

Health Law Update for 2012

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Pain Management Clinic Certification

- As of January 1, 2012, certain clinics offering pain management services are required to apply for certification with the TN Dept. of Health.
- Is your clinic a Pain Management Clinic?
 - The answer might surprise you

What is a Pain Management Clinic?

A Pain Management Clinic is defined in the statute as “a privately owned facility in which an M.D., D.O., A.P.N., or P.A. provides pain management services to a majority of the facility’s patients through prescription of opioids, benzodiazepines, barbiturates, or carisoprodol (but not including suboxone), for more than 90 days in a 12 month period.” *T.C.A. §63-1-301(5)*

What are Pain Management Services?

The term “Pain Management Services” is defined in the regulations as “evaluation, diagnosis, or treatment for the prevention, reduction, or cessation of the symptom of pain through pharmacological, non-pharmacological and other approaches.”
Tenn. R. & Regs. 1200-34-01-.02(10)

What this Means for You ...

The statute applies to more than just traditional pain management clinics. The broad statutory definition includes any clinic that meets the following criteria:

- Privately owned facility
- M.D., D.O., N.P., or P.A. provides pain management services to patients of the facility
- Majority of patients are issued prescriptions for, or are dispensed, one of the following:
 - Opioids
 - Benzodiazepine
 - Barbiturates
 - Carisoprodol
- The prescriptions are issued (or drugs dispensed) for more than 90 days (consecutive or non-consecutive) in a 12-month period

Examples of Commonly Prescribed Pain Medications

□ Opioids

- Morphine
- Fentanyl
- Vicodin
- Demerol
- Nubain
- OxyContin/Oxycodone
- Opium
- Narcan
- Imodium
- Ultram
- Levomethorphan

□ Benzodiazepines

- Xanax
- Valium
- Restyl
- Loramet
- Halcion
- Mylostan
- Tranxilium
- Rivotril
- Fluscand
- Doral
- Klonopine

Examples of Commonly Prescribed Pain Medications

□ Barbiturates

- Amobarbital
- Aprobarbital
- Alphenal
- Barbital
- Phenobarbital

□ Carisoprodol

- Soma
- Sansoma
- Carisoma

Exceptions to Certification Requirements

The statute does not apply to:

- Medical or dental schools, osteopathic medical schools, physician assistant programs or an outpatient clinic associated with any such schools or programs
- Hospitals, including any outpatient facility or clinic of a hospital
- Hospice services
- Nursing homes
- State operated facilities
- Federal government hospitals and clinics

TN Dept. of Health F.A.Q.s

In an attempt to clarify which clinics will need to register under this new law, the Tennessee Department of Health issued a document titled *FAQ's Regarding implementation of Pain Management Clinic Regulation* earlier this month.

The 2-Prong Test

In its F.A.Q.s, the TN Dept of Health proposes the following 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?

TN Dept of Health F.A.Q.s

- When asked whether the “majority of patients” was based on the total clinic patient population or on the patient population on an individual provider, the Dept responded:

“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.”

TN Dept of Health F.A.Q.s

- In response to questions regarding the provision of pain management services in an oncological setting for the treatment of malignant conditions, the Department states:

“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.”

TN Dept of Health F.A.Q.s

- In response to questions regarding the use of benzodiazepines for mental health treatment, the Department states:

“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’.”

Pain Management Clinic Requirements

- ❑ Every Pain Management Clinic must submit an application to the TN Dept. of Health for a certificate to operate the clinic
- ❑ Every Pain Management Clinic must have a qualified medical director
- ❑ Each clinic location must be certified separately regardless of whether the clinic is operated under the same business name, ownership or management as another clinic
- ❑ A change of majority ownership requires the submission of a new application for a certificate

The Application for Certification

In order to obtain a certificate as a pain management clinic, the facility must submit the following:

- A completed application form (Dept of Health Form)
- Proof of qualified physician medical director
- Proof of DEA registration for the clinic (where required)
- Proof of DEA registrations for the individual providers who provide pain mgmt services at the clinic
- Results of criminal background check(s) for all clinic owners
- List of individuals who own, co-own, operate or provide pain mgmt services in the clinic as an employee or contractor
- Disclosure of any license denial, restriction, or discipline imposed on an owner, co-owner, operator, employee or other individual who provides services at the clinic
- Application and initial certification fees (\$415.00)

Medical Director Qualifications

- ❑ The medical director must be a physician (M.D. or D.O.) licensed in TN under an unrestricted and unencumbered license; and
- ❑ Meet one of the following “training” requirements:
 - Successful completion of a residency program in or board certified in physical medicine & rehabilitation, anesthesiology, addiction medicine, neurology, neurosurgery, family practice, preventive medicine, internal medicine, surgery, orthopedics or psychiatry approved by ACGME or AOABOS;
 - Board Certification by the American Board of Pain Medicine;
 - Board certification by the American Board of Interventional Pain Physicians;

Medical Director Qualifications (con't.)

