How State Regulation of Pain Management Clinics Can Impact Your Practice

According to the Centers for Disease Control, in 2010, more than 38,000 people died of drug overdoses, and the majority of these deaths (22,134) were caused by prescription drug overdoses.

The United States is in the midst of an epidemic of drug diversion (i.e., the use of prescription drugs for nonmedical purposes) and an increase in deaths from prescription drug overdoses. Between 1999 and 2008, the deaths from prescription painkiller overdoses tripled, and the drug diversion costs to health insurers, in terms of direct healthcare costs, are over $70 billion annually.

Policymakers, healthcare associations, and state and federal governments have joined forces to fight the prescription drug overdose crisis by introducing legislation and regulations intended to prevent deaths and injuries from prescription drug abuse, misuse, and overdose.

States are taking several legislative and regulatory approaches to curb the overdoses from prescription drugs and drug diversion. These include prescription drug monitoring programs, laws to prevent tampering with prescription forms, “doctor shopping” laws, laws regulating pain management clinics, laws to discourage providers from inappropriately prescribing painkillers (i.e., imposing sanctions in such instances) and clinical guidelines for chronic pain management and issuance of prescription painkillers. This article will focus on laws regulating pain management clinics, commonly referred to as “pill mills,” and how these laws can impact CRNA practice.

Regulating “Pill Mills”

A “pill mill” is a doctor’s office, clinic, facility, or pharmacy that is prescribing or dispensing controlled substances inappropriately, without regard to medical necessity and outside the standards of medical practice. Laws regulating pain management clinics are designed to prohibit these facilities from prescribing and dispensing controlled substances to any patient seeking prescription pain pills without assessing whether these medications are medically necessary. Eleven states have passed laws regulating pain management clinics: Alabama, Florida, Georgia, Indiana, Kentucky, Louisiana, Mississippi, Ohio, Tennessee, Texas, and West Virginia.

Laws regulating pain management clinics may specify ownership requirements; operational and personnel requirements; supervision requirements; standards to ensure quality patient care; inspection and complaint procedures; certificate/license application and renewal procedures and requirements; investigations; procedures for denial or revocation of licenses/certificates; health and safety requirements; and patient billing procedures. Pain management clinics are generally regulated by the state department of health or, more often, the state board of medicine. There are aspects of these laws that can impact CRNA practice, and therefore, it is important to be aware of these laws.

As mentioned earlier, pain management clinics are regulated by the state department of health or state board of medicine.

From the CRNA perspective, it is generally preferable that pain clinics be regulated by the department of health.

Procedures vs. Pills: What is a Pain Management Clinic?

Many CRNAs who focus in the area of chronic or interventional pain management are focused on pain management procedures versus prescription pain control. Generally speaking, a pain management clinic is a facility that is primarily engaged in treating pain by prescribing or dispensing pain medications. One of the challenges with laws regulating pain management clinics is that, oftentimes, the definition of “pain management clinic” is so broad that it includes facilities focused on treating pain through pain management procedures rather than targeting only the true “pill mills.” For example, the Florida definition of “pain-management clinic” includes a publicly or privately owned facility “[t]hat advertises in any medium for any type of pain-management services” or “[w]here in any month a majority of patients are prescribed opioids, benzodiazepines, barbiturates, or carisoprodol for the treatment of chronic nonmalignant pain.” (Emphasis added.) Tennessee provides a narrower definition; in Tennessee, a “pain management clinic” is 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 opioids, benzodiazepine, barbiturates, or carisoprodol, but not including suboxone, for more than ninety (90) days in a twelve-month period."

States may limit pain management clinic ownership to physicians only or require at least one physician owner. Further, states may limit the physician owners to physicians with specific credentials in pain management. For example, Ohio law requires that a pain management clinic "be owned and operated by one or more physicians." Texas, on the other hand, exempts from regulation "a clinic owned or operated by an advanced practice nurse licensed in this state who treats patients in the nurse's area of specialty and who personally uses other forms of treatment with the issuance of a prescription for a majority of the patients." West Virginia takes a middle-ground approach, requiring that at least one owner to be a physician actively licensed to practice in West Virginia; however, West Virginia imposes a requirement of having a "designated physician" owner who must have either (i) completed a pain medicine fellowship that is accredited by the Accreditation Council for Graduate Medical Education or (ii) hold a current board certification by the American Board of Pain Medicine or current board certification by the American Board of Anesthesiology. 4

Supervision Requirements

State law may impose a restriction that only permits CRNAs to work at pain management clinics when another, specified provider is present. For example, in Georgia, the law prohibits a pain management clinic from providing medical treatment or services "unless a physician, a physician assistant authorized to prescribe controlled substances under an approved job description, or an advanced practice registered nurse authorized to prescribe controlled substances pursuant to a physician protocol is on-site at the pain management clinic." While CRNAs in Georgia are advanced practice registered nurses, they are not authorized to prescribe controlled substances via a physician protocol. Therefore, for a CRNA to provide services at a pain management clinic, another designated provider must be on-site.

One final area to note—state law regulating pain management clinics may impose supervision or oversight requirements over providers. What is important is that any supervision or similar requirement is not stricter than what is required under the state's nurse practice act or board of nursing rules. For example, in West Virginia, the pain clinic laws state that the "designated physician" must "[s]upervise, control and direct the activities of each individual working or operating at the facility ... who provides treatment of chronic pain at the clinic or is associated with the provision of that treatment. The supervision, control and direction shall be provided in accordance with rules promulgated by the secretary." (Emphasis added.) The West Virginia pain clinic law is not inconsistent with the West Virginia Nurse Practice Act, which requires CRNAs be "in the presence and under the supervision of" a physician or dentist.

Given the epidemic of drug diversion and deaths caused by prescription painkillers, we anticipate that there will be continued regulation of pain clinics to help ensure that controlled substances are prescribed to patients in an appropriate manner. CRNAs working at facilities that are considered "pain management clinics" under state law should be aware of how these facilities are regulated and if there is any impact to their scope of practice.

References
4. The Secretary of the West Virginia Department of Health and Human Resources has discretion to approve other fellowship programs and board certifications.