INDIANA

Citations for Policies Evaluated

STATUTES

- Controlled Substances Act
 Title 35. Criminal Law and Procedure; Article 48. Controlled Substances
- Medical Practice Act Title 25. Professions and Occupations; Article 22.5. Physicians
- PHARMACY PRACTICE ACT (No provisions found)
 Title 25. Professions and Occupations; Article 26. Pharmacists and Pharmacies or Drugstores
- Intractable Pain Treatment Act No policy found

REGULATIONS

- Controlled Substances Regulations
 Title 858. Controlled Substances Advisory Committee
- Medical Board Regulations
 Title 844. Medical Licensing Board of Indiana;
- PHARMACY BOARD REGULATIONS
 Title 856. Indiana Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

No policies found

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

HOMICIDE

Title 35. Criminal Law and Procedure; Article 42. Offenses Against the Person; Chapter 1. Homicide



Provisions that may ENHANCE pain management											
	1	2	3	4	5	6	7	8			
Criteria	Controlled substances are necessary for public health	Pain management is part of medical practice	Opioids are part of professional practice	Encourages pain management	Addresses fear of regulatory scrutiny	Prescription amount alone does not determine legitimacy	Physical dependence or analgesic tolerance are not confused with "addiction"	Other provisions that may enhance pain management			
STATUTES											
Controlled Substances Act			•					•			
Medical Practice Act		•									
Pharmacy Practice Act ¹											
Intractable Pain Treatment Act ²											
REGULATIONS	S										
Controlled Substances			•								
Medical Board ¹											
Pharmacy Board ¹											
OTHER GOVE	OTHER GOVERNMENTAL POLICIES ²										
RELEVANT PO	RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES										
Homicide								•			

Prov	/ision	s that	may //	/PEDE	pain ı	manaç	gement	
	9	10	11	12	13	14	15	16
Criteria	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act ¹								
Medical Practice Act ¹								
Pharmacy Practice Act ¹								
Intractable Pain Treatment Act ²								
REGULATIONS								
Controlled Substances ¹								
Medical Board			•					
Pharmacy Board								•
OTHER GOVE	RNMENT	AL POLIC	IES ²					
RELEVANT PO	LICIES C	R PROVIS	SIONS IDEN	ITIFIED BY	/ BOOLEA	N (KEY W	ORD) SEAF	RCHES
Homicide ¹								



Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Burns Ind. Code Ann. § 35-48-1-24

§ 35-48-1-24. Practitioner

"Practitioner" means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other institution or individual licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or administer a controlled substance in the course of professional practice or research in Indiana.

Burns Ind. Code Ann. § 35-48-7-8

§ 35-48-7-8. Controlled substance prescription monitoring program

The advisory committee shall provide for a controlled substance prescription monitoring program that includes the following components:

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(+) CRITERION 3:

Opioids are part of professional practice

(4) The advisory committee may require that prescriptions for controlled substances be written on a one (1) part form that cannot be duplicated. However, the advisory committee may not apply such a requirement to prescriptions filled at a pharmacy with a Type II permit (as described in IC 25-26-13-17) and operated by a hospital licensed under IC 16-21, or prescriptions ordered for and dispensed to bona fide enrolled patients in facilities licensed under IC 16-28. The committee may not require multiple copy prescription forms and serially numbered prescription forms for any prescriptions written. The committee may not require different prescription forms for any individual drug or group of drugs. Prescription forms required under this subdivision must be jointly approved by the committee and by the Indiana board of pharmacy established by IC 25-26-13-3.

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§ 35-48-7-11. Information confidential -- Protection of information -- Release of information

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- (f) The advisory committee may release to:
- (1) A member of the board, the advisory committee, or another governing body that licenses practitioners;
- (2) An investigator for the consumer protection division of the office of the attorney general, a prosecuting attorney, the attorney general, a deputy attorney general, or an investigator from the office of the attorney general; or
 - (3) A law enforcement officer who is:
- (A) Authorized by the state police department to receive the type of information released; and $\frac{1}{2} \int_{\mathbb{R}^{n}} \frac{1}{2} \left(\frac{1}{2} \int_{\mathbb{R}^{n}} \frac{1}{2}$
- (B) Approved by the advisory committee to receive the type of information released;

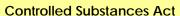
confidential information generated from computer records that identifies practitioners who are prescribing or dispensing large quantities of a controlled substance.

[CONTINUED ON NEXT PAGE]

(+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

<u>CATEGORY C:</u> Regulatory or policy issues

COMMENT: Recognizes characteristics of prescription monitoring programs that are believed to impede the appropriate medical use of Schedule II controlled substances.



- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -



(+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

<u>CATEGORY C:</u> Regulatory or policy issues

COMMENT: Establishes a mechanism (review by advisory committee member with the same professional license) to determine from prescription monitoring program information whether further investigation for a particular case of improper prescribing is warranted.

(CONTINUED)

- (g) The information described in subsection (f) may not be released until it has been reviewed by a member of the advisory committee who is licensed in the same profession as the prescribing or dispensing practitioner identified by the data and until that member has certified that further investigation is warranted. However, failure to comply with this subsection does not invalidate the use of any evidence that is otherwise admissible in a proceeding described in subsection (h).
- (h) An investigator or a law enforcement officer receiving confidential information under subsection (c), (d), or (f) may disclose the information to a law enforcement officer or an attorney for the office of the attorney general for use as evidence in the following:
 - (1) A proceeding under IC 16-42-20.
- (2) A proceeding under any state or federal law that involves a controlled substance.
- (3) A criminal proceeding or a proceeding in juvenile court that involves a controlled substance.
- (i) The advisory committee may compile statistical reports from the information described in subsection (a). The reports must not include information that identifies any practitioner, ultimate user, or other person administering a controlled substance. Statistical reports compiled under this subsection are public records.

STATUTES

Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Burns Ind. Code Ann. § 25-22.5-1-1.1

§ 25-22.5-1-1.1. Definitions

As used in this article:

- - (1) Holding oneself out to the public as being engaged in:
- (A) the diagnosis, treatment, correction, or prevention of any disease, ailment, defect, injury, infirmity, deformity, <u>pain</u>, or other condition of human beings;

(+) <u>CRITERION 2:</u> Pain management is part of medical practice



- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -



(+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

<u>CATEGORY A:</u> Issues related to healthcare professionals

COMMENT: Clarifies for physicians that there is an important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment.

Burns Ind. Code Ann. § 35-42-1-2.5

§ 35-42-1-2.5. Assisting suicide

- (a) This section does not apply to the following:
- (1) A licensed health care provider who administers, prescribes, or dispenses medications or procedures to relieve a person's pain or discomfort, even if the medication or procedure may hasten or increase the risk of death, unless such medications or procedures are intended to cause death.
- (2) The withholding or withdrawing of medical treatment or life-prolonging procedures by a licensed health care provider, including pursuant to IC 16-36-4 (living wills and life-prolonging procedures), IC 16-36-1 (health care consent), or IC 30-5 (power of attorney).
- (b) A person who has knowledge that another person intends to commit or attempt to commit suicide and who intentionally does either of the following commits assisting suicide, a Class C felony:
- (1) Provides the physical means by which the other person attempts or commits suicide.
- (2) Participates in a physical act by which the other person attempts or commits suicide.



Controlled Substances Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

856 IAC 2-1-1

856 IAC 2-1-1 Definitions

Sec. 1. Definitions. As used herein, the following terms shall have the meanings specified:

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(+) <u>CRITERION 3:</u> Opioids are part of professional practice

(h) The term "individual practitioner" means a physician, dentist, veterinarian, or other individual licensed, registered or otherwise permitted by the State of Indiana or the United States, to <u>dispense a controlled substance in the course of professional practice</u>, but does not include a pharmacist, a pharmacy, or an institutional practitioner.

REGULATIONS

Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

844 IAC 5-1-1

844 IAC 5-1-1 Definitions

Sec. 1. For purposes of the standards of professional conduct and competent practice of medicine, the following definitions apply: (a) "Professional incompetence" may include, but is not limited to, a pattern or course of repeated conduct by a practitioner demonstrating a failure to exercise such reasonable care and diligence as is ordinarily exercised by practitioners in the same or similar circumstances in the same or similar locality.

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- (d) For purposes of clarifying the terminology used in IC 25-22.5-6-2.1(b)(7), and for purposes of the standards of professional conduct and competent practice of medicine, the following definitions apply:
- (1) "Addict" means a person who is <u>physiologically and/or psychologically dependent</u> upon a drug which is classified as a narcotic, controlled substance or dangerous drug.
- (2) "Habitue" means a person who is <u>physiologically and/or psychologically dependent</u> upon any narcotic, drug classified as a narcotic, dangerous drug or controlled substance under Indiana law; or a person who consumes on a regular basis, and without any medically justifiable purpose, a narcotic drug classified as a narcotic, dangerous drug or controlled substance under Indiana law, whether or not such person has developed a physiological or psychological dependence upon such substance.

(-) <u>CRITERION 11:</u>
Physical dependence or analgesic tolerance confused with "addiction"

INDIANA

REGULATIONS

Pharmacy Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

856 IAC 2-6-3

856 IAC 2-6-3 Purpose of prescription; prohibitions

Sec. 3. Purpose of issue of prescription. (a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose in a <u>reasonable quantity</u> by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription, within the meaning and intent of IC 1971, 35-24.1-3-8 [Repealed by Acts 1976, P.L. 148, SECTION 24; Acts 1977, P.L. 26, SECTION 25. See IC 35-48.] as amended, and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

(-) <u>CRITERION 16:</u> Provisions that are ambiguous

<u>CATEGORY A</u>: Arbitrary standards for legitimate prescribing

COMMENT:

"Reasonable" implies there is a known standard, but the standard is not specified.

IOWA

Citations for Policies Evaluated

STATUTES

Controlled Substances Act

Title IV. Public Health; Subtitle 1. Alcoholic Beverages and Controlled Substances; Chapter 124. Controlled Substances

Professional Practice Act (No provisions found)

Title IV. Public Health; Subtitle 3. Health-Related Professions; Chapter 147. General Provisions, Health-Related Professions

Medical Practice Act (No provisions found)

Title IV. Public Health; Subtitle 3. Health-Related Professions; Chapter 148. Medicine and Surgery

OSTEOPATHIC PRACTICE ACT (No provisions found)

Title IV. Public Health; Subtitle 3. Health-Related Professions; Chapter 150A. Osteopathic Medicine and Surgery

PHARMACY PRACTICE ACT

Title IV. Public Health; Subtitle 3. Health-Related Professions; Chapter 155A. Pharmacy

 Intractable Pain Treatment Act No policy found

REGULATIONS

- Controlled Substances Regulations (Part of Pharmacy Board Regulations) (No provisions found)
 Pharmacy Examiners Board; Chapter 10. Controlled Substances
- Medical Board Regulations

Medical Examiners Board [653]

PHARMACY BOARD REGULATIONS (No provisions found)

Pharmacy Examiners Board [657]

OTHER GOVERNMENTAL POLICIES

PHARMACY BOARD POLICY STATEMENT

lowa Pharmacy Examiners Board. The Treatment of Pain. Adopted: February 12, 2002.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

Assisting Suicide

Title XVI. Criminal Law and Procedure; Subtitle 1. Crime Control and Criminal Acts; Chapter 707A. Assisting Suicide



Provisions that may ENHANCE pain management											
	1	2	3	4	5	6	7	8			
Criteria	Controlled substances are necessary for public health	Pain management is part of medical practice	Opioids are part of professional practice	Encourages pain management	Addresses fear of regulatory scrutiny	Prescription amount alone does not determine legitimacy	Physical dependence or analgesic tolerance are not confused with "addiction"	Other provisions that may enhance pain management			
STATUTES											
Controlled Substances Act			•					•			
Professional Practice Act ¹											
Medical Practice Act ¹											
Osteopathic Practice Act ¹											
Pharmacy Practice Act			•								
Intractable Pain Treatment Act ²											
REGULATIONS	5										
Controlled Substances ¹											
Medical Board		•	•	•				•			
Pharmacy Board ¹											
OTHER GOVE	RNMENTA	L POLICIES									
Pharmacy Board Policy Statement			•	•	•			•			
RELEVANT PO	LICIES OR	PROVISIO	NS IDENTIF	IED BY BOO	LEAN (KE	Y WORD)	SEARCHES				
Assisting Suicide								•			

Prov	/ision	s that	may //	<i>NPEDE</i>	pain ı	manaç	gement	
	9	10	11	12	13	14	15	16
Criteria	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act ¹								
Professional Practice Act ¹								
Medical Practice Act ¹								
Osteopathic Practice Act ¹								
Pharmacy Practice Act ¹								
Intractable Pain Treatment Act ²								
REGULATIONS								
Controlled Substances ¹								
Medical Board ¹								
Pharmacy Board ¹								
OTHER GOVER	RNMENT	AL POLIC	IES					
Pharmacy Board Policy Statement							•	
RELEVANT PO	LICIES C	R PROVIS	SIONS IDEN	NTIFIED BY	/ BOOLEA	N (KEY W	ORD) SEAF	RCHES
Assisting Suicide ¹								



Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

lowa Code § 124.101

124.101 Definitions.

As used in this chapter:

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25. "Practitioner" means either:

a. A physician, dentist, podiatric physician, veterinarian, scientific investigator or other person licensed, registered or otherwise permitted to <u>distribute</u>, <u>dispense</u>, <u>conduct</u> research with respect to or to administer a controlled substance in the course of professional practice or research in this state.