- Subspecialty certification in pain management, hospice and palliative medicine or geriatric medicine recognized by the ABMS or AOABOS with a certificate of added qualification from the Bureau of Osteopathic Specialists;
- Any other subspecialty certification recognized by the Board of Medical Examiners and the Board of Osteopathic Examination; or
- Completion of 40 hours of in-person, live-participatory AMA Category I or AOABOS Category I CME course in pain management completed within 7 years prior to employment or service with the clinic that addresses prescribed subject areas set forth in the regulations.

Medical Director Responsibilities

The Medical Director shall:

- Oversee all pain management services provided at the clinic
- Be on-site at least 20% of the clinic's total weekly operating hours and not less than 8 hrs per week
- Ensure all providers comply with applicable state and federal laws and rules relative to prescribing controlled substances in the clinic

Medical Director Responsibilities (con't)

- Ensure compliance with all supervision requirements for NP and PA providing pain management services at the clinic
- Ensure establishment of protocols for NPs and PAs employed by or working at the clinic
- Ensure that providers comply with such protocols, as well as any other established policies and procedures of the clinic

Medical Director Responsibilities (con't)

- Arrange for substitute Medical Director when unavailable due to illness, vacation, etc.
- Establish written policies and procedures for:
 - quality assurance,
 - health and safety,
 - infection control, and
 - patient access to medical records and continuity of care upon clinic closure.
- Ensure all providers maintain complete and accurate medical records of patient consultation, examination, diagnosis, and treatment

Provider Training

- Each health care provider shall complete 10 hours in continuing education courses (per licensure renewal cycle) in areas relative to pain management including, but not limited to:
 - Prescribing controlled substances
 - Drug screening or testing
 - Pharmacological and non-pharmacological pain treatment
 - Completing a physical exam and pain medicine history
 - Maintaining appropriate progress notes
 - Co-morbidities with pain disorders; and
 - substance abuse and misuse including alcohol and diversion and prevention of same.
- Such hours shall be a part of (not in addition to) the continuing education requirements established by each provider's respective boards

Penalties for Non-Compliance

- ❑ A Practitioner who provides pain management services at an uncertified clinic is subject to an administrative penalty of \$1,000 per day, imposed by the board which licensed that practitioner. *T.C.A. §63-1-311(b)*
- ❑ The board shall give at least 30 days notice to the practitioner of the alleged violation prior to assessing such a penalty
- ❑ Additionally, the clinic may be subject to civil monetary penalties in an amount of up to \$1,000 per day for failure to comply with the statutory requirements and regulations. *Tenn. R. & Regs. §1200-34-01-.10*

PHYSICIAN NONCOMPETE CHANGES

Effective January 1, 2012:

- ❑ T.C.A. §63-1-148, governing restrictive covenants for physicians, now applies to non-physician healthcare providers (*e.g.*, NP, PA, LCSW).
- ❑ Six-year limitation on the duration of noncompetes is removed.
- ❑ Limitations on noncompete agreements for physicians (MDs) extended to osteopathic physicians (DOs) (T.C.A. §§63-1-148 and 63-6-204), but still exclude emergency medicine practitioners

PHYSICIAN NONCOMPETE CHANGES

- ❑ Discrepancy between statutes governing noncompete agreements for hospital employed physicians (See T.C.A. §§ 63-6-204 and 68-11-205(2))
- ❑ Discrepancy caused by legislative oversight: §63-6-204 was amended to reflect changes in noncompete laws found in §63-1-148, but §68-11-205 was not amended resulting in conflicting laws where hospital-employed physicians are concerned.
- ❑ Conflicting provisions relate to physicians employed by a hospital independent of a *bona fide* practice purchase.

Physician Noncompetes

- T.C.A. §63-6-204(2) permits noncompetes that comply with §63-1-148 (*i.e.*, term \leq 2 yrs, geographic limitation: greater of 10-miles or county).
- T.C.A. §68-11-205(b)(2)(B) permits noncompetes for physicians who have practiced in the county for more than 5 years, but limits duration of restriction to 1 year.
- T.C.A. §68-11-205(b)(2)(C) where a physician has practiced in the county for less than 5 years, hospital may only restrict the physician's right to directly solicit patients treated during the course of the employment relationship; noncompete not permitted.

PRACTITIONER ID LAW

- Requires that the practice have conspicuously placed list of doctors/PAs/NPs, etc., (does not include RNs, techs) by the entrance that includes the recognized abbreviation of each practitioner's professional degree (i.e., "MD" or "NP") and the spelled out words "medical doctor", "physician", "nurse practitioner", etc., in equal size and lettering, immediately below the practitioner's name. The doctor may substitute his/her board-recognized specialty for this designation.

