

*Regulations Pertaining to
Pain Treatment*

Objectives:

1. Explain to a colleague the classification system pertaining to *controlled medications*
2. Describe the prescribing guidelines as they relate to *controlled medications*
3. Describe the New Mexico Board of Medicine guidelines for the treatment of chronic pain with opiate analgesics
4. Interpret a Board of Pharmacy Prescription Monitoring Program (PMP) report

Objectives (cont.)

Need for Balance

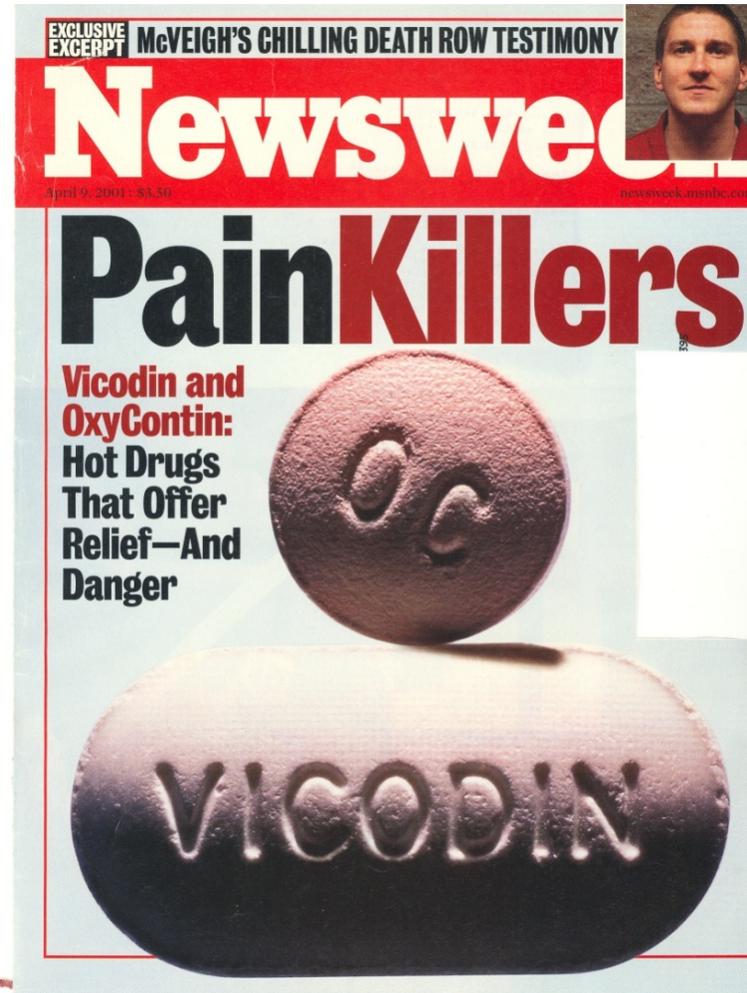
White House: Opioid abuse is an "epidemic and a "growing national crisis"

100 Million US adults have chronic pain and medications need to be accessible to them

Margaret Hamburg, FDA commissioner: "we have an important balancing act of trying to ensure that safe and effective drugs are available for patients who have real pain and need medical care."

Physicians are receiving “mixed messages” about the use of narcotic and sedative drugs

