

Delaware Medical Board Regulations

AGENCY 24. REGULATED PROFESSIONS AND OCCUPATIONS SUB-AGENCY. DEPARTMENT OF STATE; DIVISION OF PROFESSIONAL REGULATION CHAPTER 1700. BOARD OF MEDICAL LICENSURE AND DISCIPLINE; RULES AND REGULATIONS

Section 31.0 Use of Controlled Substances for the Treatment of Pain: Purpose.

The Board has adopted the Federation of State Medical Board's "Model Policy for the Use of Controlled Substances for the Treatment of Pain" ("Model Policy). These regulations have been developed to define specific requirements applicable to pain control, particularly related to the use of controlled substances, to alleviate licensed practitioners' uncertainty, to encourage better pain management, and to minimize practices that deviate from the appropriate standard of care and lead to abuse and diversion. Licensed practitioners should familiarize themselves with the Model Policy available online at www.dpr.delaware.gov. To the extent there are any inconsistencies between these regulations and the Model Policy, these regulations shall control.

The principles of quality medical practice dictate that citizens of Delaware have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. The inappropriate treatment of pain includes a wide spectrum of issues that do not provide treatment appropriate to the patients' specific needs.

The diagnosis and treatment of pain is integral to the practice of medicine. Licensed practitioners view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness. Licensed practitioners should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. These regulations are primarily directed to the treatment of chronic pain but are applicable to prescribing controlled substances for other conditions as well.

Inappropriate pain treatment may result from the practitioner's lack of knowledge about pain management. Fears of investigation or sanction by federal, state and local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating practitioner's responsibility. As such, the Board will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

The Board recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and non-pharmacologic modalities according to the judgment of the licensed practitioner. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain, and treatment outcomes. Licensed practitioners should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and alone are not the same as addiction.

The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes can pose a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, these regulations mandate that licensed practitioners incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

Licensed practitioners should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Board will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a licensed practitioner-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state or federal law is required.

The Board will judge the validity of the licensed practitioner's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors.

Allegations of inappropriate pain management will be evaluated on an individual basis. The Board will take disciplinary action against a licensed practitioner for deviating from these regulations unless contemporaneous medical records document reasonable cause for deviation. The practitioner's conduct will be evaluated to a great extent by the outcome of pain treatment, recognizing that some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in patient functioning and/or quality of life.

31.1 The following criteria must be used when evaluating the treatment of pain, including the use of controlled substances:

31.1.1 Evaluation of the Patient- A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The evaluation must document:

- 31.1.1.1 etiology, the nature and intensity of the pain, current and past treatments for pain,
- 31.1.1.2 underlying or coexisting diseases or conditions,
- 31.1.1.3 the effect of the pain on physical and psychological function, and history of substance abuse,
- 31.1.1.4 the presence of one or more recognized medical indications for the use of a controlled substance.

31.2 Treatment Plan- A written treatment plan is required and must state goals and objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. The treatment plan must address whether treatment modalities or a rehabilitation program are necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment. After treatment begins, the practitioner must adjust drug therapy to the individual medical needs of each patient.

31.3 Informed Consent - The practitioner must discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity.

31.4 Agreement for Treatment- If the patient is at high risk for medication abuse or has a history of substance abuse, the practitioner must use a written agreement between the practitioner and patient outlining patient responsibilities, including;

- 31.4.1 urine/serum medication levels screening when requested;
- 31.4.2 number and frequency of all prescription refills; and
- 31.4.3 reasons for which drug therapy may be discontinued (e.g., violation of agreement).
- 31.4.4 a requirement that the patient receive prescriptions from one licensed practitioner and one pharmacy where possible.

31.5 Periodic Review- The licensed practitioner shall periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Periodic review shall include, at a minimum, evaluation of the following:

31.5.1 continuation or modification of controlled substances for pain management therapy depending on the practitioner's evaluation of the patient's progress toward treatment goals and objectives.

31.5.2 satisfactory response to treatment as indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function must be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment.

31.5.3 if the patient's progress is unsatisfactory, the practitioner shall assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

31.6 Consultation- The practitioner shall refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention must be given to those patients with pain who are at risk for medication misuse, abuse or diversion. The management of pain in patients with a history of substance abuse or with a co-morbid psychiatric disorder requires extra care, monitoring, documentation and may require consultation with or referral to an expert in the management of such patients. At a minimum, practitioners who regularly treat patients for chronic pain must educate themselves about the current standards of care applicable to those patients,

31.7 Medical Records- The practitioner shall keep accurate and complete records. The entire record must, include the:

- 31.7.1 medical history and physical examination,
- 31.7.2 diagnostic, therapeutic and laboratory results,
- 31.7.3 evaluations and consultations,
- 31.7.4 documentation of etiology;
- 31.7.5 treatment objectives,
- 31.7.6 discussion of risks and benefits,
- 31.7.7 informed consent,
- 31.7.8 treatments,
- 31.7.9 medications (including date, type, dosage and quantity prescribed),
- 31.7.10 instructions and agreements, and
- 31.7.11 periodic review.

31.8 Records should remain current and be maintained in an accessible manner and readily available for review. Each practitioner should include documentation appropriate for each visit's level of care and will include the:

- 31.8.1 interim history,
- 31.8.2 vital signs,
- 31.8.3 assessment of progress, and
- 31.8.4 medication plan.

31.9 Compliance with Controlled Substances Laws and Regulations- To prescribe, dispense or administer controlled substances, the practitioner must be licensed in the state and comply with all applicable federal and state regulations. Licensed practitioners are referred to the Practitioner's Manual of the U.S. Drug Enforcement Administration and specific rules governing controlled substances as well as applicable state regulations.

31.10 The following terms are defined as follows:

31.10.1 Acute Pain- Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. It is generally time-limited.

31.10.2 Addiction- Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

31.10.3 Chronic Pain- Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

31.10.4 Licensed Practitioner - Licensed practitioner means those licensed individuals with prescriptive authority regulated under the Medical Practice Act including, but not limited to, physicians, physician assistants and nurse practitioners.

31.10.5 Pain- An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

31.10.6 Physical Dependence- Physical dependence is a state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

31.10.7 Pseudo addiction- The iatrogenic syndrome resulting from the misinterpretation of relief seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction. The relief seeking behaviors resolve upon institution of effective analgesic therapy.

31.10.8 Substance Abuse- Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

31.10.9 Tolerance- Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.