Federal Regulations For Prescribing Scheduled Controlled Substances

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Central Principle of "Balance" With the Use of Controlled Substances

- Dual imperative of government
  - Establish a system of controls to prevent
    - Abuse
    - Trafficking
    - Diversion

A Guide to Evaluation
Achieving Balance in Federal & State Pain Policy
Pain and Policy Studies Group
University of Wisconsin Comprehensive Cancer Center
July 2000

Central Principle of "Balance" With the Use of Controlled Substances

- Must ensure availability of controlled substances (CSs) for medical and scientific purposes
  - Should be accessible to all patients who need them, including for the relief of pain

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Achieving Balance in Federal & State Pain Policy
Pain and Policy Studies Group
University of Wisconsin Comprehensive Cancer Center
July 2000

The Tenets of Lawful Prescribing of CSs

21 CFR 1306.04

- A lawful prescription for a CS
  - Each separate prescription is issued for a legitimate medical purpose
  - By an individual practitioner acting in the usual course of professional practice

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Scheduling of Controlled Substances

- Schedule I - Cannot be prescribed
- Schedule II - High potential for abuse
- Schedule III - Less abuse potential than Schedule II
- Schedule IV - Low abuse potential relative to Schedule III
- Schedule V - Low abuse potential relative to Schedule IV

US Department of Justice, Drug Enforcement Administration. The Controlled Substances Act. In: *Drugs of Abuse*; 2005. Available at: http://www.usdoj.gov/dea/pubs/abuse/1-csa.htm#Formal. Accessed October 1, 2009.

Federal vs. State Regulations

- Healthcare professionals must comply with both federal and state laws and regulations that govern prescribing scheduled CSs.

  Model Policy for the Use of Controlled Substances for the Treatment of Pain.
  Policy Statement: Federation of State Medical Boards of the United States, Inc; 2004

- When federal laws or regulations differ from state laws or regulations, the *more* stringent rule applies.

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Federal Regulations

- Length of time a Schedule II CS prescription is valid
  - Federal Regulations
    - No limit
  - State specific
    - Virginia
      - » Six-month limitation
- What is the length of time a Schedule II CS prescription is valid in *your* state?

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Federal Regulations [cont'd]

- Amount or duration of a Schedule II CS that can be prescribed at one time
  - Federal Regulations
    - No limit
  - State specific
    - Virginia
      - No limit
  - What is the amount or duration of a Schedule II CS that can be prescribed at one time in *your* state?

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- A practitioner may prescribe methadone or any other narcotic to a narcotic addict for analgesic purposes.

Drug Enforcement Administration
Pharmacist's Manual
April, 2004, p. 54

- The Controlled Substances Act and Drug Enforcement Administration regulations contain no specific limits on the number of days worth of a Schedule II controlled substance that a physician may authorize per prescription.

Drug Enforcement Administration
Federal Register
August 26, 2005, p. 50409

Federal Regulations [cont'd]

Requirements of CS prescription

21 CFR 1306.11

- Prescriptions for Schedule II CSs must be *written*, with some exceptions

21 CFR 1306.21

- Prescriptions for Schedule II-V CSs may be written, faxed, or orally transmitted

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Federal Regulations [cont'd]

21 CFR 1306.05

- Prescriptions for CSs must be dated as of, and signed on, the day when issued
  - Must ***never*** post date a prescription
- Must include full name and address of patient, drug name, dosage form, strength, quantity, and directions for use
- Must include the name, address, registration number of practitioner
- Must be written with ink, indelible pencil, or typewriter and manually signed by the practitioner

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Federal Regulations [cont'd]

Refills of a prescription

21 CFR 1306.12

- Prescriptions for Schedule II CSs can not be refilled

21 CFR 1306.22

- Prescriptions for Schedule III-IV CSs can not be dispensed after 6 months from date of issue, or refilled more than 5 times
- Rules for refilling Schedule V CSs are not established by federal law, and the authorized number of refills depends on the professional judgment of the prescriber and the pharmacist

