
- Security
- Records
- Ordering

2

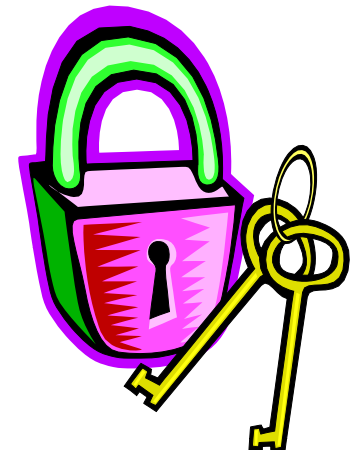
Classification of Drugs

- Dietary Supplements (NOT Drugs)
- Over the Counter (OTC)
- Prescription (“Legend Drugs”)
- Controlled Substances
- This lecture will focus on Controlled Substances

3

DEA Law & Rules

- Closed Drug Distribution System
- Everyone is registered
- Everybody keeps records
- Records available for review by DEA & State Law enforcement agencies including Board of Pharmacy



4

Controlled Substances

- Five schedules
 - Schedule I No medical use, very high abuse potential
 - Heroin, Marijuana, LSD
 - Schedule II Medical use, high abuse potential
 - Morphine, Codeine, OxyContin, Percodan, Percocet, Ritalin, Hydrocodone (single ingred.) Methamphetamine (Desoxyn) Pentobarbital, Dextropropoxyphene (single ingredient)
 - Schedule III Less abuse potential
 - Codeine combinations, Hydrocodone combinations, Marinol, Anabolic steroids, Pentobarbital suppositories

5

Controlled substances

- Five schedules continued
- Schedule IV Less abuse potential
 - Librium, Valium, other benzodiazepines
 - Dextropropoxyphene combination (Darvon , Talwin)
- Schedule V Some abuse potential
 - Some are Rx Only & Some are OTC
 - Codeine cough syrups, Tylenol elixir with codeine, antidiarrheals

6

Controlled Substances

- Schedule I Not prescribed -
 - (May prescribe 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 Same as III
- Schedule V Verbal Rx OK refill per MD up to 12 months; Some are OTC

7

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
- Know the limits for common drugs.

8

Time Limits on Prescriptions

- Legend Drugs: 12 months from date of issue
- Schedule II: 12 months BUT must use PharmD judgment - (Fentanyl patch example)
- Schedule III: 5 refills or 6 months - whichever comes first and only if authorized by prescriber.
- Schedule IV: Same as Schedule III
- Schedule V: 12 months & number of refills that are authorized by prescriber.
- Note: If refills are used up may request additional up to above limits. If time runs out, need NEW Rx

9



Registration - 1301.

- Must register for ALL activities related to Controlled Substances (e.g., Manufacturing., Distribution., Dispensing, Prescribing, Research, etc.)
- Some entities are Exempt from fee BUT must comply with law (e.g., State or U.S. Govt. Agencies)
- Separate registration for EACH location.

11

Registration 1301 Cont..

- Exemptions from Registration:
- Pharmacists & Rx Techs.
- Agents/Employees (e.g., hospital residents)
 - 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 duties- need own registration # (e.g., volunteer work, treating neighbors, etc)

12

Registration 1301 Continued

- Uniformed Service 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

13

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

14

Security Standards 1301.71-.93

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

15

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 (MD,DO,PA,RN,RPh)
 - Clients must be separate from drugs
 - Only MD, ARNP, PA, RPh may dispense for take home

16

Practitioners Security

- Securely locked
Substantially
constructed cabinet



17

Pharmacy Security

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



18

Pharmacy Security, cont.

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



19

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, takes 6+ months, employer applies for the
waiver NOT the prospective employee.

20

Security 1301 Continued

- Summary of DEA Waiver Issue:
- If you ever get convicted of a Controlled Substances Felony, forget about ever working in a pharmacy again!

21

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!

22



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.

24

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.
 - Schedule II records separate from other CS

25

Records 1304 Continued

- Pharmacies must maintain ALL records of receipt and disposition. (Invoices, 222's, Rx's, Returns, Loss Reports, Sales Invoices)
- Prescribers 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 these records to be kept.

26

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
- Records at central locations must be made available to DEA in 2 days.

27

Records 1304 Continued

- Must keep records for 2 years-7 for Medicaid
- Although must keep files to account for refills of Rx's issued before the 2 years.
- (e.g., on 12/31/08 you decide that you want to discard records back beyond 12/31/06 remember some Rx's filled from July 1st to 12/31/06 may have been refilled during the early months of 2007 therefore must keep those records until no activity on any Rx extends into the above 2 year period.)