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Iowa Code § 125.2

125.2 Definitions

For purposes of this chapter, unless the context clearly indicates otherwise:

 "Chemical dependency" means an addiction or dependency, either physical or psychological, on a chemical substance. <u>Persons who take medically prescribed drugs</u> shall not be considered chemically dependent if the drug is medically prescribed and the intake is proportionate to the medical need. (+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

<u>CATEGORY B:</u> Issues related to patients

COMMENT: This definition, used in addiction treatment, would ensure that pain patients would not be labeled as chemically dependent; however, the definition seems to confuse physical dependence with addiction for general purposes.

STATUTES

Pharmacy Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

lowa Code § 155A.3

155A.3 Definitions.

As used in this chapter, unless the context otherwise requires:

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31. "Practitioner" means a physician, dentist, podiatric physician, veterinarian, or other person licensed or registered to distribute or dispense a prescription drug or device in the course of professional practice in this state or a person licensed by another state in a health field in which, under lowa law, licensees in this state may legally prescribe drugs.

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(+) <u>CRITERION 3:</u> Opioids are part of professional practice

(+) CRITERION 3:

Opioids are part of

professional practice



Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

653 IAC 10.1(17A,147)

653-10.1(17A,147) Definitions.

The following definitions shall be applicable to the rules of the lowa state board of medical examiners:

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(+) <u>CRITERION 2:</u> Pain management is part of medical practice

"The practice of medicine and surgery" shall mean holding one's self out as being able to diagnose, treat, operate or prescribe for any human disease, <u>pain</u>, injury, deformity or physical or mental condition and who shall either offer or undertake, by any means or methods, to diagnose, treat, operate or prescribe for any human disease, <u>pain</u>, injury, deformity or physical or mental condition. This rule shall not apply to licensed podiatrists, chiropractors, physical therapists, nurses, dentists, optometrists, and pharmacists who are exclusively engaged in the practice of their respective professions.

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653—13.2(148,150,150A,272C) Standards of practice—prescribing or administering controlled substances for the treatment of patients with chronic, nonmalignant pain.

This rule establishes standards of practice for the management of chronic, nonmalignant pain. The purpose of the rule is to assist physicians who prescribe and administer drugs to provide relief and eliminate suffering in patients with chronic, nonmalignant pain as defined in this rule.

13.2(1) Definitions. As used in this rule:

"Agency for Healthcare Research and Quality" or "AHRQ" means the agency within the U.S. Department of Health and Human Services which is responsible for establishing Clinical Practice Guidelines on various aspects of medical practice.

"American Academy of Pain Medicine" or "AAPM" means the American Medical Association-recognized specialty society of physicians who practice pain medicine in the United States. The mission of the AAPM is to enhance pain medicine practice by promoting a climate conducive to the effective and efficient practice of pain medicine.

"American Pain Society" or "APS" means the national chapter of the International Association for the Study of Pain, an organization composed of physicians, nurses, psychologists, scientists and other professionals who have an interest in the study and treatment of pain. The mission of the APS is to serve people in pain by advancing research, education, treatment and professional practice.

"Chronic, nonmalignant pain (i.e., not caused by cancer)" means persistent or episodic pain of a duration or intensity that adversely affects the functioning or well-being of a patient when (1) no relief or cure for the cause of pain is possible; (2) no relief or cure for the cause of pain has been found; or (3) relief or cure for the cause of pain through other medical procedures would adversely affect the well-being of the patient.

(CONTINUED ON NEXT PAGE)

(+) <u>CRITERION 4:</u> Encourages pain management



Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) <u>CRITERION 3:</u> Opioids are part of professional practice

(CONTINUED)

- 13.2(2) General provisions. Various controlled drugs, particularly opioid analgesics, can be safely and effectively utilized to control pain in certain patients. However, inappropriate prescribing of controlled substances can lead to, or accelerate, drug abuse and diversion. Therefore, the medical management of pain shall be based on a thorough knowledge of pain assessment, pain treatment, and concern for the patient.
- a. Treatment of acute pain and cancer pain. Physicians may refer to the Clinical Practice Guidelines published by the AHRQ for counsel on the proper treatment of acute pain and chronic pain associated with cancer. The AHRQ Clinical Practice Guidelines provide a sound, compassionate, and flexible approach to the management of pain in these patients.
- b. Treatment of chronic, nonmalignant pain. The basic premise underlying this rule is that various drugs, particularly opioid analgesics, may be useful for treating patients with chronic, nonmalignant pain in a safe, effective, and efficient manner when other efforts, including those by other practitioners or the patient, have failed to remove or effectively treat the pain. The board strongly recommends that physicians who have reservations about the use of drugs in the treatment of chronic, nonmalignant pain consult: Definitions Related to the Use of Opioids for the Treatment of Pain, a consensus document from the American Academy of Pain Medicine (AAPM), the American Pain Society (APS), and the American Society of Addiction Medicine (ASAM) (2001). Copies of the document are available from the AAPM (http://www.painmed.org), the APS (http://www.ampainsoc.org), the ASAM (http://www.asam.org), and the office of the board at 400 S.W. 8th Street, Suite C, Des Moines, lowa 50309-4686.
- **13.2(3)** Effective chronic, nonmalignant pain management. To ensure that pain is properly and promptly assessed and treated, a physician who prescribes or administers controlled substances to a patient for the treatment of chronic, nonmalignant pain shall exercise sound clinical judgment by establishing accordance with the following:
- a. Patient evaluation. A patient evaluation that includes a physical examination and a comprehensive medical history shall be conducted prior to the initiation of treatment. The evaluation shall also include an assessment of the pain, physical and psychological function, diagnostic studies, previous interventions, including medication history, substance abuse history and any underlying or coexisting conditions. Consultation/referral to a physician with expertise in pain medicine, addiction medicine or substance abuse counseling or a physician who specializes in the treatment of the area, system, or organ perceived to be the source of the pain may be warranted depending upon the expertise of the physician and the complexity of the presenting patient. Interdisciplinary evaluation is strongly encouraged.
- b. Treatment plan. The physician shall establish a comprehensive treatment plan that tailors drug therapy to the individual needs of the patient. To ensure proper evaluation of the success of the treatment, the plan shall clearly state the objectives of the treatment, for example, pain relief, or improved physical or psychosocial functioning. The treatment plan shall also indicate if any further diagnostic evaluations or treatments are planned and their purposes. The treatment plan shall also identify any other treatment modalities and rehabilitation programs utilized.
- c. Informed consent. The physician shall document discussion of the risks and benefits of controlled substances with the patient or person representing the patient.

(CONTINUED ON NEXT PAGE)

(+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

<u>CATEGORY A:</u> Issues related to healthcare professionals

COMMENT: Recognizes that the goals of pain treatment should extend beyond pain scores, to include improvements in patient functioning and quality of life.



Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

- d. Periodic review. The physician shall periodically review the course of drug treatment of the patient and the etiology of the pain. Modification or continuation of drug therapy by the physician shall be dependent upon evaluation of the patient's progress toward the objectives established in the treatment plan. The physician shall consider the appropriateness of continuing drug therapy and the use of other treatment modalities if periodic reviews indicate the objectives of the treatment plan are not being met or there is evidence of diversion or a pattern of substance abuse.
- e. Consultation/referral. The physician shall consider consultation with, or referral to, a physician with expertise in pain medicine, addiction medicine or substance abuse counseling, if the objectives of the treatment plan are not being met or there is evidence of diversion or a pattern of substance abuse.
- f. Documentation. The physician shall keep accurate, timely, and complete records that detail compliance with this subrule, including patient evaluation, diagnostic studies, treatment modalities, treatment plan, informed consent, periodic review, consultation, and any other relevant information about the patient's condition and treatment.
- g. Physician-patient agreements. Physicians treating patients at risk for substance abuse shall consider establishing physician-patient agreements that specify the rules for medication use and the consequences for misuse. In preparing agreements, a physician shall evaluate the case of each patient on its own merits, taking into account the nature of the risks to the patient and the potential benefits of treatment.
- h. Termination of care. The physician shall consider termination of patient care if there is evidence of diversion or a repeated pattern of substance abuse.



Pharmacy Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

THE TREATMENT OF PAIN

The mission of the lowa Board of Pharmacy Examiners is to promote, preserve and protect the public health, safety and welfare by fostering the provision of quality pharmaceutical care to all lowans. As part of that endeavor, the Board strives to ensure that all lowans have access to pain relief medication. Appropriate and effective use of pain medication can improve a patient's quality of life and reduce costs associated with inadequately treated pain, whether due to cancer or non-cancer origins. Inadequate pain control often results from a lack of knowledge and/or understanding of proper pain management by health care professionals and patients. All pharmacists should increase their knowledge of current medical standards for the treatment of pain, develop effective strategies for delivering pharmaceutical care to patients suffering from pain, and actively participate as a member of the health care team by providing pharmaceutical expertise to the patient, physician, nurse, and hospice provider or other careciver.

The Board recognizes that the use of controlled substances, including opioid analgesics, is often essential for adequate pain control. The sustained use of these drugs may result in physical and psychological dependence: thus care must be taken to balance these risks against the desired outcome of effective pain control. Health care professionals must remain alert to the fact that these drugs are subject to abuse and some patients will seek them for illegitimate uses.

Controlled substances shall only be dispensed for legitimate medical purposes. Dispensing controlled drugs to a patient without a legitimate medical purpose violates state and federal laws. Dispensing must be based on a valid prescription issued within currently accepted medical standards for the treatment of pain. Pharmacists who dispense such medications pursuant to a legitimate prescription and in conformance with the standard of care need not fear action by the Board. By participating as a member of the health care team, pharmacists can ensure quality pharmaceutical care for patients suffering from pain and can reduce the potential for drug diversion and abuse. Proper documentation of the patient's medical condition and clinical response to treatment provides a strong foundation for establishing optimal patient care.

(+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

CATEGORY A: Issues related to healthcare professionals

COMMENT: Recognizes the need for a multidisciplinary approach to pain management.

(-) <u>CRITERION 15:</u> Other provisions that may impede pain management

COMMENT: To what extent does physical dependence constitute a risk?

(+) <u>CRITERION 4:</u> Encourages pain management

(+) <u>CRITERION 3:</u> Opioids are part of professional practice

(+) <u>CRITERION 5:</u> Addresses fear of regulatory scrutiny



Assisting Suicide

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

<u>CATEGORY A:</u> Issues related to healthcare professionals

COMMENT: Clarifies for physicians that there is an important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment.

Iowa Code § 707A.3

707A.3 Acts or omissions not considered assisting suicide

1. A licensed health care professional who administers, prescribes, or dispenses medications or who performs or prescribes procedures to relieve another person's pain or discomfort, even if the medication or procedure may hasten or increase the risk of death, does not violate section 707A.2 unless the medications or procedures are intentionally or knowingly administered, prescribed, or dispensed with the primary intention of causing death.

KANSAS

Citations for Policies Evaluated

STATUTES

- Controlled Substances Act (No provisions found)
 Chapter 65. Public Health; Article 41. Controlled Substances; Uniform Controlled Substances Act
- Medical Practice Act
 Chapter 65. Public Health; Article 28. Healing Arts; Kansas Healing Arts Act
- PHARMACY PRACTICE ACT (No provisions found)
 Chapter 65. Public Health; Article 16. Regulation of Pharmacists
- Intractable Pain Treatment Act No policy found

REGULATIONS

- Controlled Substances Regulations (Part of Pharmacy Board Regulations) (No provisions found)
 Agency 68. Kansas State Board of Pharmacy; Article 20. Controlled Substances
- Medical Board Regulations (No provisions found)
 Agency 100. Kansas State Board of Healing Arts
- PHARMACY BOARD REGULATIONS (No provisions found)
 Agency 68. Kansas State Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

Medical Board Guideline

Kansas State Board of Healing Arts. *Guidelines for the Use of Controlled Substances for the Treatment of Pain.* Adopted: October 17, 1998.

