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 name for the record.
  - Written Rx NOT valid if nurse signs doc’s name & her initials.

Cases

  - 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 continued

- Can NOT write post-dated Rx
- How do you handle if 30 day limit Rx by insurance company but 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.

Recently the DEA published a Notice of Proposed Rule Making that would again authorize the practice of writing multiple Rx’s on the same day.

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, 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

Verification of DEA Numbers

- Sample DEA # for Dr James Brown:
  - AB 1234563
  - Add 1 + 3 + 5 = 9
  - Add 2 + 4 + 6 = 12 x 2 = 24
  - Add 9 + 24 = 33
  - Terminal digits (3) are the same therefore this number is valid

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 7 days (Was 72 hours)
- Must notify DEA if do not get signed Rx in 7 days

Prescriptions continued

- Long Term Care, Hospice or Terminally Ill Patients
- 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
• 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 = 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 patient name “John Smith” but meant “Jim Smith” must return for new Rx
- If strength ordered is 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

Prescription labeling continued

- 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.

- 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 21 or >) 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 bot. from 25 of 1000 pharmacies
- Sales from the 25 ranged from 100 up to 1000 per month from one pharmacy
- One sold only on Wednesdays
- 1995 - 2000/month for 1200 pharmacies
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

- 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

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.