REVIEW OF CDC OPIOID GUIDELINES AND THE NM MEDICAL BOARD REGULATIONS FOR PAIN MANAGEMENT

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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
Opioid Overdose Deaths Continue To Climb, Federal Data Indicate.

The *Wall Street Journal* (1/6, Kamp, Subscription Publication) reported that new Federal data indicate opioid overdose fatalities rose 16 percent in 2015 from the previous year, totaling 33,091. Many local jurisdictions are still compiling data from last year, but many expect there was another increase in 2016.

The *New York Times* (1/6, Subscription Publication) reported that opioid overdose deaths “were nearly equal to the number of deaths from car crashes” in 2015, while “for the first time, deaths from heroin alone surpassed gun homicides.”
Drug overdose death rates, United States, 2014*

Drug overdose deaths per 100,000 population

- 6.3 - 11.7
- 11.9 - 14.4
- 15.1 - 18.4
- 19 - 35.5

*Age-adjusted death rate per 100,000 population

Source: CDC National Vital Statistics System
Chart 1: Drug Related Death Rates* by Cause Category, New Mexico, 2001-2015

* Rate per 100,000, age-adjusted to the 2000 US standard population
Sources: NMDOH BVRHS death files and UNM-GPS population files
In 2015, the percentage of drug overdose deaths involving heroin was triple the percentage from 2010, going from 8% to 25%.

For drug overdose deaths involving natural and semisynthetic opioid analgesics, which includes oxycodone and hydrocodone, the percentage decreased from 29% in 2010 to 24% in 2015.

The percentage of overdose deaths from methadone decreased from 12% in 2010 to 6% in 2015.

For drug overdose deaths involving synthetic opioids other than methadone, such as fentanyl and tramadol, the percentage increased from 8% in 2010 to 18% in 2015.

Percentage of drug overdose deaths involving cocaine increased from 11% in 2010 to 13% in 2015.

Drug overdose deaths involving psychostimulants, such as methamphetamines, increased from 5% to 11% in 2015.

NCHS Data Brief, #273, Feb 2017
A BIT OF GOOD NEWS FOR NM?

- For 2016, National Average for overdose deaths per 100,000 – 16.3
  - West Virginia- 41.5
  - New Hampshire- 34.3
  - Kentucky- 29.9
  - Ohio- 29.9
  - Rhode Island- 28.2
  - Pennsylvania- 26.3
  - Massachusetts- 25.7
  - New Mexico- 25.3
INITIATIVES

- Education
- Increased use of the PMP
- Increased education and availability of naloxone
- Board focus on the issue
- Decreased overall availability of prescription opioids
- Support for “MAT”, medication assisted treatment
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
NM STATUTORY BACKGROUND

- **Pain Relief Act of 1978**
  - Basically encouraged the adequate treatment of pain and protected providers from disciplinary action when treating pain with opioids. Required use of clinical expert testimony when pursuing disciplinary action. Did require proper documentation, compliance with federal controlled substances requirements, and forbade diversion by prescribers for personal use.

- **Senate Bill 215 of 2012**
  - Practice must substantially comply with accepted guidelines including rules issued by the board. Required pain management continuing education for all holders of a DEA registration to prescribe controlled substances. Created pain advisory council.

- **Senate Bill 263 of 2016**
  - Created requirement that the pharmacy monitoring program be consulted before prescribing any opioid for more than 4 days, and to re-check the PMP every 3 months (at least) for continuously prescribed opioids.
Recommended guideline for NM pain treatment regs
Now in second edition
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%202012.pdf](http://www.health.state.nm.us/pdf/opioids/NM%20Clinical%20Guidelines%20Opioids%20Final%202012.pdf)
In response to concerns about:

- Opioid pain medication misuse
- Challenges in managing chronic pain
- Concerns about patient addiction
- Insufficient training in prescribing opioids
- Beliefs that opioids can control pain but lead to over-prescribing and addiction
- Increasing opioid-related overdoses

The CDC developed guidelines focused on improving clinician knowledge, change prescribing practices and ultimately benefit patient health.

DOI:http://dx.doi.org/10.15585/mmwr.rr6501e1.
1. Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Providers should only consider adding opioid therapy if expected benefits for both pain and function are anticipated to outweigh risks to the patient (recommendation category: A, evidence type 3).
2. Before starting opioid therapy for chronic pain, providers should establish treatment goals with all patients, including realistic goals for pain and function. Providers should not initiate opioid therapy without consideration of how therapy will be discontinued if unsuccessful. Providers should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety (recommendation category: A, evidence type: 4).
3. Before starting and periodically during opioid therapy, providers should discuss with patients known risks and realistic benefits of opioid therapy and patient and provider responsibilities for managing therapy (recommendation category: A, evidence type: 3).
5. When opioids are started, clinicians should prescribe the lowest effective dosage. Providers should use caution when prescribing opioids at any dosage, should opioids are started, providers should prescribe the lowest implement additional precautions when increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should generally avoid increasing dosage to ≥90 MME/ day (recommendation category: A, evidence type: 3).
6. Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, providers should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three or fewer days usually will be sufficient for most nontraumatic pain not related to major surgery (recommendation category: A, evidence type: 4).
7. Providers should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Providers should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, providers should work with patients to reduce opioid dosage and to discontinue opioids (recommendation category: A, evidence type: 4).
8. Before starting and periodically during continuation of opioid therapy, providers should evaluate risk factors for opioid-related harms. Providers should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, or higher opioid dosages (≥50 MME), are present (recommendation category: A, evidence type: 4).
9. Providers should review the patient’s history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving high opioid dosages or dangerous combinations that put him or her at high risk for overdose. Providers should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months (recommendation category: A, evidence type: 4).
10. When prescribing opioids for chronic pain, providers should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs (recommendation category: B, evidence type: 4).
11. Providers should avoid prescribing opioid pain medication for patients receiving benzodiazepines whenever possible (recommendation category: A, evidence type: 3).
12. Providers should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder (recommendation category: A, evidence type: 3).
16.10.14.9