JOINT BOARD POLICY STATEMENT

Kansas State Boards of Healing Arts, Nursing, and Pharmacy. Joint Policy Statement by the Boards of Healing Arts, Nursing, and Pharmacy on the Use of Controlled Substances for the Treatment of Pain. Adopted: July 17, 2002.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

PREVENTION OF ASSISTED SUICIDE

Chapter 60. Procedure, Civil; Article 44. Prevention of Assisted Suicide

Provisions that may ENHANCE pain management											
	1	2	3	4	5	6	7	8			
Criteria	Controlled substances are necessary for public health	Pain management is part of medical practice	Opioids are part of professional practice	Encourages pain management	Addresses fear of regulatory scrutiny	Prescription amount alone does not determine legitimacy	Physical dependence or analgesic tolerance are not confused with "addiction"	Other provisions that may enhance pain management			
STATUTES											
Controlled Substances Act ¹											
Medical Practice Act ¹											
Pharmacy Practice Act ¹											
Intractable Pain Treatment Act ²											
REGULATIONS	S										
Controlled Substances ¹											
Medical Board ¹											
Pharmacy Board ¹											
OTHER GOVE	RNMENTA	L POLICIES									
Medical Board Guideline		•	•	•	•	•	•	•			
Joint Board Policy Statement			•	•	•		•	•			
RELEVANT PO	LICIES OR	PROVISIO	NS IDENTIF	IED BY BOC	LEAN (KE	Y WORD)	SEARCHES				
Prevention of Assisted Suicide								•			

Prov	/ision	s that	may //	<i>NPEDE</i>	pain ı	manaç	gemen	
	9	10	11	12	13	14	15	16
Criteria	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act ¹								
Medical Practice Act								•
Pharmacy Practice Act ¹								
Intractable Pain Treatment Act ²								
REGULATIONS								
Controlled Substances ¹								
Medical Board ¹								
Pharmacy Board ¹								
OTHER GOVE	RNMENT	AL POLIC	IES					
Medical Board Guideline ¹								
Joint Board Policy Statement ¹								
RELEVANT PO	LICIES C	R PROVIS	SIONS IDEN	ITIFIED BY	BOOLE A	N (KEY W	ORD) SEAF	RCHES
Prevention of Assisted Suicide ¹								



Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(-) <u>CRITERION 16:</u> Provisions that are ambiguous

<u>CATEGORY A</u>: Arbitrary standards for legitimate prescribing

COMMENT: Comment: "Excessive" implies there is a limit, but the limit is not specified.

K.S.A. § 65-2837

65-2837. Professional incompetency, unprofessional conduct; definitions.

As used in K.S.A. 65-2836, and amendments thereto, and in this section:

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(23) Prescribing, dispensing, administering, distributing a prescription drug or substance, including a controlled substance, in an <u>excessive</u>, improper or inappropriate manner or quantity or not in the course of the licensee's professional practice.

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Medical Board Guideline

For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

GUIDELINES FOR THE USE OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN

Section 1: Preamble

The Kansas State Board of Healing Arts recognizes that principles of quality medical practice dictate that the people of the State of Kansas 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 Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about effective methods of pain treatment.

Inadequate pain control may result from physicians' lack of knowledge about pain management or an inadequate understanding of addiction. Fears of investigation or sanction by federal, state and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients. Accordingly, these guidelines have been developed to clarify the Board's position on pain control, specifically as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

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 be based on current knowledge and research and include the use of both pharmacologic and non-pharmacologic modalities. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity and duration of pain. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.

The Kansas State Board of Healing Arts is obligated under the laws of the State of Kansas to protect the public health and safety. The Board recognizes that 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. Physicians should be diligent in preventing the diversion of drugs for illegitimate purposes.

Physicians should not fear disciplinary action from the Board for prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice. The Board will consider prescribing, ordering, administering or dispensing controlled substances for pain to be for a legitimate medical purpose based on sound clinical grounds. All such prescribing must be based on clear documentation of unrelieved pain and in compliance with these guidelines. If such prescribing meets these criteria, the Board will support physicians whose use of controlled substances has been questioned by another regulatory or enforcement agency.

Allegations of improper prescribing of controlled substances for pain will be evaluated on a case-by-case basis. The board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these guidelines, if good cause is shown for such deviation. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs - including any improvement in functioning - and recognizing that some types of pain cannot be completely relieved.

(CONTINUED ON NEXT PAGE)

(+) <u>CRITERION 4:</u> Encourages pain management

(+) <u>CRITERION 5:</u> Addresses fear of regulatory scrutiny

(+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

CATEGORY A: Issues related to healthcare professionals

COMMENT:

Acknowledges the need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

(+) <u>CRITERION 2:</u> Pain management is part of medical practice

(+) <u>CRITERION 7:</u> Physical dependence or analgesic tolerance are not confused with "addiction"

(+) <u>CRITERION 3:</u> Opioids are part of professional practice



Medical Board Guideline

For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) <u>CRITERION 6:</u> Prescription amount alone does not determine legitimacy

[CONTINUED]

The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors. The following guidelines are not intended to define complete or best practice, but rather to communicate what the Board considers to be within the boundaries of professional practice.

Section II: Guidelines

The Board has adopted the following guidelines when evaluating the use of controlled substances for pain control:

1. Evaluation of the Patient

The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

2. Treatment Plan

The written treatment plan should state 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. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which pain is associated with physical and psychosocial impairment.

3. Informed Consent and Agreement for Treatment

The physician 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 incompetent. The patient should receive prescriptions from one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician may employ the use of a written agreement between physician and patient outlining patient responsibilities, including

- urine/serum medication levels screening when requested;
- number and frequency of all prescription refills; and
- reasons for which drug therapy may be discontinued (i.e., violation of agreement).

4. Periodic Review

At reasonable intervals based on the individual circumstances of the patient, the physician should review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy should depend on the physician's evaluation of progress toward stated treatment objectives, such as improvement in patient's pain intensity and improved physical and / or psychosocial function, i.e., ability to work, need of health care resources, activities of daily living and quality of social life. If treatment goals are not being achieved, despite medication adjustments, the physician should reevaluate the appropriateness of continued treatment. The physician should monitor patient compliance in medication usage and related treatment plans.

[CONTINUED ON NEXT PAGE]

(+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

CATEGORY A: Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should extend beyond pain scores, to include improvements in patient functioning and quality of life.



Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

5. Consultation

The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangement pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a co-morbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

6. Medical Records

The physician should comply with and meet the requirements of K.A.R. 100-24-1 in the maintenance of an adequate record for each patient.

7. Compliance With Controlled Substances Laws and Regulations

To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations.

Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:

Acute Pain

Acute pain is the normal, predicted physiological response to an adverse chemical, thermal or mechanical stimulus and is associated with surgery, trauma and acute illness. It is generally time-limited and is responsive to opioid therapy, among other therapies.

Addiction

Addiction is a neuro-behavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as "drug dependence" and "psychological dependence." Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

Analgesic Tolerance

Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Chronic Pain

A pain state which is persistent and in which the cause of the pain cannot be removed or otherwise treated. Chronic pain may be associated with a long-term incurable or intractable medical condition or disease.

Pain

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

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Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

Physical Dependence

Physical dependence on a controlled substance is a physiologic state of neuro-adaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.

Pseudo-Addiction

Pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

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.

Tolerance

Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect, or a reduced effect is observed with a constant dose.



Joint Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

JOINT POLICY STATEMENT BY THE BOARDS OF HEALING ARTS, NURSING, AND PHARMACY ON THE USE OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN

Section 1: Preamble

The Kansas Legislature created the Board of Healing Arts, the Board of Nursing, and the Board of Pharmacy to protect the public health, safety and welfare. Protection of the public necessitates reasonable regulation of health care providers who order, administer, or dispense drugs. The boards adopt this statement to help assure health care providers and patients and their families that it is the policy of this state to encourage competent comprehensive care for the treatment of pain. Guidelines by individual boards are appropriate to address issues related to particular professions.

The appropriate application of current knowledge and treatment modalities improves the quality of life for those patients who suffer from pain, and reduces the morbidity and costs associated with pain that is inappropriately treated. All health care providers who treat patients in pain, whether acute or chronic, and whether as a result of terminal illness or non-life-threatening injury or disease, should become knowledgeable about effective methods of pain treatment. The management of pain should include the use of both pharmacologic and non-pharmacologic modalities.

Inappropriate treatment of pain is a serious problem in the United States. Inappropriate treatment of pain includes nontreatment, <u>undertreatment</u>, overtreatment, and ineffective treatment. All persons who are experiencing pain should expect the appropriate assessment and management of pain while retaining the <u>right to refuse</u> treatment. A person's report of pain is the optimal standard upon which all pain management interventions are based. The goal of pain management is to reduce the individual's pain to the lowest level possible, while simultaneously increasing the individual's level of functioning to the greatest extent possible. The exact nature of these goals is determined jointly by the patient and the health care provider.

Prescribing, administering or dispensing controlled substances, including opioid analgesics, to treat pain is considered a legitimate medical purpose if based upon sound clinical grounds. Health care providers authorized by law to prescribe, administer or dispense drugs, including controlled substances, should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.

A board is under a duty to make an inquiry when it receives information contending that a health care provider treated pain inappropriately. Proper investigation is necessary in order to obtain relevant information. A health care provider should not construe any request for information as a presumption of misconduct. Prior to the filling of any allegations, the results of the investigation will be evaluated by the health care provider's peers who are familiar with this policy statement. Health care providers who competently treat pain should not fear disciplinary action from their licensing board.

The following guidelines are not intended to define complete or best practice, but rather to communicate what the boards consider to be within the boundaries of professional practice. This policy statement is not intended to interfere with any healthcare provider's professional duty to exercise that degree of learning and skill ordinarily possessed by competent members of the healthcare provider's profession.

Section II: Principles

The boards approve the following principles when evaluating the use of controlled substances for pain control

(CONTINUED ON NEXT PAGE)

(+) <u>CRITERION 4:</u> Encourages pain management

(+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

<u>CATEGORY B:</u> Issues related to patients

COMMENT: Recognizes the patient's right to request or reject different types of treatments.

(+) <u>CRITERION 7:</u> Physical dependence or analgesic tolerance are not confused with "addiction"

(+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

CATEGORY A: Issues related to healthcare professionals

COMMENT: Recognizes that inadequate treatment of pain is subject to disciplinary action just as other substandard practices might be.

(+) <u>CRITERION 3:</u> Opioids are part of professional practice

(+) <u>CRITERION 5:</u> Addresses fear of regulatory scrutiny



Joint Board Policy Statement

For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

1. Assessment of the Patient

Pain should be assessed and reassessed as clinically indicated. Interdisciplinary communications regarding a patient's report of pain should include adoption of a standardized scale for assessing pain.

2. Treatment Plan

The written treatment plan should state 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. After treatment begins, the drug therapy plan should be adjusted to the individual medical needs of each patient. The nurse's skill is best utilized when an order for drug administration uses dosage and frequency parameters that allow the nurse to adjust (titrate) medication dosage. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment. If, in a healthcare provider's sound professional judgement, pain should not be treated as requested by the patient, the healthcare provider should inform the patient of the basis for the treatment decisions and document the substance of this communication.

3. Informed Consent

The physician retains the ultimate responsibility for obtaining informed consent to treatment from the patient. All health care providers share the role of effectively communicating with the patient so that the patient is apprised of the risks and benefits of using controlled substances to treat pain.

4. Agreement for Treatment of High-Risk Patients

If the patient is determined to be at high risk for medication abuse or to have a history of substance abuse, the health care provider should consider requiring a written agreement by the patient outlining patient responsibilities, including:

- Submitting to screening of urine/serum medication levels when requested;
- · Limiting prescription refills only to a specified number and frequency;
- Requesting or receiving prescription orders from only one health care provider;
- Using only one pharmacy for filling prescriptions; and
- Acknowledging reasons for which the drug therapy may be discontinued (i.e., violation of agreement).

5. Periodic Review

At reasonable intervals based on the individual circumstances of the patient, the course of treatment and any new information about the etiology of the pain should be evaluated. Communication among health care providers is essential to review of the medical plan of care. The health care providers involved with the management of pain should evaluate progress toward meeting treatment objectives in light of improvement in patient's pain intensity and improved physical or psychosocial function, i.e., ability to work, need of health care resources, activities of daily living and quality of social life. If treatment goals are not being achieved despite medication adjustments, the health care provider's should reevaluate the appropriateness of continued treatment.

6. Consultation

The health care provider should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangement poses a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a co-morbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

[CONTINUED ON NEXT PAGE]

(+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

CATEGORY A: Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should extend beyond pain scores, to include improvements in patient functioning and quality of life.

management

<u>CATEGORY A:</u>

Issues related to

Other provisions that

may enhance pain

(+) CRITERION 8:

Issues related to healthcare professionals

COMMENT: Recognizes the need for a multidisciplinary approach to pain management.



Joint Board Policy Statement

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

[CONTINUED]

7. Medical Records

The medical record should document the nature and intensity of the pain and contain pertinent information concerning the patient's health history, including treatment for pain or other underlying or coexisting conditions. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

8. Compliance With Controlled Substances Laws and Regulations
To prescribe, dispense or administer controlled substances within this state, the health
care provider must be licensed according to the laws of this state and comply with
applicable federal and state laws.

Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:

Acute pain is the normal, predicted physiological response to an adverse chemical, thermal or mechanical stimulus and is associated with surgery, trauma and acute illness. It is generally time-limited and is responsive to opioid therapy, among other therapies

Addiction is a neuro-behavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to as "psychological dependence." Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction. Addiction must be distinguished from pseudoaddiciton, which is a pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Chronic pain is a pain state which is persistent beyond the usual course of an acute disease or a reasonable time for an injury to heal, or that is associated with a chronic pathologic process that causes continuous pain or pain that recurs at intervals for months or years.

Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical dependence on a controlled substance is a physiologic state of neuro-adaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.

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.

Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect, or a reduced effect is observed with a constant dose.



Prevention of Assisted Suicide

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

K.S.A. § 60-4403

60-4403. Standard of conduct of licensed health care professional related to assisting suicide; family member conduct; spiritual treatment.

(a) A licensed health care professional who administers, prescribes or dispenses medications or procedures to relieve another person's pain or discomfort, even if the medication or procedure may hasten or increase the risk of death, does not violate K.S.A. 21-3406 and amendments thereto unless the medications or procedures are knowingly administered, prescribed or dispensed with the intent to cause death. A midlevel practitioner as defined in subsection (ii) of K.S.A. 65-1626 and amendments thereto who prescribes medications or procedures to relieve another person's pain or discomfort, even if the medication or procedure may hasten or increase the risk of death, does not violate K.S.A. 21-3406 and amendments thereto unless the medications or procedures are knowingly prescribed with the intent to cause death.

(+) <u>CRITERION 8:</u>

Other provisions that may enhance pain management

CATEGORY A: Issues related to healthcare professionals

COMMENT: Clarifies for physicians that there is an important distinction between physicianassisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment.

 $Note: \ \underline{Underlining} \ and/or \ \underline{shading} \ was \ added \ to \ identify \ policy \ language \ meeting \ the \ corresponding \ criterion.$

KENTUCKY

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
 Title XVII. Public Health; Chapter 218A. Controlled Substances
- Medical Practice Act

Title XXVI. Occupations and Professions; Chapter 311. Physicians, Osteopaths, Podiatrists and Related Medical Practitioners

- PHARMACY PRACTICE ACT (No provisions found)
 Title XXVI. Occupations and Professions; Chapter 315. Pharmacists and Pharmacies
- Intractable Pain Treatment Act No policy found

REGULATIONS

- Controlled Substances Regulations (No provisions found)
 Title 902. Cabinet for Health and Family Services Department for Public Health; Chapter 55. Controlled Substances
- MEDICAL BOARD REGULATIONS (No provisions found)
 Title 201. General Government Cabinet; Chapter 9. Board of Medical Licensure
- PHARMACY BOARD REGULATIONS (No provisions found)
 Title 201. General Government Cabinet; Chapter 2. Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

Medical Board Guideline

Kentucky Board of Medical Licensure. *Guidelines for the Use of Controlled Substances in Pain Treatment.* Adopted: March 22, 2001; Amended: September 18, 2003.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

SUICIDE ASSISTANCE

Title XVII. Public Health; Chapter 216. Health Facilities and Services; Suicide Assistance



Prov	Provisions that may ENHANCE pain management											
	1	2	3	4	5	6	7	8				
Criteria	Controlled substances are necessary for public health	Pain management is part of medical practice	Opioids are part of professional practice	Encourages pain management	Addresses fear of regulatory scrutiny	Prescription amount alone does not determine legitimacy	Physical dependence or analgesic tolerance are not confused with "addiction"	Other provisions that may enhance pain management				
STATUTES												
Controlled Substances Act			•									
Medical Practice Act ¹												
Pharmacy Practice Act ¹												
Intractable Pain Treatment Act ²												
REGULATIONS	S											
Controlled Substances ¹												
Medical Board ¹												
Pharmacy Board ¹												
OTHER GOVE	RNMENTA	L POLICIES										
Medical Board Guideline		•	•	•	•	•	•	•				
RELEVANT PO	RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES											
Suicide Assistance								•				

Provisions that may IMPEDE pain management										
	9	10	11	12	13	14	15	16		
Criteria	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous		
STATUTES										
Controlled Substances Act ¹										
Medical Practice Act								•		
Pharmacy Practice Act ¹										
Intractable Pain Treatment Act ²										
REGULATIONS										
Controlled Substances ¹										
Medical Board ¹										
Pharmacy Board ¹										
OTHER GOVER	RNMENT	AL POLIC	IES							
Medical Board Guideline	•									
RELEVANT PO	RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES									
Suicide Assistance ¹										



Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

KRS § 218A.010

218A.010. Definitions for chapter.

As used in this chapter:

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(+) <u>CRITERION 3:</u> Opioids are part of professional practice (26) "Practitioner" means a physician, dentist, podiatrist, veterinarian, scientific investigator, optometrist as authorized in KRS 320.240, or other person licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this state. "Practitioner" also includes a physician, dentist, podiatrist, or veterinarian who is a resident of and actively practicing in a state other than Kentucky and who is licensed and has prescriptive authority for controlled substances under the professional licensing laws of another state, unless the person's Kentucky license has been revoked, suspended, restricted, or probated, in which case the terms of the Kentucky license shall prevail.

STATUTES

Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

KRS § 311.597

§ 311.597. Acts declared to constitute dishonorable, unethical, or unprofessional conduct

As used in KRS 311.595(9), "dishonorable, unethical, or unprofessional conduct of a character likely to deceive, defraud, or harm the public or any member thereof" shall include, but not be limited to, the following acts by a licensee:

(1) Prescribes or dispenses any medication:

.

(d) In such amounts that the licensee knows or has reason to know, under the attendant circumstances, that said amounts so prescribed or dispensed are <u>excessive</u> under accepted and prevailing medical practice standards.

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(-) <u>CRITERION 16:</u> Provisions that are ambiguous

CATEGORY A: Arbitrary standards for legitimate prescribing

COMMENT: "Excessive" implies there is a limit, but the limit is not specified.



Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

GUIDELINES FOR THE USE OF CONTROLLED SUBSTANCES IN PAIN TREATMENT

Introduction

The Kentucky Board of Medical Licensure (KBML) recognizes that principles of quality medical practice dictate that the people of Kentucky have access to appropriate and effective pain relief. The appropriate application of state-of-the-art treatment modalities can serve not only to improve the quality of life for those patients who suffer from pain but also can reduce the morbidity and costs associated with inappropriately treated pain. The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic. Pain management is particularly important for patients who experience pain as a result of terminal illness and can be difficult for patients with chronic nonterminal pain. It is imperative that physicians become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

Inadequate pain control may result either from physicians' lack of knowledge about pain management or their misunderstanding of addiction. Fears of investigation or sanction by federal, state, and local regulatory agencies may also result in inappropriate or inadequate treatment of the pain patient. Accordingly, these guidelines have been developed to clarify the Board's position on pain control, especially as related to the use of controlled substances for nonterminal/nonmalignant chronic pain, in order to alleviate physician uncertainty and to encourage better pain management.

The Board recognizes that controlled substances (including opioid analgesics, benzodiazepines, and stimulants) may be essential in the treatment of acute pain and chronic pain, whether due to cancer or noncancer origins. Physicians are referred to the US Agency for Health Care Policy and Research Clinical Practice Guidelines¹ for a sound approach to the management of acute and chronic, malignant and non-malignant pain. The medical management of pain should be based on current knowledge and research and includes the use of both pharmacological and non-pharmacological modalities. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction. Addiction refers to both dependence on the use of substances for the drug's psychic effects and compulsive use of the drug despite consequences.

The KBML is obligated under the laws of the state of Kentucky to protect the public health and safety. The Board recognizes that the inappropriate prescribing of controlled substances may lead to drug diversion and abuse by individuals who seek the drugs for other than legitimate medical use. Physicians must be diligent in preventing the diversion of drugs for illegitimate purposes. The Board believes the adoption of these quidelines will protect legitimate medical uses of controlled substances, while helping to prevent drug diversion and eliminating inappropriate prescribing practices.

Physicians should not fear disciplinary action from the Board for prescribing controlled substances for a legitimate medical purpose and in the usual course of professional practice. The Board will consider the prescribing of controlled substances for pain a legitimate medical purpose if such prescribing is (1) based on accepted scientific knowledge of pain treatment and (2) if based on sound clinical grounds. All such prescribing must be grounded in clear documentation of unrelieved pain and in compliance with applicable state or federal law.

(CONTINUED ON NEXT PAGE)

(+) <u>CRITERION 4:</u> Encourages Pain Management

(+) CRITERION 7: Physical dependence or analgesic tolerance are not confused with "addiction"

(+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

<u>CATEGORY C:</u> Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

(+) <u>CRITERION 5:</u> Addresses fear of regulatory scrutiny

(+) CRITERION 2:

Pain management is

part of medical practice

(+) <u>CRITERION 3:</u> Opioids are part of professional practice



Medical Board Guideline

For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile

(CONTINUED)

Each case of prescribing for pain will be evaluated on an individual basis if and when brought to the Board's attention. The Board does not take disciplinary action against a physician who fails to adhere strictly to the provisions of these quidelines if good cause is shown for such deviation. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account: (1) whether or not the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis; (2) the patient's individual needs-including improvement in functioning; and (3) a recognition that some types of pain cannot be completely relieved.

The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than only on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors. The following guidelines are not intended to define complete or best practice, but rather to communicate what the Board considers to be within acceptable boundaries of professional practice when prescribing for recurrent or persistent chronic pain. The prescribing guidelines for acute pain would be appropriately less stringent but, in principle, the same.

Guidelines

(+) CRITERION 6:

alone does not

(+) CRITERION 8:

management

CATEGORY A:

auality of life.

Issues related to healthcare professionals

COMMENT: Recognizes

treatment should extend beyond pain scores, to

include improvements in patient functioning and

that the goals of pain

Prescription amount

determine legitimacy

Other provisions that

may enhance pain

The Kentucky Board of Medical Licensure has adopted the following guidelines when evaluating the use of controlled substances for control of recurrent or chronic pain.

1. Evaluation of the Patient

A complete medical history and physical examination must be conducted and documented in the medical record. A family history should be documented with particular reference to any history of first degree relative with chemical dependence problems. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of any substance abuse. The medical record also should document the presence of one or more recognized medical indication(s) for the use of a controlled substance.

By definition, pain is a *subjective* statement of a patient's perception of actual or potential tissue damage. The distinction between pain and suffering should be established. A patient may suffer due to pain, but may have other reasons for suffering as well. The assessment of a patient's overall condition should be made at the initial evaluation and thereafter. It is the goal of the physician to assist in the relief of suffering no matter the cause. Financial, emotional, mental, physical, and spiritual factors may contribute to the patient's suffering. Relief of the underlying reasons for suffering as well as the pain will lead to optimal treatment and utilization of controlled substances.

Before beginning a regimen of controlled drugs, the physician must determine, through actual clinical trial or through patient records and history that non-addictive medication regimens have been inadequate or are unacceptable for solid clinical reasons. Speaking with the patient's significant other or conducting a family conference can be helpful if there is any doubt regarding the patient's integrity. Utilizing the Kentucky All Schedule Prescription Electronic Reporting [i.e., KASPER Report] initially can also aid in documenting the patient's history of drug utilization.

(CONTINUED ON NEXT PAGE)

(+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

<u>CATEGORY A:</u> Issues related to healthcare professionals

COMMENT:

Acknowledges the need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

(-) <u>CRITERION 9:</u> Opioids are a last resort



Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

2. Treatment Plan

The written treatment plan should state 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, consultations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

3. Informed Consents and Treatment Agreements

The physician should discuss the risks and benefits of the use of controlled substances with the patient or his / her surrogate, including the risk of tolerance and drug dependence. If the patient is determined to be at *high risk* for medication abuse or has a history of substance abuse, the physician may employ the use of a written *agreement* between physician and patient outlining patient responsibilities, including:

- One prescribing doctor and one designated pharmacy.
- Urine / serum drug screening when requested.
- No early refills and no medications called in. If medications are lost or stolen, then a police report could be required before considering additional prescriptions.
- The reasons for which drug therapy may be is continued such as violation of a documented doctor-patient agreement.

4. Periodic Review

At reasonable intervals based on the individual circumstances of the patient, the physician should review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy should depend on the physician's evaluation of progress toward stated treatment objectives such as reduction in patient's pain intensity and improved physical and / or psychosocial function (i.e., ability to work), need of health care resources, activities of daily living, and quality of social life. If treatment goals are not being achieved despite medication adjustments, the physician should reevaluate the appropriateness of continued treatment. The physician should monitor patient compliance in medication usage and related treatment plans. Periodic requests for a KASPER Report could be utilized.

5. Consultation

The physician should be willing to refer the patient as clinically indicated for additional evaluation and in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a coexisting psychiatric disorder may require extra care, monitoring, documentation, and consultation with or referral to an expert in the management of such patients.

