

# Controlled Substances Rules

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## Part 2

# Prescriptions 1306

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- **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

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- 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.

# Prescriptions continued

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- **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

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- CASES, cont.
- Vermont & 110<sup>th</sup> 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

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- 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

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- 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

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- 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

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- 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

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- 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

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- 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.
- Check it out on the DEA website.

## Prescriptions continued

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- 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

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- 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

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

## Prescriptions continued

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

## Prescriptions continued

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- 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

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- 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 & 30 = 210

## Prescriptions - Faxing

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- 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

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- 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

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

## Prescriptions Schedule II

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- 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

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

## Prescription labeling

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- 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

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

## Prescriptions Computer Records

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- 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

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- 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

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- 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

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- 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)

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- 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

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- **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

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- **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.

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- 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

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- 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**

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- 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.

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- 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

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- 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

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- 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

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- 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

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

## Narcotic Treatment Issues

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- 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

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- 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

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- 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.

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- 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

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- 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

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- 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

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

## CSA Administrative

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

## CSA Administrative

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- 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

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- 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

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- DEA website:
  - [www.deadiversion.usdoj.gov](http://www.deadiversion.usdoj.gov)
- Board of Pharmacy website:
- [https://fortress.wa.gov/doh/hpqa1/HP\\_S4/Pharmacy/default.htm](https://fortress.wa.gov/doh/hpqa1/HP_S4/Pharmacy/default.htm)
- Also: [www.doh.wa.gov](http://www.doh.wa.gov)
- Click on licensing and then P for pharmacy etc.