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Federal Regulations [cont'd]

Partial filling of a Schedule II prescription

21 CFR 1306.13

- A pharmacist can partially fill a prescription for a Schedule II CS if:
  - Unable to supply the full quantity of a written or emergency oral prescription
  - Notates the quantity supplied on the prescription face
  - Fills remaining portion of prescription *within 72 hours*
    - A new prescription is needed if the time goes beyond 72 hrs
  - Pharmacist must notify the prescribing practitioner if unable to supply remaining portion of the prescription

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Federal Regulations [cont'd]

Partial filling of a Schedule II prescription
21 CFR 1306.13

- A patient with a terminal illness or in a long term care facility (LTCF) may have a prescription filled in partial quantities
  - Pharmacist must record on the prescription whether the patient is terminally ill or a LTCF patient
  - The prescription is valid for a period *not to exceed 60 days* from the date of issuance unless sooner terminated by the discontinuation of the medicine

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Federal Regulations [cont'd]

Facsimile of a Schedule II prescription may
serve as the original written prescription in the following situations
21 CRF 1306.11

- Patient is a resident of LTCF
  - Prescription faxed to dispensing pharmacy
- Patient enrolled in a hospice program certified/paid for by Medicare under Title XVIII or licensed by the state
  - Prescription faxed to dispensing pharmacy
    - Note on script: i.e. Hospice patient
- For compounding for "direct administration" by parenteral, I.V., I.M., SQ, or intraspinal infusion

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Federal Regulations [cont'd]

21CFR 1306.04(b)

- A prescription may not be issued in order for an individual practitioner to obtain CSs for supplying the individual practitioner for the purpose of general dispensing to patients.
  - All prescriptions must be written for a specific patient

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Federal Regulations [cont'd]

21 CFR 1306.07

- May administer, prescribe or dispense a Schedule II CS to a person with intractable pain, in which no relief or cure is possible or none has been found after a reasonable effort

  - This language has served as the basis to define "intractable pain" in state law.

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Federal Regulations [cont'd]

21 CFR 1306.07

- To administer or dispense directly (*but not prescribe*) narcotic drugs to a *narcotic-dependent* person for "detoxification" or "maintenance treatment," a physician MUST have a separate registration with the DEA as an opioid treatment program (OTP).

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Federal Regulations [cont'd]

- May treat acute/chronic pain with a Schedule II CS in a recovering narcotic-addicted patient
  - Federal law or regulations do not prohibit the prescribing, dispensing or administering of a narcotic medication to a narcotic addicted patient for the purpose of alleviating pain if such prescribing is medically appropriate within standards set by the medical community
    - One must keep good records to document the physician is treating a pain syndrome and *not* the disease of narcotic addiction

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Federal Regulations [cont'd]

21 CFR 1306.07

- DEA does *not* impose any limitations on a physician or authorized hospital staff to administer or dispense (but not prescribe) narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction.

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Federal Regulations [cont'd]

21 CFR 1306.12(a)

- Refilling of Schedule II CSs is prohibited, requiring that a new prescription be issued for each quantity of the substance

21 CFR 1306.14(e)

- A pharmacist can not fill a prescription issued as one in a series of multiple prescriptions prior to the date written by the prescribing physician

DEA's Office of Diversion Control website, www.DEAdiversion.usdoj.gov/ under "Federal Register Notices>Rules 2007."

Federal Regulations [cont'd]

Interpretation of CFR 1306.12.

- Issuance of multiple prescriptions for Schedule II CSs
  - DEA's regulations allow practitioners to provide individual patients with multiple prescriptions for a specific Schedule II CS, written on the same date, to be filled sequentially.
  - The combined effect of such sequential multiple prescriptions is that it allows a patient to receive over time up to a 90-day supply of that CS.