(CONTINUED ON NEXT PAGE)



OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

6. Medical Records

The physician should keep accurate and complete records, to include:

The medical history and physical examination;

Diagnostic, therapeutic, and laboratory results;

Evaluations and consultations;

Treatment objectives;

Discussion of risk, benefits, and limitation of treatments;

Treatments:

Medications (including date, type, dosage, and quantity prescribed);

Instructions and agreements;

Periodic reviews; and

Records should remain current and be maintained in an accessible manner and readily available for review.

Initial or periodic **KASPER Report(s)** should not be part of the patient's records and should not be released to the patient or a third party.

7. Compliance with Controlled Substances Laws and Regulations

To prescribe, dispense, or administer controlled substances, the physician must have an active license in the state and comply with applicable federal and state regulations. Kentucky physicians can refer to prior Board-published recommendations for prescribing Scheduled II drugs including opioids³, benzodiazepines⁴, and stimulants⁵.

Physicians should studiously <u>avoid</u> prescribing scheduled drugs for themselves, immediate family, or staff in accordance with the American Medical Association's Code of Medical Ethics and the KRS Medical Practice Act.

Conclusion

By publishing these guidelines, the KBML wishes to encourage Kentucky physicians to utilize adequate medications to treat their patients with serious pain complaints without undue fear of legal or licensure repercussions. Concurrently, the Board strives to prevent as much as possible, drug diversion and inappropriate prescribing practices.



Suicide Assistance

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

<u>CATEGORY A:</u> Issues related to healthcare professionals

COMMENT: Clarifies for physicians that there is an important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment.

KRS § 216.304

§ 216.304. Actions of licensed health care professional that are not violative of KRS 216.302

(1) A licensed health care professional who administers, prescribes, or dispenses medications or procedures to relieve another person's pain or discomfort, even if the medication or procedure may hasten or increase the risk of death, shall not be deemed to have violated KRS 216.302 unless the medications or procedures are knowingly and intentionally administered, prescribed, or dispensed to cause death.

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LOUISIANA

Citations for Policies Evaluated

STATUTES

- Controlled Substances Act
 - Title 40. Public Health and Safety; Chapter 4. Food and Drugs; Part 10. Uniform Controlled Substances Law
- MEDICAL PRACTICE ACT (No provisions found)
 Title 37. Professions and Occupations; Chapter 15. Physicians, Surgeons, and Midwives;
- PHARMACY PRACTICE ACT
 Title 37. Professions and Occupations; Chapter 14. Louisiana Pharmacy Practice Act
- Intractable Pain Treatment Act No policy found

REGULATIONS

- Controlled Substances Regulations (Part of Pharmacy Board Regulations) (No provisions found)
 Title 46. Professional and Occupational Standards; Part LIII. Pharmacists; Chapter 35.
 Pharmacy Prescription Drugs
- Medical Board Regulations
 Title 46. Professional and Occupational Standards; Part XLV. Medical Professions
- PHARMACY BOARD REGULATIONS (No provisions found)
 Title 46. Professional and Occupational Standards; Part LIII. Pharmacists

OTHER GOVERNMENTAL POLICIES

No policies found

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

Pain Management Clinics

Title 40. Public Health and Safety; Chapter 11. State Department of Hospitals; Part 12-A. Pain Management Clinics



Provisions that may ENHANCE pain management											
	1	2	3	4	5	6	7	8			
Criteria	Controlled substances are necessary for public health	Pain management is part of medical practice	Opioids are part of professional practice	Encourages pain management	Addresses fear of regulatory scrutiny	Prescription amount alone does not determine legitimacy	Physical dependence or analgesic tolerance are not confused with "addiction"	Other provisions that may enhance pain management			
STATUTES											
Controlled Substances Act			•				•				
Medical Practice Act ¹											
Pharmacy Practice Act			•								
Intractable Pain Treatment Act ²											
REGULATIONS	5										
Controlled Substances ¹											
Medical Board		•	•				•	•			
Pharmacy Board ¹											
OTHER GOVE	OTHER GOVERNMENTAL POLICIES ²										
RELEVANT PO	LICIES OR	PROVISIO	NS IDENTIF	IED BY BOC	LEAN (KE	Y WORD)	SEARCHES				
Pain management clinics ¹											

Prov	/ision	s that	may //	<i>NPEDE</i>	pain ı	manaç	gement				
	9	10	11	12	13	14	15	16			
Criteria	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous			
STATUTES											
Controlled Substances Act			•								
Medical Practice Act ¹											
Pharmacy Practice Act ¹											
Intractable Pain Treatment Act ²											
REGULATIONS											
Controlled Substances ¹											
Medical Board	•	•									
Pharmacy Board ¹											
OTHER GOVER	OTHER GOVERNMENTAL POLICIES ²										
RELEVANT PO	RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES										
Pain management clinics				•							



Controlled Substances Act

For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

La. R.S. 40:961

961. Definitions

As used in this Part, the following terms shall have the meaning ascribed to them in this Section unless the context clearly indicates otherwise:

(18) "Drug dependent person" means a person who is using a controlled dangerous substance and who is in a state of psychic or physical dependence, or both, arising from administration of that controlled dangerous substance on a continuous basis. Drug dependence is characterized by behavioral and other responses which include a strong compulsion to take the substance on a continuous basis in order to experience its psychic effects, or to avoid the discomfort of its absence.

(-) CRITERION 11: Physical dependence or analgesic tolerance confused with "addiction"

La. R.S. 40:961

§ 40:961. Definitions

As used in this Part, the following terms shall have the meaning ascribed to them in this Section unless the context clearly indicates otherwise:

(+) CRITERION 3:

Opioids are part of

professional practice

(31) "Practitioner" means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or administer a controlled dangerous substance in the course of professional practice or research in this state.

(38) "Substance abuse" or "addiction" means a compulsive disorder in which an individual becomes preoccupied with obtaining and using a substance, despite adverse social, psychological, or physical consequences, the continued use of which results in a decreased quality of life. The development of controlled dangerous substance tolerance or physical dependence does not equate with substance abuse or addiction

(+) CRITERION 7: Physical dependence or analgesic tolerance are not confused with "addiction"



Pharmacy Practice Act
- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

La. R.S. 37:1164

§ 37:1164. Definitions

As used in this Chapter, the following terms have the meaning ascribed to them by this Section:

(+) <u>CRITERION 3:</u> Opioids are part of professional practice

(42) "Practitioner" means an individual currently licensed, registered, or otherwise authorized by the appropriate licensing board to <u>prescribe and administer drugs in the course of professional practice</u>.



Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

LAC 46:XLV 6915-6923 (non-seq)

§ 6915. Scope of Subchapter

The rules of this subchapter govern physician responsibility for providing effective and safe pain control for patients with noncancer-related chronic or intractable pain.

§ 6917. Definitions

As used in this subchapter, unless the content clearly states otherwise, the following terms and phrases shall have the meanings specified:

Board--the Louisiana State Board of Medical Examiners.

Chronic Pain--pain which persists beyond the usual course of a disease, beyond the expected time for healing from bodily trauma, or pain associated with a long-term incurable or intractable medical illness or disease.

Controlled Substance--any substance defined, enumerated, or included in federal or state statute or regulations 21 C.F.R. §§ 1308.11-15 or R.S. 40:964, or any substance which may hereafter be designated as a controlled substance by amendment or supplementation of such regulations and statute.

Diversion--the conveyance of a controlled substance to a person other than the person to whom the drug was prescribed or dispensed by a physician.

Intractable Pain--a chronic pain state in which the cause of the pain cannot be eliminated or successfully treated without the use of controlled substance therapy and, which in the generally accepted course of medical practice, no cure of the cause of pain is possible or no cure has been achieved after reasonable efforts have been attempted and documented in the patient's medical record.

Noncancer-Related Pain--that pain which is not directly related to symptomatic cancer.

Physical Dependence—the physiological state of neuroadaptation to controlled substance which is characterized by the emergence of a withdrawal syndrome if the controlled substance use is stopped or decreased abruptly, or if an antagonist is administered. Withdrawal may be relieved by readministration of the controlled substance.

Physician--physicians and surgeons licensed by the Board.

Protracted Basis--utilization of any controlled substance for the treatment of noncancerrelated chronic or intractable pain for a period in excess of 12 weeks during any 12month period.

Substance Abuse (may also be referred to by the term Addiction)—a compulsive disorder in which an individual becomes preoccupied with obtaining and using a substance, despite adverse social, psychological, and/or physical consequences, the continued use of which results in a decreased quality of life. Ihe development of controlled substance tolerance or physical dependence does not equate with substance abuse or addiction.

(CONTINUED ON NEXT PAGE)

(+) <u>CRITERION 7:</u> Physical dependence or analgesic tolerance are not confused with "addiction" (-) <u>CRITERION 10:</u> Implies opioids are not part of professional practice



Medical Board Regulations

For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile

(CONTINUED)

Tolerance–refers to the physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect or a reduced effect is observed with a constant dose. Controlled substance tolerance refers to the need to increase the dose of the drug to achieve the same level of analgesia. Controlled substance tolerance may or may not be evident during controlled substance treatment.

§ 6919. General Conditions/Prohibitions

The treatment of noncancer-related chronic or intractable pain with controlled substances constitutes legitimate medical therapy when provided in the course of professional medical practice and when fully documented in the patient's medical record. A physician duly authorized to practice medicine in Louisiana and to prescribe controlled substances in this state shall not, however, prescribe, dispense, administer, supply, sell, give, or otherwise use for the purpose of treating such pain, any controlled substance unless done in strict compliance with applicable state and federal laws and the rules enumerated in this subchapter.

§ 6921. Use of Controlled Substances, Limitations

A. Requisite Prior Conditions. In utilizing any controlled substance for the treatment of noncancer-related chronic or intractable pain on a protracted basis, a physician shall comply with the following rules:

- 1. Evaluation of the Patient. Evaluation of the patient shall initially include relevant medical, pain, alcohol and substance abuse histories, an assessment of the impact of pain on the <u>patient's physical and psychological functions</u>, a review of previous diagnostic studies, previously utilized therapies, an assessment of coexisting illnesses, diseases, or conditions, and an appropriate physical examination.
- 2. Medical Diagnosis. A medical diagnosis shall be established and fully documented in the patient's medical record, which indicates not only the presence of noncancer-related chronic or intractable pain, but also the nature of the underlying disease and pain mechanism if such are determinable.
- 3. Treatment Plan. An individualized treatment plan shall be formulated and documented in the patient's medical record which includes medical justification for controlled substance therapy. Such plan shall include documentation that other medically reasonable alternative treatments for relief of the patient's noncancer-related chronic or intractable pain have been considered or attempted without adequate or reasonable success. Such plan shall specify the intended role of controlled substance therapy within the overall plan, which therapy shall be tailored to the individual medical needs of each patient.
- 4. Informed Consent. A physician shall ensure that the patient and/or his guardian is informed of the benefits and risks of controlled substance therapy. Discussions of risks and benefits should be noted in some format in the patient's record.
- B. Controlled Substance Therapy. Upon completion and satisfaction of the conditions prescribed in §6921.A, and upon a physician's judgment that the prescription, dispensation, or administration of a controlled substance is medically warranted, a physician shall adhere to the following rules.

(CONTINUED ON NEXT PAGE)

(+) <u>CRITERION 3:</u> Opioids are part of professional practice

(+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

CATEGORY A: Issues related to healthcare professionals

COMMENT: Recognizes that the goals of pain treatment should extend beyond pain scores, to include improvements in patient functioning and quality of life.

(-) <u>CRITERION 9:</u> Opioids are a last resort

(+) CRITERION 2:

of medical practice

Pain management is part



Medical Board Regulations

For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile

(CONTINUED)

- 1. Assessment of Treatment Efficacy and Monitoring. Patients shall be seen by the physician at appropriate intervals, not to exceed 12 weeks, to assess the efficacy of treatment, assure that controlled substance therapy remains indicated, and evaluate the patient's progress toward treatment objectives and any adverse drug effects. Exceptions to this interval shall be adequately documented in the patient's record. During each visit, attention shall be given to the possibility of decreased function or quality of life as a result of controlled substance treatment. Indications of substance abuse or diversion should also be evaluated. At each visit, the physician should seek evidence of under treatment of pain.
- 2. Drug Screen. If a physician reasonably believes that the patient is suffering from substance abuse or that he is diverting controlled substances, the physician shall obtain a drug screen on the patient. It is within the physician's discretion to decide the nature of the screen and which type of drug(s) to be screened.
- 3. Responsibility for Treatment. A single physician shall take primary responsibility for the controlled substance therapy employed by him in the treatment of a patient's noncancer-related chronic or intractable pain.
- 4. Consultation. The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation, and consultation with or referral to an expert in the management of such patients.
- 5. Medications Employed. A physician shall document in the patient's medical record the medical necessity for the use of more than one type or schedule of controlled substance employed in the management of a patient's noncancer-related chronic or intractable pain.
- 6. Treatment Records. A physician shall document and maintain in the patient's medical record, accurate and complete records of history, physical and other examinations and evaluations, consultations, laboratory and diagnostic reports, treatment plans and objectives, controlled substance and other medication therapy, informed consents, periodic assessments, and reviews and the results of all other attempts at analgesia which he has employed alternative to controlled substance therapy.
- 7. Documentation of Controlled Substance Therapy. At a minimum, a physician shall document in the patient's medical record the date, quantity, dosage, route, frequency of administration, the number of controlled substance refills authorized, as well as the frequency of visits to obtain refills.
- C. Termination of Controlled Substance Therapy. Evidence or behavioral indications of substance abuse or diversion of controlled substances shall be followed by tapering and discontinuation of controlled substance therapy. Such therapy shall be reinitiated only after referral to and written concurrence of the medical necessity of continued controlled substance therapy by an addiction medicine specialist, a pain management specialist, a psychiatrist, or other substance abuse specialist based upon his physical examination of the patient and a review of the referring physician's medical record of the patient.

