

Regulatory Registration Deadline Approaching For Each “Provider”, Regardless of Specialty, Who Prescribes Any Controlled Substances



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Under Section 456.44, Florida Statutes (“Section 456.44”), every “Provider” (medical doctor, osteopath physician, podiatrist and dentist) who

prescribes any controlled substances for non-malignant pain (pain unrelated to cancer or rheumatoid arthritis which persists beyond the normal course of the disease or more than 90 days after surgery) to patients **MUST** (1) register with Florida’s Department of Health (“DOH”), and (2) update his or her Department of Health Practitioner Profile, by January 1, 2012, including information about the Provider’s controlled substance prescription practices (NOTE; This law deals specifically with Providers who “prescribe” controlled substances. Different laws deal with Providers who “dispense” such medications).

Section 456.44 also establishes new standards of care and medical recordkeeping requirements for Providers who prescribe controlled substances.

These requirements set out specific treatment and prescription drug

information that must be in the patient’s medical record, and govern the manner and timeframes under which a Provider is to see a patient who has been prescribed a controlled substance.

The patient must be seen by the physician “at regular intervals, not to exceed 3 months,” to assess the efficacy of treatment and to ensure that controlled substance therapy remains necessary.

The patient’s medical record must include at least the 13 items listed in the statute, which include (1) a complete medical history and examination, including history of drug dependence, (2) results of any drug testing, (3) a photocopy of the patient’s government-issued photo identification, (3) a copy of the written prescription for a controlled substance and (4) documentation of periodic patient reviews.

The Provider and patient also must enter into a “written controlled substance agreement” outlining the patient’s responsibilities. At a minimum, the agreement **MUST** include information regarding (1) the number and frequency of controlled substance prescriptions and refills, (2) patient compliance and reasons for which drug therapy may be discontinued (such as a violation of the agreement), and (3) an agreement that controlled substances prescribed for non-malignant pain are to be

prescribed by a “single treating physician” unless otherwise authorized by the treating physician and documented in the medical record.

Providers must also develop a written individualized treatment plan for each patient. The treatment plan must state the objectives that will be used to determine treatment success, such as pain relief and improved physical function, and shall indicate if any further diagnostic evaluations or other treatments are planned. Use of any interdisciplinary treatment (such as a rehabilitation program) must also be documented.

The statute also requires the Provider to immediately refer a patient with a sign of substance abuse to a board-certified pain-management or drug-addiction specialist.

Those who do not strictly adhere to the new requirements can find themselves the subject of overpayment audits, licensure, and in, some cases, criminal penalties. It is essential for Providers who prescribe controlled substances to understand and comply with these new requirements.

Please contact Mike Igel at 727-820-3963 or migel@trenam.com or Jacqueline Myles Crain at 727-824-6179 or jcrain@trenam.com to discuss how this legislation may affect your practice or business.