

Prescribing Controlled Dangerous Substances: What Practitioners Need To Know

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The Preparation of Patient Records Rule

1. The rule requires that patient records be prepared contemporaneously.
2. Records should contain:
 - a. date of treatment
 - b. complaint, history, findings and progress notes
 - c. diagnosis or medical impression
 - d. treatment ordered
 - e. if there is a prescription, documentation of specific dosages, quantities and strengths of medication ordered, and instructions as to frequency of use

The Preparation of Patient Records Rule (Cont'd)

3. Documentation of prescriptions can be accomplished by:
 - a. maintaining a copy of the prescription in the patient record; or
 - b. a note containing the necessary information; or
 - c. both

Requirements For Issuing Written Prescriptions

1. Written prescriptions must be issued only on New Jersey Prescription Blanks.
2. The prescription must contain not only the patient's full name, but also the age and the address of the patient.
3. It must include the name, strength and quantity of the medication prescribed.
4. There must be a signature in the physician's handwriting – i.e., not a stamped signature.

Requirements For Issuing Written Prescriptions (Cont'd)

5. In the case of Schedule II CDS, it must contain words indicating the number of pills prescribed – not just numerals.
6. Each prescription for a CDS must be on a separate prescription blank.

Special Rules For Prescribing Controlled Dangerous Substances

1. Preliminary Requirements:
 - a. a thorough medical history
 - b. an appropriate medical examination
 - c. a treatment plan identifying objectives, with focus on the cause of pain
 - d. a medical record containing the “complete name of the controlled substance,” the dosage, strength, and quantity of medications and instructions as to frequency of use
 - e. access of the Prescription Monitoring Program

Special Rules For Prescribing Controlled Dangerous Substances (Cont'd)

2. Prescription of Schedule II CDS “shall be at the lowest effective dose.”
3. Prior to issuing an initial prescription for Schedule II CDS or “any opioid drug,” there must be a discussion as to why the medication is being prescribed, possible alternative treatments, and risks associated with the medication, including:
 - a. risks of addiction
 - b. physical or psychological dependence

Special Rules For Prescribing Controlled Dangerous Substances (Cont'd)

- c. overdose, including the risk of taking opioid drugs with alcohol, benzodiazepines and other nervous system depressants.

ALL OF THIS MUST BE DOCUMENTED

- 4. At the time of or prior to the third prescription:
 - a. a similar discussion must occur and be documented.
 - b. a pain management contract must be signed and dated by the physician and patient, which contains:

Special Rules For Prescribing Controlled Dangerous Substances (Cont'd)

- i. a description of the pain management plan, the patient's obligation for responsible use, storage and disposal
- ii. other modes of treatment (e.g., physical therapy) being utilized
- iii. how the physician will monitor compliance
- iv. the process for terminating the contract

Special Rules For Prescribing Controlled Dangerous Substances (Cont'd)

5. When CDS are prescribed for management of chronic pain:
 - a. the patient's course of treatment and progress must be reviewed at least every three months
 - b. the patient must be "assessed" each time a prescription is written
 - c. unless clinically contraindicated, there must be a "periodic" attempt to stop or taper the medication or try other medications to reduce potential for abuse or dependence
 - d. the Prescription Monitoring Program must be accessed
 - e. compliance with the pain management agreement must be monitored

Special Rules For Prescribing Controlled Dangerous Substances (Cont'd)

- f. random urine monitoring must be done at least once every 12 months
 - g. the availability of an opioid antidote must be discussed
 - h. if objectives are not being met, the patient should be referred to a pain management or addiction specialist
6. There are special rules for initial prescriptions for acute pain

The Prescription Monitoring Program

1. Either the physician or a certified medical assistant (a “delegate”) may access the program.
2. The physician must confirm the education, training and certification of the delegate.
3. Access must be gained the first time a Schedule II CDS is prescribed for acute or chronic pain, unless the first prescription is only for a five-day supply or unless it is post-surgery and the prescription is for less than a 30-day supply.
4. Thereafter, access must be gained at least every three months.

The Prescription Monitoring Program (Cont'd)

5. Documentation procedures must be established by the physician.
6. Non-compliance with the regulation “may be deemed professional misconduct.”