§ 6923. Effect of Violation

Any violation of or failure of compliance with the provisions of this subchapter, §§6915-6923, shall be deemed a violation of R.S. 37:1285(A)(6) and (14), providing cause for the board to suspend or revoke, refuse to issue, or impose probationary or other restrictions on any license held or applied for by a physician to practice medicine in the state of Louisiana culpable of such violation.



Pain Management Clinics

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

La. R.S. 40:2198.12

§ 40:2198.12. Licensure of pain management clinics; rules and regulations

A. Except as provided in Subsection D of this Section, all pain management clinics shall be owned and operated by a physician certified in the subspecialty of pain management by a member board of the American Boards of Medical Specialties.

- B. (1) The department shall prescribe and publish minimum standards, rules, and regulations as necessary to effectuate the provisions of this Section. Such rules and regulations shall include but not be limited to all of the following:
 - (a) Operational and personnel requirements.
- (b) Practice standards to assure quality of care, including the requirement that prescriptions may be written for the medication to last a period of <u>no longer than thirty days</u> without any refills. A refill may be authorized only if the individual is personally examined by the pain specialist.

(-) <u>CRITERION 12:</u> Medical decisions are restricted

<u>CATEGORY C</u>: Restrictions regarding quantity prescribed or dispensed

MAINE

Citations for Policies Evaluated

STATUTES

- Controlled Substances Act No policy found
- MEDICAL PRACTICE ACT (No provisions found)
 Title 32. Professions and Occupations; Chapter 48. Board of Licensure in Medicine
- OSTEOPATHIC PRACTICE ACT (No provisions found)
 Title 32. Professions and Occupations; Chapter 36. Osteopathic Physicians
- PHARMACY PRACTICE ACT
 Title 32. Professions and Occupations; Chapter 117. Maine Pharmacy Act
- Intractable Pain Treatment Act No policy found

REGULATIONS

- Controlled Substances Regulations (No provisions found)
 - Agency 16. Department of Public Safety; Sub-Agency 230. Maine Drug Enforcement Agency; Chapter 001. Requirements for written prescriptions of Schedule II drugs
- Medical Board Regulations
 - Agency 02. Department of Professional and Financial Regulation; Sub-Agency 373. Board of Licensure in Medicine
- OSTEOPATHIC BOARD REGULATIONS (No provisions found)
 - Agency 02. Department of Professional and Financial Regulation; Sub-Agency 383. Osteopathic Licensure Board
- PHARMACY BOARD REGULATIONS (No provisions found)
 - Agency 02. Department of Professional and Financial Regulation; Sub-Agency 392. Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

No policies found

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- Controlled Substances Prescription Monitoring
 - Title 22. Health and Welfare; Subtitle 4. Human Services; Part 3. Drug Abuse; Chapter 1603. Controlled Substances Prescription Monitoring
- HOSPICE LICENSING
 - Agency 10. Department of Health and Human Services; Sub-Agency 144. General; Chapter 120. Regulations Governing the Licensing and Functioning of Hospice Programs



Provisions that may ENHANCE pain management										
	1	2	3	4	5	6	7	8		
Criteria	Controlled substances are necessary for public health	Pain management is part of medical practice	Opioids are part of professional practice	Encourages pain management	Addresses fear of regulatory scrutiny	Prescription amount alone does not determine legitimacy	Physical dependence or analgesic tolerance are not confused with "addiction"	Other provisions that may enhance pain management		
STATUTES										
Controlled Substances Act ¹										
Medical Practice Act ¹										
Osteopathic Practice Act ¹										
Pharmacy Practice Act			•							
Intractable Pain Treatment Act ²										
REGULATIONS	S	l	ı	<u>'</u>	<u>'</u>	ı	l	<u> </u>		
Controlled Substances ¹										
Medical Board		•	•	•	•		•	•		
Osteopathic Board ¹										
Pharmacy Board ¹										
OTHER GOVE	RNMENTA	L POLICIES ²	2							
RELEVANT PO	LICIES OR	PROVISIO	NS IDENTIF	IED BY BOC	LEAN (KE	Y WORD)	SEARCHES			
Controlled Substances Prescription Monitoring								•		
Hospice Licensing								•		

Prov	vision	s that	may //	ЛРЕDE	pain ı	manaç	gemen	t
	9	10	11	12	13	14	15	16
Criteria	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act ¹								
Medical Practice Act ¹								
Osteopathic Practice Act ¹								
Pharmacy Practice Act ¹								
Intractable Pain Treatment Act ²								
REGULATIONS	S							
Controlled Substances ¹								
Medical Board ¹								
Osteopathic Board ¹								
Pharmacy Board ¹								
OTHER GOVE	RNMENT	AL POLIC	IES ²					
RELEVANT PO	LICIES C	R PROVIS	SIONS IDEN	ITIFIED BY	/ BOOLE	N (KEY W	ORD) SEAF	RCHES
Controlled Substances Prescription Monitoring ¹								
Hospice Licensing ¹								



Pharmacy Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

\$ 13702. Definitions

As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings.

23. PRACTITIONER. "Practitioner" means an individual who is licensed, registered or otherwise authorized in the appropriate jurisdiction to prescribe and administer drugs in the course of professional practice.

(+) <u>CRITERION 3:</u> Opioids are part of professional practice



Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

CMR 02-373-011

02 373 011 Use of Controlled Substances for Treatment of Pain

(+) CRITERION 2:

(+) CRITERION 4:

Encourages pain

management

of medical practice

Pain management is part

Preamble: The Boards recognize that principles of quality medical practice dictate that the people of the State of Maine have access to appropriate and effective pain relief.

The Boards acknowledge 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. Fears of investigation by federal, state and local regulatory agencies should not preclude appropriate and adequate treatment of chronic pain patients. However, the Boards recognize that 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.

The Boards encourage physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and as especially important for patients who experience pain as a result of a terminal illness. All physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

Accordingly, the Boards adopt these rules to clarify their positions on pain control and prescribing, specifically related to the use of controlled substances, to alleviate physician uncertainty and to encourage-better-pain-management.

- § 1. Definitions: As used by the Boards when evaluating practice and prescribing issues.
- A. "Acute Pain" is the normal, predicted physiological response to an adverse chemical, thermal, or mechanical stimulus and is associated with surgery, trauma and acute illness. It is generally time limited and is responsive to controlled substances therapy, among other therapies.
- B. "Addiction" is a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as "drug dependence" and "psychological dependence." Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.
- C. "Analgesic Tolerance" is the need to increase the dose of controlled substances to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.
- D. "Chronic Pain" is a pain state which is persistent and in which the cause of the pain cannot be removed or otherwise treated. Chronic pain may be associated with a long-term incurable or intractable medical condition or disease.
- E. "Pain" is an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.
- F. "Physical Dependence" on a controlled substance is a physiologic state of neuroadaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.

(CONTINUED ON NEXT PAGE)

(+) <u>CRITERION 3:</u> Opioids are part of professional practice

(+) <u>CRITERION 5:</u> Addresses fear of regulatory scrutiny

(+) <u>CRITERION 7:</u> Physical dependence or analgesic tolerance are not confused with "addiction"



Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

- G. "Pseudoaddiction" is a pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.
- H. "Substance Abuse" is the use of any controlled substance(s) for non-therapeutic purposes; or use of medication for purposes other than those for which it is prescribed.
- I. "Tolerance" is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect or a reduced effect is observed with a constant dose.
- § 2. Principles of Proper Patient Management: Each of these principles is essential in the treatment of patients with pain.
- A. Evaluation of the Patient: Evaluation should initially include a pain history and assessment of the impact of pain on the patient, a directed physical examination, a review of previous diagnostic studies, a review of previous interventions, a drug history, and an assessment of coexisting diseases or conditions.
- B. Treatment Plan: Treatment planning should be tailored to both the individual and the presenting problem. Consideration should be given to different treatment modalities, such as a formal pain rehabilitation program, the use of behavioral strategies, the use of non-invasive techniques, or the use of medications, depending upon the physical and psychosocial impairment related to the pain. If a trial of controlled substances is selected, the physician should ensure that the patient or the patient's legally authorized representative is informed of the risks and benefits of controlled substance use and the conditions under which controlled substances will be prescribed. Some practitioners find a written agreement specifying these conditions to be useful. A controlled substances trial should not be done in the absence of a complete assessment of the pain complaint.
- If the evaluation cannot be completed at the initial visit, controlled substances should only be prescribed in limited quantities, until completion of the evaluation, using the best judgment of the prescribing practitioner based on the information available.
- In the instance of chronic end of life pain, please see Section 3.
- C. Informed Consent and Agreement for Treatment: The physician should discuss treatment with the patient, persons designated by the patient, or with the patient's legally authorized representative if the patient is incompetent. The patient should receive prescriptions from one physician and one pharmacy, where possible. If the patient is determined to be at high risk for medication abuse or has a history of substance abuse, the physician may employ the use of a written agreement between physician and patient outlining patient responsibilities. Suggested elements of such an agreement are provided in Appendix 1.
- D. Consultation: The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a co-morbid psychiatric disorder may require extra care, monitoring, documentation, and consultation with or referral to an expert in the management of such patients.

(CONTINUED ON NEXT PAGE)



Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

- E. Periodic review of treatment efficacy: Review of treatment efficacy should occur periodically to assess the <u>functional status of the patient</u>, continued analgesia, controlled substances side effects, <u>quality of life</u> and indications of medications abuse. Periodic re-examination is warranted to assess the nature of the pain complaint and to ensure that controlled substances therapy is still indicated. Attention should be given to the possibility of a decrease in global function or quality of life as a result of controlled substance abuse.
- F. Documentation: Documentation is essential for supporting the evaluation, the reason for controlled substance prescribing, the overall pain management treatment plan, any consultations received, and periodic review of the status of the patient. The physician should document drug treatment outcomes and rationale for changes.

Every prescription must be clearly documented in the patient record. All written prescriptions must include name, address, drug name, amount prescribed, as well as instructions.

- G. Reportable Acts: Information gained as part of the doctor/patient relationship, even if it gives knowledge of possible criminal acts, remains part of the confidential doctor/patient relationship. This needs to be contrasted with persons who use the physician to perpetrate illegal acts such as illegal acquisition or selling of drugs, etc. The physician has an obligation to deal with this behavior up to and including reporting to law enforcement. Reports from other providers, such as pharmacists and ER physicians, suggesting inappropriate or drug-seeking behavior, should be dealt with appropriately.
- \S 3. The Principles of End of Life Pain Therapy:

In the instance of chronic end of life pain, a treatment plan which addresses the goals of comfort and personal dignity, developed at the time of original diagnosis is sufficient. Certain suggestions and considerations as noted in Section 2.2, 3, 4, & 5 may well not apply to this category of patient. Evaluation and documentation to ensure patient comfort and dignity as well as to manage other aspects of the underlying illness are expected to continue.

Appendix 1.

- 1. Controlled Substances Contract: Suggested elements of a controlled substance contract are as follows:
- a) specifies that the physician is the single source of controlled substances;
- b) may specify the pharmacy;
- c) written, informed consent to release contract to local emergency departments and pharmacies;
- d) if written consent is given for release to local emergency departments and/or pharmacies, consent is also being given to the other providers to report violations of the contract back to the physician,
- e) specifies that if the physician becomes concerned that there has been illegal activity, the physician may notify the proper authorities;

(CONTINUED ON NEXT PAGE)

(+) <u>CRITERION 8:</u> Other provisions that may enhance pain

management

<u>CATEGORY C:</u> Regulatory or policy issues

COMMENT: Exempts patients with chronic end-of-life pain from the treatment considerations for patients with other types of chronic pain.

(+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

<u>CATEGORY A:</u> Issues related to healthcare professionals

COMMENT: Recognizes that the goals of pain treatment should extend beyond pain scores, to include improvements in patient functioning and quality of life.



