Federal Rules on Prescribing Controlled Substances*

SUMMARIZED BY
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*with references to NM Board of Pharmacy rules
Controlled Substances

- Per the Controlled Substances Act, the Drug Enforcement Administration (DEA) was created in 1973.
- The CSA set forth federal law around illicit and pharmaceutical controlled substances.
- The DEA is responsible for ensuring that all controlled substance transactions occur within a closed system from manufactures to patients.
- To prevent diversion and ensure availability for legitimate medical, scientific and research uses.

Reference:  
Schedules of Controlled Substances

- Drugs and other substances considered controlled substances under CSA are divided into five classes.
- Based on accepted medical use and likelihood of causing dependence and abuse.
- Each class may have different rules around the prescribing, administering or dispensing.
Definitions

- **Prescription**: an order for a medication to be dispensed to a patient by a second party, eg, pharmacist, but not in a hospital setting

- **Dispensing**: to deliver the drug itself to the ultimate user, eg, patient picks up the drug from a pharmacist

- **Administering**: The direct application of the drug to the patient via injection, inhalation, ingestion, etc.
Schedules of Controlled Substances

- **Schedule I Controlled Substances**
  - Substances in this schedule have a high potential for abuse, have no currently accepted medical use in treatment in the United States, and there is a lack of accepted safety for use of the drug or other substance under medical supervision.
  - Some examples of substances listed in schedule I are: heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), peyote, methaqualone, and 3,4-methylenedioxymethamphetamine (“ecstasy”).
Schedules of Controlled Substances

- **Schedule II Controlled Substances**
  - Substances in this schedule have a high potential for abuse which may lead to severe psychological or physical dependence.
  - Examples of single entity schedule II narcotics include morphine and opium. Other schedule II narcotic substances and their common name brand products include: hydromorphone (Dilaudid®), methadone (Dolophine®), meperidine (Demerol®), oxycodone (OxyContin®), and fentanyl (Sublimaze® or Duragesic®).
  - Examples of schedule II stimulants include: amphetamine (Dexedrine®, Adderall®), methamphetamine (Desoxyn®), and methylphenidate (Ritalin®). Other schedule II substances include: cocaine, amobarbital, glutethimide, and pentobarbital.
Schedules of Controlled Substances

- **Schedule III Controlled Substances**
  - Substances in this schedule have a potential for abuse less than substances in schedules I or II and abuse may lead to moderate or low physical dependence or high psychological dependence.
  - Examples of schedule III narcotics include combination products containing less than 15 milligrams of hydrocodone per dosage unit (Vicodin®) and products containing not more than 90 milligrams of codeine per dosage unit (Tylenol with codeine®). Also included are buprenorphine products (Suboxone® and Subutex®) used to treat opioid addiction.
  - Examples of schedule III non-narcotics include benzphetamine (Didrex®), phendimetrazine, ketamine, and anabolic steroids such as oxandrolone (Oxandrin®).
Schedules of Controlled Substances

- **Schedule IV Controlled Substances**
  - Substances in this schedule have a low potential for abuse relative to substances in schedule III.
  - An example of a schedule IV narcotic is propoxyphene (Darvon® and Darvocet-N 100®).
  - Other schedule IV substances include: alprazolam (Xanax®), clonazepam (Klonopin®), clorazepate (Tranxene®), diazepam (Valium®), lorazepam (Ativan®), midazolam (Versed®), temazepam (Restoril®), triazolam (Halcion®) and carisoprodol (Soma).
Schedules of Controlled Substances

**Schedule V Controlled Substances**
- Substances in this schedule have a low potential for abuse relative to substances listed in schedule IV and consist primarily of preparations containing limited quantities of certain narcotics. These are generally used for antitussive, antidiarrheal, and analgesic purposes.
- Examples include cough preparations containing not more than 200 milligrams of codeine per 100 milliliters or per 100 grams (Robitussin AC® and Phenergan with Codeine®).