Pain management rules (not just guidelines).

A. Proper treatment of pain is a legitimate and appropriate part of the practice of medicine. This includes treating pain in patients with addiction, physical dependence or tolerance who have legitimate pain.

Link to copy of NM 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 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. When prescribing for chronic pain, urine drug testing shall be obtained before starting opioid therapy, and then at least every 6 months thereafter.

• 8. 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.
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.

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.

E. The board will review both over-prescription and under-prescription of pain medications using the same standard of patient protection.
16.10.14.8 PRESCRIPTION MONITORING PROGRAM (PMP) REQUIREMENTS:

A. All licensees with a DEA registration and a NM CS registration shall register with NM PMP.

B. Practitioners may use a delegate to obtain the PMP report per Board of Pharmacy rules.

C. Before a practitioner prescribes or dispenses for the first time, a controlled substance in schedule II, III, IV or V to a patient for a period greater than four days, or if there is a gap in prescribing the controlled substance for 30 days or more, the practitioner shall review a prescription monitoring report for the patient for the preceding 12 months. When available, the practitioner shall review similar reports from adjacent states. The practitioner shall document the receipt and review of such reports in the patient’s medical record.
D. A prescription monitoring report shall be reviewed a minimum of once every three months during the continuous use of a controlled substance in schedule II, III, IV or V for each patient. The practitioner shall document the review of these reports in the patient’s medical record. Nothing in this section shall be construed as preventing a practitioner from reviewing prescription monitoring reports with greater frequency than that required by this section.
E. A practitioner does not have to obtain and review a prescription monitoring report before prescribing, ordering, or dispensing a controlled substance in schedule II, III, IV or V:

- (1) for a period of four days or less; or
- (2) to a patient in a nursing facility; or
- (3) to a patient in hospice care; or
- (4) when prescribing, dispensing or administering of:
  - (a) testosterone; or
  - (b) pregabalin; or
  - (c) lacosamide; or
  - (d) ezogabine; or
- (e) stimulant therapy for pediatric patients less than age 14.
F. Upon review of a prescription monitoring report for a patient, the practitioner shall identify, document and be aware of a patient currently:

- (1) receiving opioids from multiple prescribers;
- (2) receiving opioids and benzodiazepines concurrently;
- (3) receiving opioids for more than 12 consecutive weeks;
- (4) receiving more than one controlled substance analgesic;
- (5) receiving opioids totaling more than 90 morphine milligram equivalents per day;
- (6) exhibiting potential for abuse or misuse of opioids and other controlled substances, such as over-utilization, requests to fill early, requests for specific opioids, requests to pay cash when insurance is available, receiving opioids from multiple pharmacies.
G. Upon recognizing any of the above conditions described in Subsection F of 16.10.14.8 NMAC, the practitioner, using professional judgment based on prevailing standards of practice, shall take action as appropriate to prevent, mitigate, or resolve any potential problems or risks that may result in opioid misuse, abuse, or overdose. These steps may involve counseling the patient on known risks and realistic benefits of opioid therapy, prescription and training for naloxone, consultation with or referral to a pain management specialist, or offering or arranging treatment for opioid or substance use disorder. The practitioner shall document actions taken to prevent, mitigate, or resolve the potential problems or risks.
H. Practitioners licensed to practice in an opioid treatment program, as defined in 7.32.8 NMAC, shall review a prescription monitoring report upon a patient’s initial enrollment into the opioid treatment program and every three months thereafter while prescribing, ordering, administering, or dispensing opioid treatment medications in schedule II, III, IV or V for the purpose of treating opioid use disorder. The practitioner shall document the receipt and review of a report in the patient’s medical record.
SUMMARY OF NMMB RULE CHANGES AS OF JANUARY 1, 2017

Key changes to the regulations are as follow:

1. The PMP needs to be consulted before prescribing more than a 4 day supply of any controlled substance.
2. The PMP must be consulted every three months when prescribing opioids for chronic pain.
3. However, the following are exceptions to the above:
   a. Not needed for patient in nursing facility or hospice care.
   b. Not needed when prescribing testosterone, pregabalin, lacosamide, ezogabine.
   c. Not needed when prescribing stimulants to patients under the age of 14.
4. Urine tox screens must be obtained before prescribing opioids for chronic pain, and then obtained every six months thereafter.
5. The PMP must be consulted before prescribing methadone for patients as part of a substance abuse treatment program (for methadone maintenance).
On obtaining and renewing a NM license:
- 5 CME units course must be completed 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
  - Management of the treatment of pain
- 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 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