Medical Board Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

- f) if the physician has obtained a written release, ER personnel and other providers shall report violations of the contract back to the doctor who prescribed the controlled substance(s).
- g) specifies that a violation of the contract will result in a tapering and discontinuation of the narcotics prescription;
- h) specifies that a risk of chronic narcotics treatment is physical dependence (as defined);
- i) specifies that a risk of chronic narcotics treatment is addiction (as defined);



Controlled Substances Prescription Monitoring

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

22 M.R.S. § 7245

§ 7245. Legislative intent

It is the intent of the Legislature that the prescription monitoring program established pursuant to this chapter serve as a means to promote the public health and welfare and to detect and prevent substance abuse. This chapter is not intended to interfere with the legitimate medical use of controlled substances.

(+) CRITERION 8:

Other provisions that may enhance pain management

<u>CATEGORY C:</u> Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

REGULATIONS

Hospice Licensing

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

CMR 10-144-120

10 144 120 Regulations Governing the Licensing and Functioning of Hospice Programs

. 5.G. Training

A hospice program shall provide an <u>educational program</u> that offers a comprehensive overview of hospice philosophy and hospice care. A minimum of eighteen (18) hours of education, including four (4) hours of orientation, is required for all direct service providers delivering hospice care. The educational program must include, but is not limited to, the following subjects:

5.G.1. Hospice philosophy,

5.G.2. Family dynamics;

5.G.3. Pain and symptom management;

COMMENT: Establishes a mechanism (educational program) for hospices to ensure that pain management is an essential part of

(+) <u>CRITERION 8:</u> Other provisions that may enhance pain

management

CATEGORY C:

patient care.

issues

Regulatory or policy

 MD

MARYLAND

Citations for Policies Evaluated

STATUTES

Controlled Substances Act

Criminal Law; Title 5. Controlled Dangerous Substances, Prescriptions, and Other Substances

Medical Practice Act (No provisions found)
 Health Occupations; Title 14. Physicians

PHARMACY PRACTICE ACT (No provisions found)
 Title Health Occupations; Title 12. Pharmacists and Pharmacies

 Intractable Pain Treatment Act No policy found

REGULATIONS

Controlled Substances Regulations

Title 10. Department of Health and Mental Hygiene; Subtitle 13. Drugs; Chapter 01. Dispensing of Prescription Drugs by a Licensee

MEDICAL BOARD REGULATIONS (No provisions found)
 Title 10. Department of Health and Mental Hygiene; Subtitle 32. Board of Physicians

PHARMACY BOARD REGULATIONS (No provisions found)

Title 10. Department of Health and Mental Hygiene; Subtitle 34. Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

Medical Board Guideline

Maryland Board of Physicians. *Prescribing Controlled Substances*. Maryland BPQA Newsletter. Vol. 4, No. 1, pp. 1-3. Adopted: March, 1996.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

Assisted Suicide

Criminal Law; Title 3. Other Crimes Against the Person; Subtitle 1. Assisted Suicide

RIGHTS OF INDIVIDUALS

Health-General; Title 19. Health Care Facilities; Subtitle 3. Hospitals and Related Institutions; Part IV. Rights of Individuals

Hospice Care Programs

Title 10. Department of Health and Mental Hygiene; Subtitle 07. Hospitals; Chapter 21. Hospice Care Programs



Prov	Provisions that may ENHANCE pain management										
	1	2	3	4	5	6	7	8			
Criteria	Controlled substances are necessary for public health	Pain management is part of medical practice	Opioids are part of professional practice	Encourages pain management	Addresses fear of regulatory scrutiny	Prescription amount alone does not determine legitimacy	Physical dependence or analgesic tolerance are not confused with "addiction"	Other provisions that may enhance pain management			
STATUTES											
Controlled Substances Act	•		•					•			
Medical Practice Act ¹											
Pharmacy Practice Act ¹											
Intractable Pain Treatment Act ²											
REGULATIONS	S										
Controlled Substances			•								
Medical Board ¹											
Pharmacy Board ¹											
OTHER GOVE	RNMENTA	L POLICIES									
Medical Board Guideline					•		•	•			
RELEVANT PO	LICIES OR	PROVISIO	NS IDENTIF	IED BY BOO	LEAN (KE	Y WORD)	SEARCHES				
Assisted Suicide								•			
Rights of Individuals								•			
Hospice Care Programs								•			

Prov	/ision	s that	may //	<i>NPEDE</i>	pain ı	manaç	gement	
	9	10	11	12	13	14	15	16
Criteria	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act			•					
Medical Practice Act ¹								
Pharmacy Practice Act ¹								
Intractable Pain Treatment Act ²								
REGULATIONS								
Controlled Substances								•
Medical Board ¹								
Pharmacy Board ¹								
OTHER GOVE	RNMENT	AL POLIC	IES					
Medical Board Guideline ¹								
RELEVANT PO	LICIES C	R PROVIS	SIONS IDEN	TIFIED BY	/ BOOLEA	N (KEY W	ORD) SEAF	RCHES
Assisted Suicide ¹								
Rights of Individuals ¹								
Hospice Care Programs ¹								



Controlled Substances Act

For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Md. CRIMINAL LAW Code Ann. § 5-101

§ 5-101. Definitions

(a) In general. -- In this title the following words have the meanings indicated.

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(d) Authorized provider. --

(1) "Authorized provider" means:

(i) a person licensed, registered, or otherwise allowed to <u>administer</u>, <u>distribute</u>, <u>dispense</u>, <u>or conduct research on a controlled dangerous substance in the State in the course of professional practice</u> or research;

(+) <u>CRITERION 3:</u> Opioids are part of professional practice

(-) <u>CRITERION 11:</u> Physical dependence or analgesic tolerance confused with "addiction"

(+) <u>CRITERION 1:</u> Controlled substances

health

are necessary for public

(n) Drug dependent person. -- "Drug dependent person" means a person who:

(1) is using a controlled dangerous substance; and

(2) is in a state of psychological or physical dependence, or both, that:

(i) arises from administration of that controlled dangerous substance on a continuous basis; and

(ii) is characterized by behavioral and other responses that include a strong compulsion to take the substance on a continuous basis in order to experience its psychological effects or to avoid the discomfort of its absence.

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Md. CRIMINAL LAW Code Ann. § 5-102

§ 5-102. Legislative findings and purpose of title

(a) Findings. -- The General Assembly finds that:

(1) many of the substances listed in this title have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the people of the State: but

(2) the illegal manufacture, distribution, possession, and administration of controlled dangerous substances have a substantial and detrimental effect on the health and general welfare of the people of the State.

(b) Purpose. --

(1) The purpose of this title is to establish a uniform law to control the manufacture, distribution, possession, and administration of controlled dangerous substances and related paraphernalia to:

(i) ensure their availability for legitimate medical and scientific purposes; but

(ii) prevent their abuse, which results in a serious health problem to the individual and represents a serious danger to the welfare of the people of the State

(2) This title shall be liberally construed to accomplish this purpose.

professional practice

(+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

<u>CATEGORY C:</u> Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.



Controlled Substances Regulations

For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

COMAR 10.19.03.02

.02 Definitions.

A. As used in this chapter, unless otherwise provided, those definitions appearing in Criminal Law Article, § 5-101, Annotated Code of Maryland, shall apply.

B. In this chapter, the following terms have the meanings indicated.

C. Terms Defined.

(7) Individual Practitioner.

(a) "Individual practitioner" means a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted by the United States or the jurisdiction in which the individual practitioner practices, to dispense a controlled dangerous substance in the course of professional practice.

(+) CRITERION 3:

Opioids are part of

professional practice

COMAR 10.19.03.07

.07 Prescriptions.

F. Administering or Dispensing of Narcotic Drugs (21 CFR § 1306.07).

(3) A physician or authorized hospital staff may administer or dispense narcotic drugs:

(a) In a hospital to maintain or detoxify an individual as an incidental adjunct to medical or surgical treatment of conditions other than addiction; or

(b) To an individual with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts.

(-) CRITERION 16: Provisions that are ambiguous

CATEGORY B: Unclear intent leading to possible misinterpretation

COMMENT: Does this imply that opioids are a treatment of last resort?



OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

PRESCRIBING CONTROLLED SUBSTANCES

In a recent AMA survey of physicians, the majority of physicians responding reported that their prescribing of controlled drugs was negatively influenced by a fear of licensing board sanctions. The issue of prescribing adequate pain medication for the terminally ill, generally patients with cancer, has received extensive attention. But what about patients with chronic noncancer pain? Little has been done to alleviate physician anxiety that regularly prescribing controlled drugs to such patients will result in the physician being accused of diverting drugs illegally or supporting addictive patients in their habits. How can a physician both meet their patients' needs and avoid coming to the attention of the licensing authorities?

BPQA, by statute, has a minimum of eleven Board members who are actively practicing physicians. We see these patients in our offices, too, and we recognize that there are many painful conditions which cannot be cured and that diagnoses may be totally based on subjective symptoms. As physicians, our role is to relieve suffering; we may have no hard evidence that "proves" the patient is in pain, yet we believe our patients and we try to help them. All the members of BPQA wish to reassure Maryland physicians that they need not under-prescribe needed medications for fear of Board action. Under-prescribing results in unnecessary suffering.

But what about all those Board actions you've read about in which the doctors are sanctioned for "inappropriate" controlled dangerous substance prescribing practices? Were these physicians just trying to alleviate suffering with the end result that the Board sanctioned them? Hardly. Most of the physicians charged under this provision of the Medical Practice Act were clearly acting in other than the best interest of their patients. Usually, obvious addicts were buying prescriptions from the physicians and the transactions were disguised as office visits. Occasionally, truly naive physicians, once they have been targeted as "easy writes," attract every addict in town. All of us in practice occasionally have been duped by a patient in this way. But some physicians simply don't recognize addiction. Usually, in addition to inappropriate prescribing, we find that the physician's practice is substandard in multiple other areas. It is rare that an otherwise well-trained and competent physician is identified as a naive prescriber.

Because the Board is concerned that fear of disciplinary action may lead to inappropriately restrictive prescribing of controlled drugs, the following guidelines are offered by Dr. Charles Hobelmann Jr., who has served on the Board since 1991. Although the primary focus of his remarks is analgesic prescribing, these guidelines can be applied to every prescribing and treatment situation. It's just good medical practice spelled out, and it's how the Board evaluates the delivery of all medical care, not just controlled drug prescribing. His comments follow.

In order to help the physicians whose patients may require long-term analgesic medications, a common sense approach coupled with experience and medical knowledge is essential. It is important to realize that habituation and tolerance to drugs are not the same as addiction. These are expected consequences of long-term analgesic therapy and do not have the characteristics of sociopathy and psychologic dependence associated with addiction. Whereas it is inappropriate to prescribe analgesics to maintain addiction, it is good medical care to provide relief from chronic pain even in the face of habituation and tolerance. Some general guidelines may be helpful both in the management of these patients and in protecting one's self from legal or Board action in prescribing for them. The following comments have been adapted from published material of the Medical Board of California and provide a useful guide in this area.

(CONTINUED ON NEXT PAGE)

(+) <u>CRITERION 5:</u> Addresses fear of regulatory scrutiny

(+) <u>CRITERION 7:</u> Physical dependence or analgesic tolerance are not confused with "addiction"

COMMENT: However, it is preferable to substitute "physical dependence" for the archaic term "habituation."



OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

<u>History and Physical</u> Generally speaking, it is improper to prescribe any medication for any patient without first taking the steps essential to evaluation. This is particularly true of the chronic pain patients because other treatment modalities may be beneficial and because it is important to recognize the addict who may complain of pain as a means to maintain a habit. Prescribing narcotics without a documented evaluation always represents substandard care.

<u>Ireatment Plan</u> Just as treatment for diabetes or hypertension has a specific objective, so should treatment for chronic pain. <u>Frequently, the pain cannot be completely relieved but the use of analgesic drugs may lead to an improved sense of well-being, better sleep or even a return to work. The goal of analgesic therapy should be documented and the patient's progress measured against this goal.</u>

<u>Informed Consent</u> Since long-term narcotic use will usually result in habituation and tolerance, these risks should be discussed with the patient. Alternatives should be offered if they exist and the clinical record should refer to the discussion.

<u>Periodic Review</u> The course of treatment and the meeting of therapeutic goals should be periodically reviewed as is the case with any patient suffering from chronic disease. Modification of treatment or its discontinuation should be considered depending upon how well goals are being met. New information about the etiology of the pain or its treatment should be evaluated.

<u>Consultation</u> The complexity of chronic pain frequently requires evaluation by consultants who may suggest alternatives or additions to therapy. This may be particularly true in the patient who is at risk for drug misuse. The patient with a history of substance abuse requires special care in documentation, evaluation and consultation before long-term opiate treatment can be safely prescribed. Some pain management specialists recommend a written agreement with these and other patients before such therapy.

<u>Records</u> Adequate documentation is the key to management of these difficult patients and is the key to protecting the physician from legal or Board action. Documentation of the steps noted above should be recorded in a fashion that would allow another practitioner to understand and follow through with treatment.

