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, as amended by Public Chapter 430 signed by the Governor on May 16, 2013, a “pain management clinic” is defined as “a privately-owned facility in which a medical doctor, an osteopathic physician, an advanced practice nurse, a physician assistants, or any other health care provider licensed under Title 63 provides pain management services to patients, a majority of whom are issued a prescription for opioids, benzodiazepines, barbiturates, or carisoprodol and provides prescriptions for more than ninety (90) days in a twelve-month period. For purposes of determining if a clinic should be registered under this part, patients of health care providers who do not prescribe controlled substances shall be excluded from the count. ‘Pain management clinic’ shall also mean any privately-owned, facility or office which advertises in any medium for any type pain management services and in which one (1) or more employees or contractors prescribe controlled substances.”

On October 1, 2011, the Department of Health promulgated emergency rules to effectuate the purposes of Public Chapter 340. Permanent rules went into effect on March 26, 2012. Rule 1200-34-01-.02(10) of the rules defines “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 the Tennessee Code, 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.

1. **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”.

2. Question: Are Suboxone and buprenorphine considered opioids, such that provision of these drugs requires registration as a pain clinic?

Answer: Suboxone and buprenorphine are opioids and, if used in any form for purposes which include pain management, must be counted when determining whether a clinic requires registration as a pain clinic. However, if and only if these drugs are used in accordance with their FDA indication solely in the context of a bona fide program for Medication-Assisted Treatment (MAT) for opioid dependence, this would not be considered pain management services and those patients should not be counted as such.

3. 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.

4. 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.

5. 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.

6. Question: Is codeine an opioid?

Answer: Yes.
7. **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:** Yes. T.C.A. §63-1-310(a) specifically limits pain clinics to accepting checks or credit cards. Of course, the law does authorize 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.

8. **Question:** What is the penalty for operating or working in an unregistered pain clinic?

**Answer:** T.C.A. §63-1-311 provides that a practitioner who provides pain management services in an uncertified pain management clinic is subject to an administrative penalty of up to $5,000 per day.