

Guidelines for Use of Controlled Substances for the Treatment of Pain

Components	Applicable to this Guideline(s):
<p>1.0 Purpose: Use of Controlled Substances for the Treatment of Pain</p> <p>The Physicians Advisory Committee for Controlled Substances of the Medical Society of Delaware supports the Federation of State Medical Board's "Model Policy for the Use of Controlled Substances for the Treatment of Pain" ("Model Policy"). These guidelines 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. 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.</p> <p>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 guidelines are directed to the treatment of pain.</p> <p>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. The Committee recognizes that some types of pain cannot be completely relieved.</p> <p>The Committee 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</p>	<p>Chronic pain</p> <p>Acute/Subacute pain</p> <p>Emergency Medicine</p> <p>Hospice</p>

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<p>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.</p> <p>The Committee 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 guidelines mandate that licensed practitioners incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.</p> <p>These guidelines support the ordering, prescribing, dispensing or administering of controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice 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.</p> <p>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.</p> <p><i>Disclaimer: These guidelines are only an educational tool. Clinicians should use their own clinical judgment and not base clinical decisions solely on this document. This document should not be used to establish any standard of care. No legal proceeding, including medical malpractice proceedings or disciplinary hearings, should reference a deviation from any part of this document as constituting a breach of professional conduct.</i></p>	

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<p>2.0 Guidelines - The following criteria must be used when evaluating the treatment of pain, including the use of controlled substances:</p> <p>2.1 Evaluation of the Patient- A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The evaluation must document:</p> <p>2.1.1 etiology, the nature and intensity of the pain, current and past treatments for pain,</p> <p>2.1.2 underlying or coexisting diseases or conditions,</p> <p>2.1.3 the effect of the pain on physical and psychological function, and history of substance abuse,</p> <p>2.1.4 the presence of one or more recognized medical indications for the use of a controlled substance.</p>	<p>Chronic pain Acute/Subacute pain Emergency Medicine Hospice</p>
<p>2.2 Treatment Plan- A treatment plan should be discussed and should include goals and objectives that will be used to determine treatment outcomes, 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 should 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 should adjust drug therapy to the individual medical needs of each patient.</p>	<p>Chronic pain Acute/Subacute pain Hospice</p>
<p>2.2 Treatment Plan - Prescribing pain medicine for chronic pain from the Emergency Department should be limited to only the immediate treatment of acute exacerbations of pain associated with objective findings of uncontrolled pain, all of which shall be discussed with the patient up front. [Chronic pain treatment requires monitoring the effects of the medication on pain levels and patient’s level of functioning. Such monitoring would be impossible to provide for the emergency medical provider, who therefore is unable to provide a long term treatment plan as it relates to the patient's response to the prescription of chronic opioids.]</p>	<p>Emergency Medicine</p>

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2.3 Informed Consent - The practitioner should 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.	Chronic pain Acute/Subacute pain Emergency Medicine Hospice
2.4 Agreement for Treatment- The practitioner should use a written agreement between the practitioner and patient outlining mutual responsibilities, including; 2.4.1 urine/serum medication levels screening when requested; 2.4.2 number and frequency of all prescription refills; and 2.4.3 reasons for which drug therapy may be discontinued (e.g., violation of agreement). 2.4.4 a requirement that the patient receive prescriptions from one licensed practitioner and one pharmacy where possible.	Chronic Pain
2.4 Agreement for Treatment- If, based on clinical assessment, the patient is at high risk for medication abuse or has a history of substance abuse, or a past history of chronic pain, the practitioner should use an agreement (or should document a discussion) between the practitioner and patient outlining mutual responsibilities, including; 2.4.1 urine/serum medication levels screening when requested; 2.4.2 number and frequency of all prescription refills; and 2.4.3 reasons for which drug therapy may be discontinued (e.g., violation of agreement). 2.4.4 a requirement that the patient receive prescriptions from one licensed practitioner and one pharmacy where possible.	Acute/Subacute pain

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2.4 Agreement for Treatment- Not applicable	Emergency Medicine Hospice
<p>2.5 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:</p> <p>2.5.1 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.</p> <p>2.5.2 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.</p> <p>2.5.3 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.</p>	Chronic pain Acute/Subacute pain Hospice
<p>2.5 Review of Emergency Department care (in lieu of Periodic Review)</p> <p>2.5.1 Ideally, one medical provider should provide all opioids to treat a patient's chronic pain.</p> <p>2.5.2 The administration of intravenous and intramuscular opioids in the Emergency Department (ED) for the relief of acute exacerbations of chronic pain should be carefully considered.</p> <p>2.5.3 The administration of Demerol R-(Meperidine) in the ED is discouraged</p> <p>2.5.4 Emergency medical providers should not provide replacement prescriptions for controlled substances that were lost, destroyed or stolen.</p> <p>2.5.5 Emergency medical providers should not provide replacement doses of</p>	Emergency Medicine