**Individual states may make rules to add substances to the schedule**
- Tramadol (Ultram) is a schedule IV drug in NM
Federal Rules for Prescribing Controlled Substances

- All prescriptions:
- must be dated, signed, with patient’s name and address, practitioner’s name, address and DEA number
- Requires drug name, strength, dosage form, quantity, directions and number of refills
- Must be written in ink, manually signed by practitioner. A designee may prepare the prescription for practitioner’s signature.
- Note: electronic prescribing is being permitted if certain conditions are met.
Federal Rules for Prescribing Controlled Substances

- Purposes of Issue:
- Must be for a legitimate medical use in the normal course of professional practice
- Responsibility is shared by the prescriber and the pharmacist
- Knowingly providing and obtaining a prescription for non-legitimate use if illegal.
- It is not legal for a prescriber to write a prescription to obtain drugs to then dispense to patients
Schedule II – Must always be written and signed, but no expiration date nor quantity limit (states may have limits)

- Oral orders only in emergencies, written Rx must get to pharmacy within 7 days
- Refills are prohibited
- Multiple prescriptions are allowed up to 90 days, must include instructions on when to fill
- Faxed prescriptions are generally not allowed
Federal Rules for Prescribing Controlled Substances: Schedules III-V

- Prescriptions may be written, called in or faxed to pharmacist
- May be refilled up to 5 times, up to 6 months
- Then a new prescription is needed

- **Note:** NM Board of Pharmacy now restricts phone-in new opiate prescriptions (III-V) to a 10-day supply
- And no Schedule III-V prescription can be refilled until 75% of the drug has been used based on directions for use, unless approved by the prescriber
Federal Rules on Prescribing Opiates to Opiate-Addicted Patients

- One may only prescribe an opiate to an opiate-addicted patient for the purposes of treating the addiction (including detox or maintenance) in the context of a:
  - Narcotic Treatment Program – to dispense methadone, or,
  - By obtaining a special DEA waiver for the prescribing of buprenorphine for the treatment of opioid addiction

- Opiates can be prescribed for the treatment of pain in an opiate-addicted patient, but this should be carefully documented.
Section 1306.07 Administering or dispensing of narcotic drugs.

(a) A practitioner may administer or dispense directly (but not prescribe) a narcotic drug listed in any schedule to a narcotic dependant person for the purpose of maintenance or detoxification treatment if the practitioner meets both of the following conditions:

(1) The practitioner is separately registered with DEA as a narcotic treatment program.

(2) The practitioner is in compliance with DEA regulations regarding treatment qualifications, security, records, and unsupervised use of the drugs pursuant to the Act.

(b) Nothing in this section shall prohibit a physician who is not specifically registered to conduct a narcotic treatment program from administering (but not prescribing) narcotic drugs to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment. Not more than one day's medication may be administered to the person or for the person's use at one time. Such emergency treatment may be carried out for not more than three days and may not be renewed or extended.

(c) This section is not intended to impose any limitations on a physician or authorized hospital staff to administer or dispense 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, or to administer or dispense narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts.

(d) A practitioner may administer or dispense (including prescribe) any Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment to a narcotic dependent person if the practitioner complies with the requirements of §1301.28 of this chapter.

[39 FR 37986, Oct. 25, 1974, as amended at 70 FR 36344, June 23, 2005]
New Mexico Medical Board

REVISED RULES FOR
THE MANAGEMENT OF PAIN WITH
CONTROLLED SUBSTANCES

Summarized by Steve Jenkusky, MD
NMMB Member
In New Mexico:
- Opioid sales increased by 111.5% from 2001 to 2010
- Oxycodone sales increased by 233.3%
- Drug overdose rate increased by 61%
- 2008: NM number 1 in drug overdose deaths nationally (27.0 per 100,000 vs national average of 11.9/100,000)
- Prescription drug death rate now higher than from street drugs
- 55% of abuse prescription drugs come from friends and families
- Heroin use in Albuquerque high school kids twice the national average
Background: Chronic Pain in the US

- Challenge of treating chronic pain:
  - 20 to 50% of patients in primary care have chronic pain
  - Annual cost of treating chronic pain in the US estimated at $560-$635 billion, with estimated 100 million suffering from chronic pain
  - No good evidence that opioids effectively treat chronic, non-cancer pain
  - Lack of comprehensive pain management clinics
  - Poor access to psychiatric and substance abuse assessment and treatment in many communities
Background

- New Mexico Medical Board:
  - Original Guidelines “Prescribing for Pain” - 1996
  - Has had rules in place on the treatment of pain since 2003
  - Uses these rules to assess licensees for injudicious prescribing and has taken action on the most egregious prescribers
  - Regulates medical doctors and physician assistants
Senate Bill 215, passed in February 2012, amended the Pain Relief Act

- Practice must substantially comply with accepted guidelines including rules issued by the board
- All licensees with a DEA must do CME’s on non-cancer pain management.
- Created the “Prescription Drug Misuse and Overdose Prevention Advisory Council”
- Other boards (nurse practitioners, osteopaths, midwives, board of pharmacy) will also be promulgating rules
The New Mexico Department of Health and HM77 Prescription Drug Abuse and Overdose Task Force prepared and presented recommendations for the prescribing of opioids in 2011.