PRACTITIONER ID LAW

Additionally, the ID law requires that each licensed practitioner either:

- ❑ wear a photo id with his/her designated title at all times during patient encounters; or
- ❑ provide in writing to each patient at the patient's initial office visit the practitioner's full name and type of license. This requirement may be satisfied by presenting the patient with a business card containing the required information.

PRACTITIONER ID LAW

These requirements do not apply:

- ❑ to healthcare practitioners working in licensed healthcare facilities, or
- ❑ to practitioners who work in no-patient care settings and have no direct patient care interactions.

Physicians Billing “Incident To” Other Physicians

- Generally, a practice group can bill services provided by its “auxiliary” personnel as “incident to” one of the group’s physicians.
- “Auxiliary” personnel traditionally means mid-level providers, e.g., NPs and PAs.
- However, CMS allegedly has confirmed in an email that a physician’s services may be billed “incident to” another physician.
- This proves very helpful where a new group physician has yet to be credentialed.

STAGE 2: “Meaningful Use”

- ❑ On February 23, 2012, CMS released the Stage 2 proposed rules for EHR “meaningful use.”
- ❑ The Stage 1 rules (2010), required EPs to meet 15 core objectives. Stage 1 also offered an additional 10 objectives in a “menu,” and required that EPs choose 5 objectives to complete during Stage 1, with the remaining 5 to be completed in Stage 2.
- ❑ In Stage 2, EPs will be required to meet (or qualify for an exclusion to) 17 core objectives and 3-5 “menu” objectives.
- ❑ The Stage 2 rules propose to delay implementation of the new criteria for one year, allowing EPs to continue attesting to compliance through 2013. Beginning in 2014, EPs would have to comply with the proposed Stage 2 “meaningful use” criteria.

Differences Between Stage 1 and Stage 2

- Most of the Stage 1 core and menu objectives have been retained.
- Significant changes include:
 - Changes to the denominator of computerized provider order entry (CPOE) (Stage 1 Optional, Stage 2 Required)
 - Changes to the age limitations for vital signs (Stage 1 Optional, Stage 2 Required)
 - Replacing the “exchange of key clinical information” core objective from Stage 1 with a “transitions of care” core objective requiring electronic exchange of summary of care documents in Stage 2 (Effective Stage 2)
 - Replacing “provide patients with an electronic copy of their health information” with a “view online, download and transmit” core objective. (Effective Stage 2)
 - An increase in objectives that may be applicable to some specialty providers.

Reporting Clinical Quality Measures

- The Stage 2 rules also propose to bring the reporting requirements into line with existing quality programs EPs may already be participating in.
- For example:
 - Physician Quality Reporting System;
 - Medicare Shared Savings Program;
 - National Council for Quality Assurance for medical home accreditation;
 - Children's Health Insurance Program Reauthorization Act; and
 - Adult Health Quality Measures set forth in the Affordable Care Act.

Payment Adjustments and Exceptions

- ❑ Medicare payment adjustments are required by statute to take effect in 2015.
- ❑ The proposed rule clarifies how providers can avoid payment adjustments.
- ❑ EPs who demonstrate “meaningful use” by 2013 will avoid penalty.
- ❑ EPs who demonstrate “meaningful use” by 2014 will also avoid penalty if the EP can establish that the EP engaged in “meaningful use” at least three months prior to the end of the calendar or fiscal year, and can meet the statutory attestation and registration requirements by October 1, 2014.

Proposed 60-Day Rule

- ❑ On February 13, 2012, CMS issued proposed guidance for the "60-Day Rule."
- ❑ PPACA requires all Medicare or Medicaid participating providers and suppliers to report and refund known overpayments within 60 days from the date the overpayment is "identified."
- ❑ The failure to make such a report and repayment creates an "obligation" for which a provider can be subject to liability under the False Claims Act and under the Civil Monetary Penalties Law.

“Identified” Clarified. Kind of...

- ❑ CMS proposes that a “person has identified an overpayment if the person has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the existence of the overpayment.”
- ❑ Providers may have information that creates an obligation to make a “reasonable inquiry” to determine whether an overpayment exists. CMS advises that such inquiries be made with “all deliberate speed.”
- ❑ Proposed "overpayment" definition: any funds that a person receives or retains under the Medicare program to which the person, after applicable reconciliation, is not entitled.
- ❑ Examples: payments for non-covered services, payments in excess of allowed amounts, and receipt of funds from Medicare when another party is primarily liable.

Significant Addition: 10 Year Look-Back

- ❑ Current Medicare reopening regulations permit look-back periods up to 4 years for simple overpayments (i.e., when there is no fraud).
- ❑ Under the proposed regulations, overpayments must be reported and returned if identified within 10 years of the date the overpayment is received.
- ❑ Also proposes to similarly amend current reopening regulations.

QUESTIONS

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