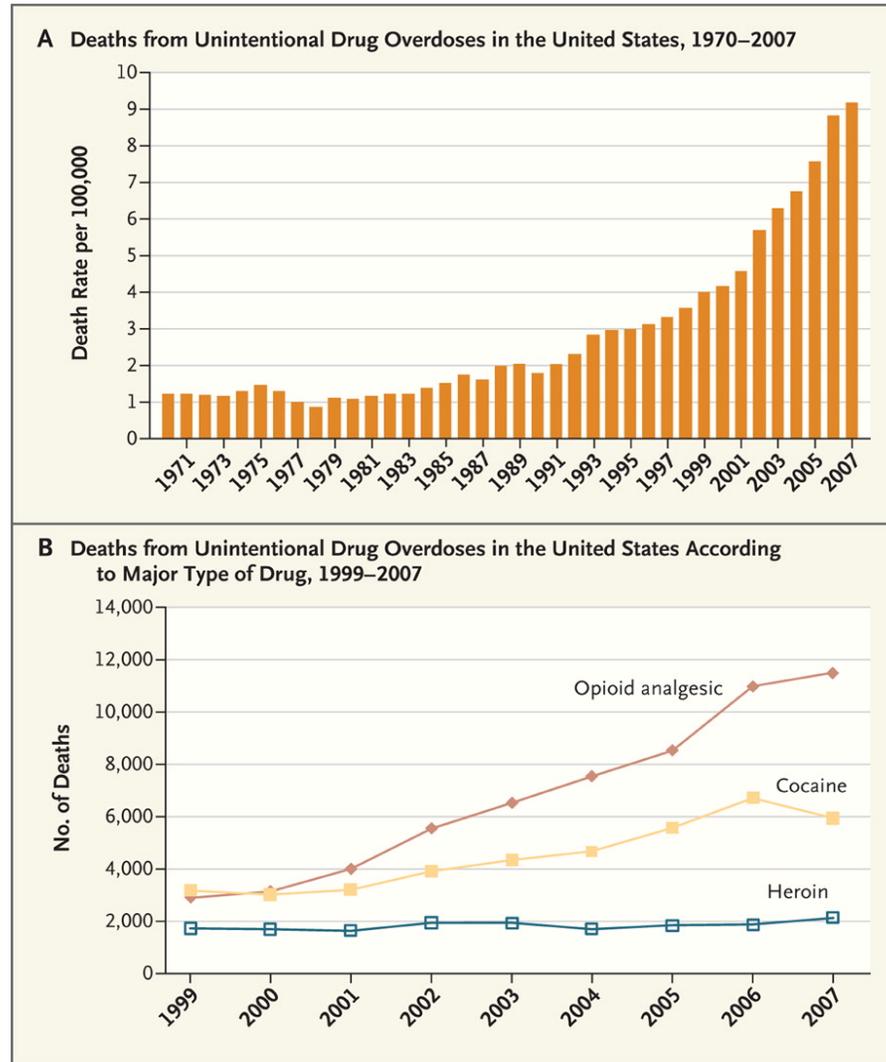
“Damned if you do...”



...and “damned” if you don’t

**We are using more opiates and sedatives
than ever before...**

U.S. Rates of Death from Unintentional Drug Overdoses and Numbers of Deaths, According to Major Type of Drug.



Okie S. N Engl J Med 2010;363:1981-1985.



Physicians have an obligation to understand...

- the indications for these medications
 - the potential problems ensuing from the use of these medications
 - **the regulatory guidelines that inform our prescribing of these medications**
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Case #1

- CG is a 44 y/o male with a history of chronic low back pain. You treat him with oxycodone 5mg tid. You have monitored him for aberrant behaviors, perform regular UDMs and have queried the PMP and all is in order. He requests that you phone his oxycodone in to his pharmacy. You attempt to do so but are told by the pharmacist that you can not phone in “C-2s.”

Questions to consider:

- What are *controlled substances*?
- What special prescribing requirements do they have?

Regulation of “Narcotic Drugs”

- US Opium Exclusion Act of 1909
- Harrison Narcotic Act of 1914
- Controlled Substance Act of 1970

The Controlled Substance Act of 1970

- Means of categorizing dangerous drugs according to medical utility and abuse liability
- Means of regulating manufactory, distribution and prescription of these drugs
- Creation of the Drug Enforcement Agency (DEA)

Controlled Substance Act

Schedule I: Heroin, LSD, (Marijuana)

- Can not be prescribed
- Very high abuse potential, no medical utility

Schedule II: Morphine, Cocaine, hydrocodone combination
meds

Very high abuse potential, medically useful

- Can be prescribed for one month
- No refills, no phone-in

Schedule II Considerations

- ▶ Until April 8, 2015, refills on existing scripts MAY be used
- ▶ In reality, many pharmacies will NOT honor these refills
- ▶ Best practice: identify these patients and make arrangements to minimize interruptions in care

Schedule II Considerations - Emergencies

- ▶ May call in a limited supply , and then provide a written and signed script within seven days [OK per IHS and Federal regs]

Schedule II Considerations

- ▶ Per Federal and IHS regulations, provider does NOT need to see patient monthly
- ▶ OK to give upto 90 day supply [three 30-day scripts, or six 15-day scripts or ninety -day scripts!]
- ▶ Each script must not exceed 30 days
- ▶ Conditions to be met:
 - Each separate script issued for legitimate medical reason
 - Appropriate date on each script
 - Document consideration of risk vs. benefit
 - **Verify state laws!!**

Controlled Substances Act

- ▶ **Schedule III: benzodiazepines**
 - ▶ Can be prescribed for one month
 - ▶ Can refill for 5 months, can phone-in (10-day supply only is new Rx)

- ▶ **Schedule IV: Valium, Ativan, Ambien**
 - ▶ Can be prescribed for one month
 - ▶ Can refill for 5 months, can phone-in (10-day supply only if new Rx)

Controlled Substances Act

- ▶ **Schedule V:** Pregabalin, guaifenesin with codeine
 - Used to be OTC in some states
 - Can be prescribed for one month
 - Can refill for 5 months, can phone-in

Latest News - a state of flux!

