

Controlled Substances Laws & Rules

Part 2

Readings for this Section

- 21CFR1300
- 1301
- 1302
- 1304
- 1305
- 1306
- 1307

Objectives

- Subjects to be covered:
 - Prescriptions
 - Dispensing
 - Labeling
 - Records
 - Schedule V OTC Sales
 - Misc. Issues
 - Administrative

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 Treatment 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 caller's name for the record.
 - Written Rx NOT valid if nurse signs doc's name & RN's 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.

Recent Washington Case

- WA RPh contacted by Internet Site
- How many Rx's can you fill for us?
- \$\$\$\$
- Rx's arrive from all around the USA
- Purchases of hydrocodone products rapidly escalate.
- Wholesaler fails to notify DEA of suspicious orders

Recent Washington Case, cont.

- DEA reviews all CS purchases & notes trends
- What happened to the pharmacy
- What happened to the pharmacist
- What happened to the wholesaler
- What happened to...

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

Questions

- What is an indelible pencil?

Prescriptions continued

- Prescribers may NOT write post-dated Rx
- How do you handle if 30 day limit Rx by insurance company but doctor visits are only needed every 90 days?

Schedule II limitations

- With DEA and State approval practitioners WERE doing this:
 - Date 3 prescriptions with today's date
 - Write "Do not fill before _____"
 - Each Rx may then be filled at 30 day intervals.
- HOWEVER DEA suddenly objected to this procedure. An MD tried to use DEA's statement on their website as a defense of his practice.

Schedule II limitations

- For 2+ years DEA said the following:
- For a physician to prepare multiple prescriptions for a schedule II controlled substance on the same day with instructions to fill on different dates is tantamount to writing a prescription authorizing refills of a schedule II controlled substance. To do so conflicts with the provisions of the CS Act which provides: "No prescription for a controlled substance in schedule II may be refilled."

Schedule II limitations

- DEA's suggestions:
 - **1. Could see patient more frequently**
 - **2. Could mail Rx to patient or pharmacy**
 - **3. Could Fax Rx to pharmacy to facilitate filling BUT pharmacy must have original Rx in hand before dispensing the Rx to the patient.**

Schedule II limitations

- In 2006 the DEA published a Notice of Proposed Rule
- Finalized on Nov 7, 2007
 - May issue multiple Schedule II Rx's on same day
 - Not to exceed 90 days supply
 - Indicate earliest date subsequent Rx may be filled
- RPh may not fill before the above date
- <http://www.dea diversion.usdoj.gov/>

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

Prescriptions - DEA Numbers

- Consist of 2 letters and seven numbers
- First letter A, B, F, 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

Questions

- Which of the following DEA numbers be valid for:
- Thomas K. Hazlet, PharmD
- AH 2468754
- MH 2468759

Prescriptions continued

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

Prescriptions continued

- Schedule II Prescriptions
- May NOT be refilled

Prescriptions continued

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

Prescriptions continued

- Schedule III, IV & V Prescriptions
- 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 quantity at each dispensing otherwise DEA assumes 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.
- Electronic Signatures are NOT acceptable to DEA at this time.
- You must confirm each electronic CS Rx
- 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 patient name "John Smith" but meant "Jim Smith" must obtain new Rx
- If strength ordered is not in stock
 - OK to change and change directions & quantity (Notify prescriber)
 - Must document changes



Prescription labeling

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

Prescription labeling

- Transfer caution label
 - Caution (State) or federal law prohibits the transfer of this drug to any person other than the one for whom it was prescribed.

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)

Prescriptions Computer Records

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

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 CS drug to pharmacy in hospitals but NOT from NH's

Prescription Transfer (1306.25)

- Transferring a prescription to another pharmacy for filling.
- 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)

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

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

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

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.

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

Misc. 1307

- Discontinuance or Transfer of Business
- Send 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 parties 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 Must administer onsite or limited “take home” supply
- May NOT prescribe for addiction
- Methadone may be prescribed for PAIN
- OK to continue Methadone for NT in Hospital NOT in nursing home
- Mobile NTP Van operated by Evergreen Tx
- HMC Branch office of a NTP

Narcotic Treatment CHANGE!!!

- 2003, 2005, 2006 Changes
- Physician office treatment
 - Buprenorphine SL (Subutex)
 - Buprenorphine SL with Naloxone (Suboxone)
 - 30 patient limit per practice(originally)
 - Now 30 per doctor & up to 100 patients after doctor has one year of experience
 - MD must be Qualified & Notify DHHS/DEA
 - MD may prescribe or dispense – Pharmacy may fill Rx

Misc. Issues, Exemptions

- Some CS are exempt from control
- Butalbital & Aspirin (Fiorinal IS a CS)
- Butalbital & APAP (Fioricet is NOT a CS)
- DEA calculated the ratio of CS to total contents and determined that one should be controlled and the other not.
- Go figure
- Actually MORE Fioricet shows up in DAWN!
- Both forms are controlled if Codeine is added

Misc. Issues, Exemptions, cont.

- Phenobarbital combos (TEP, etc)
- Laboratory Reagents
- Steroid-Estrogen combos
- Steroids for Vet implants
 - Unless they are injected into humans



DEA CS Schedules 1308.01 - .15

- DEA 21CFR 1308.01(15)
- See also RCW 69.50.203 to 212
 - RCW has not been updated since Legislature gave the Board authority to schedule.
- See also WAC 246-887
 - Board website should be the most current list.

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, etc. must report BUT pharmacy records will suffice if have info. (See 1310.06(d))
- Also see State law and rules - discuss later

CSA Administrative

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

CSA Administrative

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

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/HP_S4/Pharmacy/default.htm
- Also: www.doh.wa.gov
- Click on licensing and then P for pharmacy etc.