

Pain Management Regulations Affect More Than Pain Management Specialists

By:
Linda A. Keen
of counsel to The Florida Healthcare Law Firm

The recently passed House Bill 7095 affects more than just pain management specialists. Practitioners who prescribe controlled substances for individuals with "chronic nonmalignant pain" also are required to comply with new state regulations, including designation "as a controlled substance prescribing practitioner on the physician's practitioner profile" with the state Board of Medicine by January 1, 2012. What follows is a bulleted summary of the new regulations.

Prescriptions for controlled substances must be either written or electronic. Telephone prescriptions no longer are allowed.

Written Prescriptions for Controlled Substances

- Must have quantity in textual and numerical format
- Must be dated with the abbreviated month written out
- Must be written on a standardized counterfeit-proof prescription pad produced by a DOH approved vendor

Physicians who prescribe any controlled substance for the treatment of "chronic nonmalignant pain" must designate him or herself as a controlled substance prescribing physician on the physician's practitioner profile and must comply with statutory requirements and applicable board rules

- "Chronic nonmalignant pain" is defined as pain unrelated to cancer or rheumatoid arthritis which persists beyond the usual course of disease or the injury that is the cause of the pain or more than 90 days after surgery.

A complete medical history and physical exam must be documented in the medical record

The exact nature of the examination is not dictated, but it must be proportionate to the diagnosis that justifies treatment and must minimally document:

- The pain's nature and intensity
- Current and past treatment for pain
- Underlying or coexisting diseases or conditions
- The effect of the pain on physical and psychological functions
- A review of previous medical records and previous diagnostic studies
- History of alcohol and substance abuse
 - Notably, patients with such a history require referral to, or consultation with, a psychiatrist or addictionologist
- The presence of one or more recognized indications for the use of a controlled substance

A written individualized treatment plan must be documented and include at a minimum:

- Objectives to determine treatment success, such as pain relief and improved physical and psychosocial function
- Indication of further planned diagnostic evaluations or other treatments

- After treatment begins, adjustment of drug therapy to the individual's medical needs
- Consideration of other treatment modalities, including rehabilitation, depending on the etiology and extent to which pain is associated with physical and psychosocial impairment
- Use of an interdisciplinary approach to the pain

Risks and benefits of the uses of controlled substances must be discussed with the patient, persons designated by the patient, or the patient's surrogate or guardian, if the patient is incompetent and must include:

- Risks of abuse and addiction
- Physical dependence and its consequences
- Although not specifically required by law, a written and signed consent should be obtained

The physician must enter into a written controlled substance agreement outlining the patient's responsibilities and include at least the following:

- Number and frequency of controlled substance prescriptions and refills
- Patient compliance expectations
- Reasons why drug therapy may be discontinued
- Controlled substances for the treatment of the patient's chronic nonmalignant pain will be prescribed by a single treating physician unless the treating physician authorizes otherwise and documents it in the medical record

The patient must be seen at regular intervals, at least every 3 months to:

- Assess the efficacy of treatment
- Ensure the controlled substance therapy remains indicated
- Evaluate the patient's progress toward treatment objectives
- Consider adverse drug effects
- Review pain etiology
- Determine whether to continue or modify the therapy, based on the evaluation and progress
- Reevaluate the appropriateness of continued treatment if treatment goals are not being achieved
- Monitor compliance in medication usage, related treatment plans, controlled substance agreements, and indication of substance abuse or diversion at a minimum of 3 month intervals
- Although not required by law, a notation that the treatment plan was reviewed and updated as necessary is recommended
- Before writing a prescription for a controlled substance, a physician should ask the patient whether he or she is being prescribed controlled substances by another practitioner and it should be documented in the medical record
 - If the physician doesn't, and prescribes as well, the physician could be held complicit in prescribing medically unnecessary medication, in violation of Florida law

In order to achieve treatment objectives, the physician shall refer a patient as necessary for additional evaluation and treatment to achieve treatment objectives

- Special attention must be given to those at risk for misusing medication or those with living arrangements that pose a risk for misuse or diversion

Patients with a history of substance abuse or a comorbid psychiatric disorder require referral to, or consultation with, a psychiatrist or addictionologist.

Accurate, current, and complete medical records that are accessible and readily available must comply with law, and the physician's applicable practice act and board rules. The record should include, at a minimum:

- Medical history and physical, including history of drug abuse or dependence
- Diagnostic, therapeutic, and laboratory results
- Evaluations and consultations
- Treatment objectives
- Discussion of risks and benefits
- Treatments
- Medications, including date, type, dosage, and quantity prescribed. Instructions and agreements
- Periodic reviews
- Results of any drug testing
- A photocopy of the patient's government-issued photo ID
- If a written prescription of a controlled substance is given to a patient, a duplicate of the prescription.
- The physician's LEGIBLE full name
- Although not required by law, the treatment plan, controlled substance agreement, and informed consent for treatment document signed by the patient should be included in the medical record

Patients with signs or symptoms of substance abuse must be referred immediately to a board-certified pain management physician, an addiction medicine specialist, or a mental health addiction facility

- While waiting for the consultant's report, a prescribing physician must clearly and completely document justification for continued use of controlled substances and steps taken to ensure medically appropriate use of the medication
- On receipt of the consultant's report, the consultant's recommendations for controlled substance therapy should be incorporated into the treatment plan, documenting resulting changes in therapy

If a physician identifies evidence or behavioral indications of diversion, the controlled substance therapy must be discontinued and the patient must be discharged from care

- Results of testing and all actions taken must be documented in the medical record

Physicians who dispense medications from their office may not dispense Schedule II or Schedule III controlled substances, unless:

- The drugs are complimentary and labeled as a drug sample or complimentary drug and are provided to the practitioner's own patients in the regular course of medical practice without any kind of fee or remuneration
- The controlled substance is dispensed in association with the performance of a surgical procedure
 - No greater than a 14 day supply can be dispensed, and only one 14 day supply per surgical procedure
 - If a physician's practice requires this to occur, the physician should research and follow applicable law and rules, as they are too involved to discuss here

The Department of Health has established an electronic database for those who dispense controlled substances and will provide advisory reports upon practitioner request

- Prescribers will have access to database information relating to their patients if they want to review a patient's controlled substance prescription history

The new law also affects pain management clinics, various pain management specialists, pharmacies, pharmacists and drug distributors.

This is a general overview of compliance requirements for general practice practitioners. Continued interpretation of the law and rule development is expected. Practitioners are encouraged to pay close attention to

their licensure boards and medical society information as further interpretation and refinement occurs. Practitioners who must comply with the law should consult an attorney for guidance. A link to House Bill 2095 is attached. The reader is encouraged to read it in its entirety to assure compliance.

<http://www.flSenate.gov/Session/Bill/2011/7095/BillText/er/PDF>