DEA's Office of Diversion Control website, www.DEAdiversion.usdoj.gov/ under "Federal Register Notices>Rules 2007."

Federal Regulations [cont'd]

21 CFR 1306.12

- Sequential prescriptions up to a 90-day supply of a Schedule II CS are permitted
  - Example: Writing three prescriptions to be dispensed every 30 days by the pharmacist (all prescriptions have the same date of issuance)
    - Write one prescription for one-third of the total quantity of CS to be prescribed
    - Write a second prescription for one third of the total quantity of CS to be prescribed
      - Write DO NOT FILL UNTIL __/__/__ on the second prescription, with the date 30 days after the first prescription date of issue
    - Write a third prescription for one third of the total quantity of CS to be prescribed
      - Write DO NOT FILL UNTIL __/__/__ on the third prescription, with the date 60 days after the first prescription date of issue

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Federal Regulations [cont'd]

John Doe M.D.
83 Arlington Blvd. Suite 532 Date: 10/01/10
Fairfax, VA 22031 Reg. No.: _____

_____

Patient's name: _____
Address: _____
Drug: _____
Disp: #_____# (write out quantity)
Sig: _____

Signature of doctor: _____

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Federal Regulations [cont'd]

John Doe M.D.
83 Arlington Blvd. Suite 532
Fairfax, VA 22031

Date: 10/01/10

Reg. No.: _____

_____

Patient's name: _____

Address: _____

Drug: _____

Disp: #_____# (write out quantity)

Sig: _____

Do Not Fill Until: 10/31/10

Signature of doctor: _____

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Federal Regulations [cont'd]

- Drug Addiction Treatment Act of 2000
  - Office Based Opioid Treatment (OBOT)
    - Buprenorphine with or without naloxone
  - Prescribed by certified and specially trained physicians
    - Has received a waiver from the requirement to register as an NTP from the Center for Substance Abuse Treatment (CSAT) of the Substance Abuse and Mental Health Services Administration (SAMHSA)

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Federal Regulations [cont'd]

- The Office of National Drug Control Policy Reauthorization Act of 2006 (P.L. 109-469, ONDCPRA)
  - Modified restriction on the number of patients **(30)** a physician authorized under the Drug Addiction Treatment Act of 2000 (DATA 2000) can treat with buprenorphine with or without naloxone
- Under, ONDCPRA, physicians who meet the following criteria may notify the Secretary of Health and Human Services (HHS) of their need and intent to treat up to **100** patients at any one time

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Federal Regulations [cont'd]

- Criteria for the physician
  - Must currently be qualified under DATA 2000
  - At least one year must have elapsed since the physician submitted the initial notification for authorization
  - Must certify his/her capacity to refer patients for appropriate counseling and other ancillary services
  - Must certify that that the total number of patients at any one time will not exceed the applicable number

http://buprenorphine.samhsa.gov/faq.html

Can One Use Suboxone® or Subutex® for Analgesia?

- The off-label use of the sublingual formulations of buprenorphine (Suboxone®/Subutex®) for the treatment of pain is *not* prohibited under DEA requirements.
  - One does not need a wavier from CSAT but a valid license to prescribe a Schedule III CS

Heit HA, Covington E, Good PA
(Former Chief Liaison and Policy Section
Office of Diversion Control):
Dear DEA.
Pain Medicine, 2004, Vol .5, No. 3: 303-08

Federal Regulations [cont'd]

21 CFR 1306.07

Narcotic-dependent patient

- Can administer (not prescribe) a narcotic drug to relieve acute withdrawal symptoms while arranging for a referral to an opioid treatment program (OTP)

  In or out patient

  - One day's medication at a time
  - Can be done for 3 days
  - Can *not* be renewed or extended

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Federal Regulations [cont'd]

Emergency situation

21 CFR 1306.11

- A pharmacist may dispense a Schedule II CS after receiving an oral authorization if:
  - Quantity is limited to the emergency period only!
  - Prescription shall be reduced to writing with all the required information except the signature of the practitioner
  - The pharmacist makes a reasonable attempt to make sure the oral authorization came from a registered practitioner

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Federal Regulations [cont'd]

Emergency situation [cont'd]

21 CFR 1306.11

- A pharmacist *MUST* receive the written prescription within 7 days from an oral authorization
  - The prescription should include:
    - A Notation: "Authorization for Emergency Dispensing"
    - Date of oral authorization
- If the information is not received within 7 days, the pharmacist is required to report this missing information to the DEA.