28

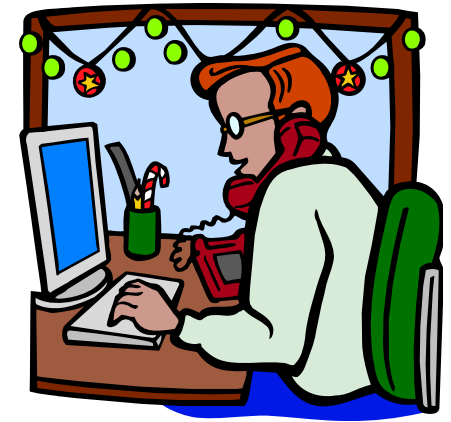
DEA Rule Change 3/97

- NOTE: Formerly, certain CS prescriptions had to be identified with a one 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.
- Some pharmacies still use these stamps BUT do not have to.
- ALL WA pharmacies now have computers

29

The last holdout pharmacy without a computer

- Got reported by insurance company
- Could not account for all refills on DEA audit
- Refilled MANY CS Rx's over 5 times in 6 months!
- Paid \$ 40,000 fine
- Bought Rx Computer



30

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.

31

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 Standard.”
- Law requires complete and accurate records
- Lesson: Be careful, thorough and accurate!

32

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 CSA violation.

33

Inventories 1304.11-19

- New Pharmacies take on Opening day (even if zero)
Previously there were very specific date requirements, now biennial inventories must be just be taken within two years of previous inventory.
- NOTE: Some States require annual inventories.

34

Inventories 1304.11-19

- Perpetual Inventories:
 - Some pharmacies maintain a perpetual inventory of all CS - usually hospitals & some nursing home pharmacies
 - Some have perpetual inventory for II's only.
 - Some chain pharmacies are starting to require this.
- These do NOT meet the requirement for a biennial inventory UNLESS...

35

Biennial Inventory Requirements

- Must be written, typewritten, or printed form
- Must include ALL CS under control of registrant
 - Hospital - Phey, clinic & nursing unit stock
 - LTC Pharmacy - Phey & NH emergency kits
- Must show date & time of inventory (beginning of business or end of business) & DEA #

36

DEA Inventories, cont.

- Drug strength, quantity, & form (tab, cap, etc.) & # of commercial pkg (e.g., 100 tablet bottle plus 10 loose tabs = 1.1 commercial packages)
- Must be signed by person taking inv.
- Must be identified as, “Biennial Inventory”

37

Inventories, Continued

- Newly controlled substances-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

38

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.)

39

This is page 1 of your Biennial Inventory.

Acme Pharmacy, 222 1st AVE, Seattle WA 98101
Biennial Inventory Oct 1, 2007 Beginning of Business
Completed by Mary Johnson, PharmD

Is the page complete?

If not, what is missing?

40

This is page 2 of your DEA inventory

Morphine Sulfate 30 mg Tablets 100's,	157 tabs
Vicodin 5mg/325mg tablets, 500's,	750 tabs
Hydrocodone/APAP 10mg/500mg, tab 500's	250 tabs
Diazepam 5 mg tablets,500's,	400 tabs
Tylenol w/Codeine elixir, 20mg/5ml	473 ml

Acme pharmacy is a very small pharmacy, this is all of the CS that you have on hand.

Are there any problems with this inventory?
If so, what are they?

41



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 forms.
- Person with Power of Attorney may sign.
- Keep Powers of Attorney with Schedule II records

43

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

44

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

45

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

46

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.

47

Electronic Order Forms, CFR1311 & 1321 et seq

- DEA has developed rules to allow electronic ordering of Schedule II drugs. (CSOS)
- 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.

48

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 10 mg			
5	--1--	100	Demerol-50-mg-Tablets	cancelld		
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 DEACOPY 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
James Jones

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

Board of Pharmacy 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

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 did not know that it was providing the drugs.
- Pharmacist had license suspended for 6 months

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.

53

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

54

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.

55

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.

56

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
- 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 licensed & registered as wholesaler)
- May return CS to supplier

57

Questions

- You have just been appointed to be the Responsible Manager of a pharmacy. The previous manager was promoted and has transferred to another pharmacy. It is your responsibility to order all controlled substances, including Schedule II's
- What do you do first in order to perform your ordering duties?

58

End of Part 1 Controlled Substances

59