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<p>methadone for patients in a methadone treatment program.</p> <p>2.5.6 Long-acting or controlled-release opioids (such as OxyContin®, fentanyl patches, and methadone) should not be prescribed from the ED.</p> <p>2.5.7 Patients who are found to receive prescriptions for controlled substances from multiple providers should not receive additional prescriptions for controlled substances from the ED.</p> <p>2.5.8 Emergency medical providers should attempt to coordinate care with primary care and pain management physicians for patients presenting to the ED with acute exacerbations of chronic pain.</p> <p>2.5.9 EDs should coordinate the care of patients who frequently visit the ED using an ED care coordination program.</p> <p>2.5.10 EDs should maintain a list of primary care providers for patients of all payer types.</p> <p>2.5.11 Prescriptions for opioid pain medication from the ED for acute injuries, such as fractured bones, or acute painful conditions, such as kidney stones, in most cases should not exceed 30 pills. If the provider prescribes greater than a 72-hour supply of opiates, the Delaware Prescription Monitoring Program should be accessed as per Delaware law.</p> <p>2.5.12 The emergency physician is required by law to evaluate an ED patient who reports pain. The law allows the emergency physician to use their clinical judgment when treating pain and does not require the use of opioids.</p>	
<p>2.6 Consultation- The practitioner should consider referring 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.</p>	<p>Chronic pain Acute/Subacute pain Hospice</p>

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At a minimum, practitioners who regularly treat patients for chronic pain must educate themselves about the current standards of care applicable to those patients,	
2.6 Consultation- Not applicable	Emergency Medicine
2.7 Medical Records- The practitioner (or hospice, if applicable) shall keep accurate and complete records. The entire record must include the: 2.7.1 medical history and physical examination, 2.7.2 relevant diagnostic, therapeutic and laboratory results, 2.7.3 relevant evaluations and consultations, 2.7.4 documentation of etiology; 2.7.5 treatment objectives, 2.7.6 discussion of risks and benefits, 2.7.7 informed consent, as per Section 1.3, 2.7.8 treatments, 2.7.9 medications (including date, type, dosage and quantity prescribed), 2.7.10 instructions and agreements, and 2.7.11 periodic review and/or appropriate referral.	Chronic pain Acute/Subacute pain Hospice
2.7 Medical Records- The practitioner shall keep accurate and complete records. The entire record must, include the: 2.7.1 medical history and physical examination, 2.7.2 relevant diagnostic, therapeutic and laboratory results, 2.7.3 relevant evaluations and consultations, 2.7.4 documentation of etiology; 2.7.5 treatment objectives, 2.7.6 discussion of risks and benefits,	Emergency Medicine

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<p>2.7.7 informed consent,</p> <p>2.7.8 treatments,</p> <p>2.7.9 medications (including date, type, dosage and quantity prescribed),</p> <p>2.7.10 instructions, and appropriate referral.</p>	
<p>2.8 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:</p> <p>2.8.1 interim history and examination, when applicable</p> <p>2.8.2 vital signs, when appropriate</p> <p>2.8.3 assessment of progress, and</p> <p>2.8.4 medication plan.</p>	<p>Chronic pain</p> <p>Acute/Subacute pain</p> <p>Emergency Medicine</p> <p>Hospice</p>
<p>2.9 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.</p>	<p>Chronic pain</p> <p>Acute/Subacute pain</p> <p>Emergency Medicine</p> <p>Hospice</p>
<p>3.0 Definitions - The following terms are defined as follows:</p> <p>3.1 Acute/Subacute 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.</p> <p>3.2 Addiction- Addiction is a primary, chronic, neurobiological 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.</p> <p>3.3 Chronic Pain- Chronic pain is a state in which pain persists beyond the</p>	<p>Chronic pain</p> <p>Acute/Subacute pain</p> <p>Emergency Medicine</p> <p>Hospice</p>

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<p>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.</p> <p>3.4 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.</p> <p>3.5 Pain- An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.</p> <p>3.6 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.</p> <p>3.7 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.</p> <p>3.8 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.</p> <p>3.9 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.</p> <p>3.10 Emergency Medicine - The care provided to a patient within an Emergency Department.</p> <p>3.11 Hospice care – Hospice pain management is pain relief provided to patients in a certified Hospice program where patients are terminally ill with survival of 6-12 mos. The goal is to relieve suffering and pain, not necessarily to extend life. Hospice organizations are responsible for a policy to safeguard controlled substances in the home and to educate staff on this matter.</p>	

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*Notes:

1. Delaware Board of Medical Licensure and Discipline adopted the FSMB Model Policy as basis for Regulation 32 as part of 15 DE Reg. 1184 on February 1, 2012.
2. These Guidelines are the first such policies to consolidate all four of these areas into one set of Guidelines. No other set of policies exist which are applicable to all Chronic (C), Acute/Subacute (A/S), Emergency Medicine (EM) or Hospice (H) patient care. MSD has reviewed over many different guidelines, protocols, pathways and algorithms in this initial development process (see www.guideline.gov).
3. Physicians Advisory Committee is an ad hoc committee of the Medical Society of Delaware composed of physicians from primary care, surgery, rehabilitation medicine, pain management, oncology pain management, hospice, psychiatry and Emergency Medicine:

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4. Approved by the Physicians Advisory Committee on 08/13/12.