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Federal Regulations [cont'd]

Emergency situation [cont'd]

21 CFR 290.10

- Immediate administration of the CS is necessary for proper treatment
- No appropriate alternatives are available, including drugs in lower schedules or non-controlled drugs
- Not reasonably possible for practitioner to provide a written prescription before dispensing

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Federal Regulations [cont'd]

Electronic Prescriptions for Controlled Substances

21 CFR 75(61).16236

- Effective June 1, 2010 the CFR was revised to:
  - Provide practitioners with the option of writing prescriptions for CSs electronically
    - Addition to, not a replacement of, existing rules
  - Permit pharmacies to receive, dispense, and archive these electronic prescriptions
  - Provide pharmacies, hospitals, and practitioners with the ability to use modern technology for CS prescriptions while maintaining the closed system of controls on CSs

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Federal Regulations [cont'd]

Electronic Prescriptions

21 CFR 1306.08

- A practitioner may sign and transmit e-prescriptions if all of the following requirements are met:
  - Must comply with all other requirements for issuing CS prescriptions
  - Must use an application that meets specific requirements (in Part 1311)
  - Must comply with requirements for electronic orders and prescriptions (in Part 1311)

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Federal Regulations [cont'd]

Electronic Prescriptions

21 CFR 1311.102

- Practitioner responsibilities
  - Rapid reporting of identified breaches
  - Same responsibilities when issuing e-prescriptions for CSs as when issuing a paper or oral prescription
    - Including issuing prescriptions only for a legitimate medical purpose and in the usual course of professional practice
  - The prescription must conform in all essential respects to the law and regulation

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Amendable Errors

- Changes a pharmacist can make to a prescription for a CS
  - May add or change patient's address upon verification
  - May change or add dosage form, drug strength, quantity, direction for use, or issue date
    - Only after consultation with and agreement of the prescribing practitioner
    - Such changes are noted on the prescription and medical records
    - In compliance with state/local laws, regulations, or policies

    http://www.deadiversion.usdoj.gov/faq/general.htm#x_change

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Non-Amendable Errors

- Changes a pharmacist can not make to a prescription for a CS
  - May never change the patient's name
  - May never change the CS prescribed - except for generic substitution permitted by state law
  - May never change the prescriber's signature

http://www.deadiversion.usdoj.gov/faq/general.htm#rx_change

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Differentiating Between a Legitimate and an Appropriate Prescription

- Legitimate
  - Doctor – patient relationship
  - Diagnosis for which the medication might be prescribed for reasonable therapeutic trial
  - Practitioner lawfully able to prescribe the agent within the usual and customary practice
- Appropriate
  - All of the above **plus**
    - Careful assessment of risk (i.e. substance use disorder etc)

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Federal Regulations

- For additional information about controlled substances diversion and its prevention
  - www.DEAdiversion.usdoj.gov./
- A complete copy of these slides are available on the following web sites
  - American Society of Addiction Medicine's (ASAM)
    - http://www.asam.org/pain-and-addiction
  - American Academy of Pain Medicine (AAPM)
    - http://www.painmed.org/clinical_info/index.html
  - University of Wisconsin Pain & Policy Studies Group
    - http://www.painpolicy.wisc.edu/

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Conclusion:

Healthcare practitioners can prescribe scheduled controlled substances approved by the FDA consistent with state and federal regulations to give their patients the best quality of life possible given the reality of their medical condition.

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