Strong Recommendation: Make a copy of the patient’s prescriptions and place it in the medical record.

Complying with the Regulations and Avoiding Scrutiny: A Review

- NJ Medical Board Licensee/CDS Registrant Checklist
- Prescription Monitoring Program (PMP)
- Exemptions from PMP mandatory lookup
- 72-Hour quantity rule
- What practitioners should discuss with their patients
- Five steps when prescribing, dispensing or administering any CDS
- Pain treatment with opioid medications: patient agreement

The Practitioner as Employer: Important Considerations

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The Opioid Epidemic Has Hit The Workplace

- A 2017 study* by the National Safety Council found:
 - More than 70% of employers report problems with prescription drug misuse in the workplace
 - 65% of employers felt misuse was justifiable reason to fire employee
 - 70% of employers would like to help employees return to work after treatment

*Source: <http://www.nsc.org/Connect/NSCNewsReleases/Lists/Posts/Post.aspx?ID=182>



What Physician Employers Must Know About Opioid Use In The Workplace

- Multiple laws that impact how you handle the issue
- Burden is on employer to understand its obligations and employee's rights
- Ignorance of the law is not a defense
- Even unintentional violations will lead to legal liabilities



Disability-Related Obligations Under State And Federal Law

- Family Medical Leave Act (FMLA)
- Americans with Disabilities Act (ADA)
- New Jersey Law Against Discrimination (NJLAD)
- ADA & NJLAD protect employees that have (i) a current disability (ii) a prior disability (iii) a perceived disability and (iv) an association with someone who has a disability
- ADA & NJLAD require “reasonable accommodations” for disabilities
 - Must engage in interactive process
 - Accommodations may include leave of absence, job restructuring, modified/part-time work
 - Do not have to eliminate employee’s essential functions

The Challenges Of Opioid-Related Disabilities In The Physician Setting

- Has opioid use been disclosed or is it suspected?
- Lawful opioid use may still impair employee's ability to perform job
- The likelihood of lawful opioid leading to abuse
 - Roughly 21 to 29 percent of patients prescribed opioids for chronic pain misuse them*
 - Between 8 and 12 percent develop an opioid use disorder**
 - 75% of those struggling with substance use disorder are in workforce***
- What's the disability?
 - The medical condition being treated by opioids?
 - Opioid abuse or perceived abuse?
 - Some other disability?
 - Of the 20.2 million adults in the U.S. who experience a substance abuse disorder, 50.5% (10.2 million adults) had co-occurring mental illness**

*Source: <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-crisis>

**Source: <https://www.nami.org/Learn-More/Mental-Health-By-the-Numbers>

***Source: <http://www.nsc.org/Connect/NSCNewsReleases/Lists/Posts/Post.aspx?ID=182>

What's The “Right” Approach To Opioids In The Workplace?

- Some typical employer approaches:
 - Paternalistic/offer assistance
 - Immediate confrontation, accusation and/or discipline
 - Ignore the problem
- The “right” approach will depend upon the circumstances
 - “Right” approach typically combines elements from each of the above



What Happens If The Employer Doesn't Handle It "Right"?

- In 2016, EEOC recovered \$348 million in monetary benefits based upon violations
 - \$131 million was for claims of disability discrimination under the ADA
 - Represents almost 38% of total
- Initial reports on 2017 EEOC data show focus on disability claims continues
- Private lawsuits extremely prevalent



*Source: EEOC Fiscal Year 2016 Enforcement and Litigation Data

There's More . . . Other Employee Rights and Legal Obligations

- Employees may have privacy rights in the workplace
 - Limitations on substance testing
 - Limitations on certain inquiries about medical conditions
 - Limitations on workplace searches
- Physician employers may have mandatory reporting obligations
 - Health care providers who are impaired
 - Stolen prescription blanks
- Patient safety issues
- Liabilities to other third parties

Some Practical Guidance For Handling Opioid Use In The Workplace

- Be able to identify the opioid use problem areas
- Make sure policies are up to date and consistent with applicable law
- Ensure staff are properly trained on how to handle opioid-related issues
- Be proactive in dealing with disability accommodation issues
- Forget the concept of “at-will” employment
- Be proactive in dealing with employee performance/discipline issues (even if possibly caused by a disability)

Questions?