- Based on guidelines from the Utah Department of Health
- See: NM DOH website or http://www.health.state.nm.us/pdf/opioids/NM%20Clinical%20Guidelines%20Opioids%20final%2012011.pdf
Summary of Revised NMMB Rules

- 16.10.14.9
- Pain management guidelines now called rules.
  - A. Proper treatment of pain is a legitimate and appropriate part of the practice of medicine. This includes treating pain in patients with addictions.

Link to copy of NM Rules:
Summary of Revised NMMB Rules

○ B. When using controlled substances for pain:
  ▷ 1. Do a physical exam
  ▷ 2. Obtain history and include:
    ○ any previous history of significant pain,
    ○ past history of alternate treatments for pain,
    ○ potential for substance abuse,
    ○ coexisting disease or medical conditions,
    ○ and the presence of a medical indication or contra-indication against the use of controlled substances.

○ C. Be familiar with and use screening tools, use a variety of modalities to treat pain, and use an integrative approach to pain management
3. Document an individualized treatment plan with objectives, including how pain relief and improved function will be measured.

Include plans for additional testing, consultation, referral and other treatment modalities.

4. Discuss and document the risks and benefits of using controlled substances with the patient.
5. Complete and accurate records of care provided and drugs prescribed shall be maintained.

- Document the name of the drug, quantity, prescribed dosage and number of refills authorized shall be recorded.
- Prescriptions for opioids shall include indications for use.
- For chronic pain patients treated with opiates use a written agreement for treatment with the patient outlining patient responsibilities.
- As part of a written agreement, chronic pain patients shall receive all chronic pain management prescriptions from one practitioner and one pharmacy whenever possible.
Summary of Revised NMMB Rules

6. Patients must be monitored, with a documented update at least every 6 months. Consider the use of consultants expert in pain control when indicated by the patients condition.

7. If, in a practitioner’s medical opinion, a patient is seeking pain medication for reasons that are not medically justified, the practitioner is not required to prescribe controlled substances for the patient.

C. Pain management for patients with substance use disorders shall include:

(1) a contractual agreement;

(2) appropriate consultation;

(3) drug screening when other factors suggest an elevated risk of misuse or diversion; and

(4) a schedule for re-evaluation at appropriate time intervals at least every six (6) months.
Summary of Revised NMMB Rules

D. The board will evaluate the quality of care based on:
   - appropriate diagnosis and evaluation;
   - appropriate medical indication for the treatment prescribed;
   - documented change or persistence of the recognized medical indication;
   - follow-up evaluation with appropriate continuity of care.

   - the validity of prescribing will be based on the practitioner’s treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing.

E. The board will review both over-prescription and under-prescription of pain medications using the same standard of patient protection.

The goal is to control the patient’s pain for its duration while effectively addressing other aspects of the patient’s functioning, including physical, psychological, social, and work-related factors.
16.10.14.10  PRESCRIPTION MONITORING PROGRAM (PMP) REQUIREMENTS: The intent of the New Mexico medical board in requiring participation in the PMP is to assist practitioners in balancing the promotion of the safe use of controlled substances for the provision of medical care and services with the need to impede illegal and harmful activities involving these pharmaceuticals.

A. All licensees with a NM CS registration shall register with NM PMP.
   ○ (note- now also a board of pharmacy rule)

B. A PMP report must be pulled on any new patient being prescribed controlled substances for more than 10 days, and should be re-checked every 6 months.

Website for PMP: 
http://www.rld.state.nm.us/boards/Pharmacy_Prescription_Monitoring_Program.aspx
Pain Management Continuing Education

• Immediate 5 CME units course on;
  □ Review of these rules
  □ Pharmacology and risks of controlled substances
  □ Basic awareness of the problems of abuse, addiction and diversion
  □ Awareness of state and federal regulations for the prescription of controlled substances
  □ Completed by July 1, 2014

• Applicability of specific CME’s to this requirement is subject to board approval

• Subsequent requirement of 5 CME’s on pain management for each 3 year renewal cycle (as part of total of 75 CME’s needed for renewal)
Key Points

- NMMB supports the proper treatment of pain
- Patients must be properly assessed, informed, and treated, and this must be documented
- The PMP should be used, especially for chronic opioid prescribing
- Pain management CME’s are now required
- NMMB has regulations in place that will be used to assess if a practitioner is engaging in injudicious prescribing that will require intervention by the board