- ▶ 2014: 208 pain related laws signed around the US
- ▶ 45 states have issued best practices for management of patients with chronic pain
- ▶ 49 states have agreed to prescription monitoring programs; Missouri continues to resist!
- ▶ IHS pain management website online
- ▶ <http://www.ihs.gov/painmanagement/>
- ▶ As of October, ok for select pharmacies to take back unused medications

Latest News

- January 2013: FDA Drug Safety and Risk Management Advisory Committee recommended reclassifying hydrocodone combination products as Schedule II controlled substances [19-10 vote]
- February 2013: FDA issues draft guidance for abuse deterrent opioid development
- September 2013: FDA announces safety labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics

Case #2

Your office nurse reports that a very serious man is at the front desk to talk to you. When told that you were busy with patients, the man produced a badge and indicated that he was from Santa Fe. You receive him in your private office and he indicates that he is an investigator from the Board of Medicine. A pharmacist has filed a complaint with the Board alleging that you over prescribe Schedule II drugs. What would you like your records to reflect when this man reviews the charts of your chronic pain patients?

- Boards of Medicine across the country have developed guidelines which:
 1. Define safe prescribing practices
 2. Describe conditions that must be met by the prescribing physician in order to demonstrate the (s)he is using these drugs appropriately and safely.

New Mexico Board of Medicine Guidelines for treatment of Chronic Pain with Controlled Substances

Board of Medicine Rules

- A proper treatment plan must be implemented and is characterized by the following:

Rules...

Document a Detailed Patient Evaluation:

- Complete H & P including...
 - the history and nature of the pain
 - effect on functioning
 - past treatment regimens (and their effect)
 - history of and potential for substance abuse
 - coexisting diseases/co-morbidities
 - detailed psychological history especially relating to depression, suicide, etc.
 - indications for opioid therapy

Rules...

- Be familiar with the use of screening tools
- Use a variety of treatment modalities
- Use an integrative approach to pain

Rules...

- **Document an individualized Treatment Plan**
 - Describe goals and objectives for pain relief and how they will be measured
 - Include plans for additional testing, referral, consultation
 - Describe ancillary treatment modalities

Rules...

Discuss and document the risk and benefits of using controlled substances

- Common and serious side effects
 - Pregnancy
 - Risk of combination with alcohol/drugs
 - Driving
 - Dependence/Addiction
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Rules...

- **Maintain complete and accurate records of care provided and drugs prescribed**
- Indications
- Document the name, dosage, quantity, and refills
- Use a written Controlled substances Agreement
- As part of the written agreement, the patient shall receive prescriptions from one clinician and one pharmacy whenever possible

Controlled Substance Agreements

- “Formal” agreement between patient and physician regarding:
 - Terms of treatment
 - Risks/benefits/alternatives
 - Expectations (patient/physician)
 - Points of termination

Rules...

- **Patients must be monitored and a periodic review of treatment plan must occur at least every 6 months**
 - Are goals and objectives being met?
 - Is there a change in patient status (progress or lack thereof)?
 - Is the patient complying with treatment plan?

Rules...

□ **Obtain Consultation...**

- When additional assistance is needed for patient evaluation and treatment.
- When comorbid psychiatric or substance abuse diagnoses occur.

Rules...

- Patients must be monitored at least every 6 months

- Pain management for patients with substance abuse disorders shall include:
 - A contractual agreement
 - Appropriate consultation
 - Drug screening
 - Re-evaluation at least q 6 months

Rules...

- **Comply with all regulatory requirements**
 - New Mexico Board Guidelines
 - Controlled Substance Act

Rules...

- Clinicians are NOT obligated to fill opiate prescriptions if they feel that patient is using drugs in a medically inappropriate fashion

Prescription monitoring program

- All practitioners with a DEA will register with the PMP
- A PMP report **MUST** be generated on any new patient being prescribed opiates for more than 10 days and rechecked every 6 months

Board Guidelines

- ❑ Thorough Patient Evaluation
- ❑ Treatment Plan
- ❑ Informed Consent
- ❑ Periodic Review of Treatment Plan
- ❑ Consultation in Difficult Cases
- ❑ Maintain Accurate Medical Records
- ❑ Comply with ALL Regulatory Requirements

The Board will evaluate the quality of care based upon:

- ❑ Appropriate diagnosis and evaluation
- ❑ Appropriate indication for treatment
- ❑ Document change or persistence of condition requiring opiates
- ❑ Regular follow-up evaluation
- ❑ Validity of prescribing based upon quality of care NOT quantity of opiates prescribed
- ❑ Goal: effectively and safely control pain taking into consideration bio/psycho/social and work considerations

Summary

- We have talked about:
 - ❖ The Controlled Substance Act and the regulations pertaining to “scheduled” (controlled) drugs
 - ❖ The NM Board of Medicine Guidelines and Requirement with regard to the use of opioids in the treatment of patients with non-cancer pain