

FAQ'S REGARDING IMPLEMENTATION OF PAIN MANAGEMENT CLINIC REGULATION

Effective January 1, 2012, pursuant to Public Chapter 340, as codified in T.C.A. § 63-1-301 et seq., all pain management clinics in Tennessee must be registered with the State.

Pursuant to T.C.A. § 63-1-301, a “**pain management clinic**” is defined as “a privately-owned facility in which a medical doctor, an osteopathic physician, an advanced practice nurse and/or a physician assistant provides pain management services to patients, a majority of whom are issued a prescription for, or are dispensed, opioids, benzodiazepines, barbiturates, or carisoprodol, but not including suboxone, for more than ninety (90) days in a twelve-month period.”

On October 1, 2011, the Department of Health promulgated emergency rules to effectuate the purposes of Public Chapter 340. Permanent rules were promulgated on December 22, 2011 and will be effective March 26, 2012. Rule 1200-34-01-.02(10) of these rules define “**pain management services**” as “evaluation, diagnosis, or treatment for the prevention, reduction, or cessation of the symptom of pain through pharmacological , non-pharmacological and other approaches.”

The following FAQ responses and statements do not supercede the terms of Public Chapter 340, but are merely provided as guidance for purposes of implementation and enforcement. They are provided in a good faith effort at transparency in the Department's regulatory role. The questions are informational in nature and do not constitute legal advice. Moreover, the questions and answers are subject to change. Those who are or may be subject to this regulation are strongly urged to review the applicable laws and rules and seek their own legal counsel if necessary. The Department is not bound by this guidance in its interpretation of the law because each situation is unique. Professional societies were consulted in creating these FAQs, and the Department thanks them for their role while acknowledging its sole responsibility for the FAQs.

Question: Does the provision of mental health treatment by mental health professionals fall within the ambit of Public Chapter 340 or the rules promulgated by the Department?

Answer: The Department does not believe that the use of benzodiazepines for treatment of mental health conditions (such as anxiety or depression) and not for pain management falls within the scope of Public Chapter 340, which specifically references pain management services in the definition of “pain management clinic”.

Question: Does the provision of pain management services in an oncological setting for the treatment of malignant conditions fall within the scope of Public Chapter 340 or the rules promulgated by the Department?

Answer: The Department does not believe that the incidental use of opioids, benzodiazepines, barbiturates or carisoprodol in the treatment of malignant conditions in an oncological setting falls within the scope of Public Chapter 340, which specifically excludes hospices and hospitals.

Question: How do I determine if my clinic's operation falls within the scope of Public Chapter 340?

Answer: In addition to consulting your own legal counsel and reviewing applicable laws and rules, a clinic could consider the following 2-prong test, as guidance only.

2-Prong Test for Qualification as a Pain Management Clinic

- 1) Does (or will) the provider evaluate, diagnose or treat for physical pain prevention, reduction or cessation for non-malignant, non-acute pain episodes?
- 2) Are more than 50% of the provider's patients receiving (or will they receive) more than 90 days worth of prescriptions for opioids, benzodiazepines, barbiturates, or carisoprodol, but not including suboxone, in any 12-month period?

Question: Is the calculation relating to the majority of patients based on the total clinic patient population (across all providers in a group) or based on an individual provider's patient population?

Answer: The Department believes that the intention of the legislation was to provide that if any single provider qualified under the above 2-prong test, then that clinic or provider would need to register as a pain management clinic. In this regard, the Department notes that the definition refers to a "a privately-owned facility in which a medical doctor, an osteopathic physician, an advanced practice nurse and/or a physician assistant provides pain management services [emphasis added]..."

Question: With reference to the 90 days of prescriptions in a twelve-month period, does this only refer to 90 consecutive days of such prescriptions?

Answer: No. The Department believes that 90 days of such prescriptions within a twelve-month period, whether consecutive or not, would fall within the scope of Public Chapter 340 and the Department's rules. While the Department does not believe that treatment for acute pain episodes fall within that scope, treatment for sufficient acute episodes for more than 90 days out of a twelve-month period would rise to that level.

Question: Is Tramadol (Ultram) an opioid such that the prescribing of it should be counted for purposes of assessing whether a provider must register as a pain clinic?

Answer: While Tramadol (Ultram) is not specifically included or excluded in Public Chapter 340, it may be considered an opiate inasmuch as it does work on the brain's opiate receptor and, for purposes of these regulations, should be considered in assessing whether a provider must register as a pain clinic.

Question: Is codeine an opioid?

Answer: Yes.

Question: I heard that the new law prohibits cash-only transactions for registered pain clinics. Would that prohibition also preclude the patient's use of money orders?

Answer: No. T.C.A. §63-1-310(a) specifically authorizes pain clinics to accept money orders (or checks or credit cards). Of course, the law also authorizes pain clinics to accept cash for a co-pay, coinsurance, or deductible when the remainder of the charge is submitted to the patient's insurance plan for reimbursement.