Finally, the physician who uses scheduled drugs should be familiar with federal and local laws regulating their use. The U.S. Drug Enforcement Administration publishes a physicians' manual and Maryland laws are available through the Board. The Board hopes that physicians will use these guidelines to help them manage patients with chronic pain without fear of regulatory scrutiny. At the same time, the Board maintains its commitment to prevent the diversion and abuse of controlled substances.

(+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

<u>CATEGORY A:</u> Issues related to healthcare professionals

COMMENT: Recognizes that the goals of pain treatment should extend beyond pain scores, to include improvements in patient functioning and quality of life.



Assisted Suicide

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

CATEGORY A: Issues related to healthcare professionals

COMMENT: Clarifies for physicians that there is an important distinction between physicianassisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment.

Md. CRIMINAL LAW Code Ann. § 3-101

§ 3-103. Exceptions

(a) Palliative care -- Pain relief. -- A licensed health care professional does not violate § 3-102 of this subtitle by administering or prescribing a procedure or administering, prescribing, or dispensing a medication to relieve pain, even if the medication or procedure may hasten death or increase the risk of death, unless the licensed health care professional knowingly administers or prescribes the procedure or administers, prescribes, or dispenses the medication to cause death.

STATUTES

Rights of Individuals

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

<u>CATEGORY C:</u> Regulatory or policy issues

COMMENT: Establishes a responsibility for hospitals to ensure that pain management is an essential part of patient care.

Md. HEALTH-GENERAL Code Ann. § 19-342

§ 19-342. Hospitals

(a) Patient's bill of rights. -- Each administrator of a hospital is responsible for making available to each patient in the hospital a copy of the patient's bill of rights that the hospital adopts under the Joint Commission on Accreditation of Hospitals' guidelines.

(b) Same -- Statement. -- The patient's bill of rights shall include a statement that a patient has a right to expect and receive appropriate assessment, management, and treatment of pain as an integral component of the patient's care.



Hospice Care Programs

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

COMAR 10.07.21.13

- .13 Physician Services.
- A. Medical Director. The hospice care program shall have a medical director who shall be:
 - (1) A physician licensed to practice medicine in this State; and
 - (2) Knowledgeable about the psychosocial and medical aspects of hospice care.
 - B. Medical Director Duties. The medical director is responsible for:
- (1) Reviewing, coordinating, and managing the clinical and medical care for all patients in the hospice care program;
 - (2) Consulting with attending physicians regarding pain and symptom control;

.

- . .21 Patient's Rights.
- A. The hospice care program shall provide the patient or representative with a written notice of the patient's rights in advance of furnishing care. Documentation verifying receipt of and understanding of this information shall be included as part of the patient's record.
 - B. The patient has the right to:

(9) <u>Be informed of short-term inpatient care options available for pain control, management, and respite</u>:

.

care.

issues

(+) <u>CRITERION 8:</u> Other provisions that

may enhance pain management

CATEGORY C:

Regulatory or policy

COMMENT: Establishes

to ensure that pain

management is an essential part of patient

mechanisms for hospices

MA

MASSACHUSETTS

Citations for Policies Evaluated

STATUTES

CONTROLLED SUBSTANCES ACT

Part 1. Administration of the Government; Title XV. Regulation of Trade; Chapter 94C. Controlled Substances Act

Medical Practice Act (No provisions found)

Part 1. Administration of the Government; Title XV1. Public Health; Chapter 112. Registration of Certain Professions and Occupations; Registration of Physicians and Surgeons

OSTEOPATHIC PRACTICE ACT (No provisions found)

Part 1. Administration of the Government; Title XV1. Public Health; Chapter 112. Registration of Certain Professions and Occupations; [Osteopathy]

PHARMACY PRACTICE ACT (No provisions found)

Part 1. Administration of the Government; Title XV1. Public Health; Chapter 112. Registration of Certain Professions and Occupations; Registration of Pharmacists

 Intractable Pain Treatment Act No policy found

REGULATIONS

Controlled Substances Regulations (No provisions found)

Title 105. Department of Public Health; Chapter 701.000. Regulations Adopted Jointly by the Department of Public Health and the Board of Registration in Pharmacy for the Implementation of M. G. L. c. 94C

- MEDICAL BOARD REGULATIONS (No provisions found)
 Title 243. Board of Registration in Medicine
- PHARMACY BOARD REGULATIONS (No provisions found)
 Title 247. Board of Registration in Pharmacy

OTHER GOVERNMENTAL POLICIES

Medical Board Guideline

Massachusetts Board of Registration in Medicine. *Model Policy for the Use of Controlled Substances for the Treatment of Pain.* Adopted: December 15, 2004.



RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

HOSPITAL LICENSURE

Title 105. Department of Public Health; Chapter 130.000. Hospital Licensure; Subpart D Supplementary Standards: Particular Services

HOSPICE LICENSURE

Title 105. Department of Public Health; Chapter 141.000. Licensure of Hospice Programs; Subpart B General Requirement; Administration



Prov	isions	that m	ay <i>EN</i>	IHANCI	Epain	mana	ageme	ent
	1	2	3	4	5	6	7	8
Criteria	Controlled substances are necessary for public health	Pain management is part of medical practice	Opioids are part of professional practice	Encourages pain management	Addresses fear of regulatory scrutiny	Prescription amount alone does not determine legitimacy	Physical dependence or analgesic tolerance are not confused with "addiction"	Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act		•	•					
Medical Practice Act ¹								
Osteopathic Practice Act ¹								
Pharmacy Practice Act ¹								
Intractable Pain Treatment Act ²								
REGULATION:	S							
Controlled Substances ¹								
Medical Board ¹								
Pharmacy Board ¹								
OTHER GOVE	RNMENTA	L POLICIES						
Medical Board Guideline		•	•	•	•	•	•	•
RELEVANT PO	LICIES OR	PROVISIO	NS IDENTIF	IED BY BOC	LEAN (KE	Y WORD)	SEARCHES	
Hospital Licensure								•
Hospice Licensure								•

Prov	/ision	s that	may //	ЛРЕDE	pain ı	manaç	gement	
	9	10	11	12	13	14	15	16
Criteria	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES								
Controlled Substances Act				•				
Medical Practice Act ¹								
Osteopathic Practice Act ¹								
Pharmacy Practice Act ¹								
Intractable Pain Treatment Act ²								
REGULATIONS								
Controlled Substances ¹								
Medical Board ¹								
Pharmacy Board ¹								
OTHER GOVER	RNMENT	AL POLIC	IES					
Medical Board Guideline ¹								
RELEVANT PO	LICIES C	R PROVIS	SIONS IDEN	NTIFIED BY	/ BOOLE	N (KEY W	ORD) SEAF	RCHES
Hospital Licensure ¹								
Hospice Licensure ¹								



Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

LM GL ch. 94C, § 1

§ 1. Definitions.

As used in this chapter, the following words shall, unless the context clearly requires otherwise, have the following meanings:

.

"Practitioner",

(+) <u>CRITERION 3:</u> Opioids are part of professional practice (a) A physician, dentist, veterinarian, podiatrist, scientific investigator, or other person registered to <u>distribute</u>, <u>dispense</u>, <u>conduct research with respect to</u>, <u>or use in teaching or chemical analysis</u>, <u>a controlled substance in the course of professional practice</u> or research in the commonwealth.

Mass. Ann. Laws ch. 94C, § 9

§ 9. Authorized Possession, Administration and Dispensation of Controlled Substances; Records.

(a) A physician, dentist, podiatrist, optometrist as limited by sections 66 and 66B of chapter 112 and paragraph (h) of section 7, nurse practitioner and psychiatric nurse mental health clinical specialist as limited by paragraph (g) of said section 7 and section 80E of said chapter 112, physician assistant as limited by said paragraph (g) of said section 7 and section 9E of said chapter 112, a certified nurse-midwife as provided in section 80C of said chapter 112 or a veterinarian when registered pursuant to the provisions of said section 7 and acting in accordance with the provisions of applicable federal law and any provision of this chapter which is consistent with federal law, in good faith and in the course of a professional practice for the alleviation of pain and suffering or for the treatment or alleviation of disease, may possess such controlled substances as may reasonably be required for the purpose of patient treatment and may administer controlled substances or may cause the same to be administered under his direction by a nurse.

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Mass. Ann. Laws ch. 94C, § 23

§ 23. Further Regulation of Prescriptions.

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(-) <u>CRITERION 12:</u> Medical decisions are restricted

<u>CATEGORY C</u>: Restrictions regarding quantity prescribed or dispensed (d) In regard to a controlled substance in Schedule II or III, no prescription shall be filled for more than a thirty-day supply of such substance upon any single filling; provided, however, that with regard to dextro amphetamine sulphate and methyl phenidate hydrochloride, a prescription may be filled for up to a sixty-day supply of such substance upon any single filling if said substance is being used for the treatment of minimal brain dysfunction or narcolepsy; provided further, that subject to regulations of the department and the board of pharmacy, prescriptions for implantable infusion pumps consisting of Schedule II or Schedule III controlled substances may be filled for a maximum of 90 days.

(+) <u>CRITERION 2:</u> Pain management is part of medical practice



OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Model Policy for the Use of Controlled Substances for the Treatment of Pain

Federation of State Medical Boards of the United States, Inc.

The recommendations contained herein were adopted as policy by the House of Delegates of the Federation of State Medical Boards of the United States, Inc., May 2004

Introduction

The Federation of State Medical Boards (the Federation) is committed to assisting state medical boards in protecting the public and improving the quality and integrity of health care in the United States. In 1997, the Federation undertook an initiative to develop model guidelines and to encourage state medical boards and other health care regulatory agencies to adopt policy encouraging adequate treatment, including use of opioids when appropriate for patients with pain. The Federation thanks the Robert Wood Johnson Foundation for awarding a grant in support of the original project, and the American Academy of Pain Medicine, the American Pain Society, the American Society of Law, Medicine, & Ethics, and the University of Wisconsin Pain & Policy Studies Group for their contributions.

Since adoption in April 1998, the *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* have been widely distributed to state medical boards, medical professional organizations, other health care regulatory boards, patient advocacy groups, pharmaceutical companies, state and federal regulatory agencies, and practicing physicians and other health care providers. The *Model Guidelines* have been endorsed by the American Academy of Pain Medicine, the Drug Enforcement Administration, the American Pain Society, and the National Association of State Controlled Substances Authorities. Many states have adopted pain policy using all or part of the *Model Guidelines*. **Despite increasing concern in recent years regarding the abuse and diversion of controlled substances, pain policies have improved due to the efforts of medical, pharmacy, and nursing regulatory boards committed to improving the quality of and access to appropriate pain care.

Notwithstanding progress to date in establishing state pain policies recognizing the legitimate uses of opioid analgesics, there is a significant body of evidence suggesting that both acute and chronic pain continue to be undertreated. Many terminally ill patients unnecessarily experience moderate to severe pain in the last weeks of life. The undertreatment of pain is recognized as a serious public health problem that results in a decrease in patients' functional status and quality of life and may be attributed to a myriad of social, economic, political, legal and educational factors, including inconsistencies and restrictions in state pain policies. Circumstances that contribute to the prevalence of undertreated pain include: (1) lack of knowledge of medical standards, current research, and clinical guidelines for appropriate pain treatment; (2) the perception that prescribing adequate amounts of controlled substances will result in unnecessary scrutiny by regulatory authorities; (3) misunderstanding of addiction and dependence; and (4) lack of understanding of regulatory policies and processes. Adding to this problem is the reality that the successful implementation of state medical board pain policy varies among jurisdictions.

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OTHER GOVERNMENTAL POLICY

Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

In April 2003, the Federation membership called for an update to its *Model Guidelines* to assure currency and adequate attention to the undertreatment of pain. The goal of the revised model policy is to provide state medical boards with an updated template regarding the appropriate management of pain in compliance with applicable state and federal laws and regulations. The revised policy notes that the state medical board will consider inappropriate treatment, including the undertreatment of pain, a departure from an acceptable standard of practice. The title of the policy has been changed from *Model Guidelines* to *Model Policy* to better reflect the practical use of the document.

The Model Policy is designed to communicate certain messages to licensees: that the state medical board views pain management to be important and integral to the practice of medicine; that opioid analgesics may be necessary for the relief of pain; that the use of opioids for other than legitimate medical purposes poses a threat to the individual and society; that physicians have a responsibility to minimize the potential for the abuse and diversion of controlled substances; and that physicians will not be sanctioned solely for prescribing opioid analgesics for legitimate medical purposes. This policy is not meant to constrain or dictate medical decision-making.

Through this initiative, the Federation aims to achieve more consistent policy in promotion of adequate pain management and education of the medical community about treating pain within the bounds of professional practice and without fear of regulatory scrutiny. In promulgating this *Model Policy*, the Federation strives to encourage the legitimate medical uses of controlled substances for the treatment of pain while stressing the need to safeguard against abuse and diversion.

State medical boards are encouraged, in cooperation with their state's attorney general, to evaluate their state pain policies, rules, and regulations to identify any regulatory restrictions or barriers that may impede the effective use of opioids to relieve pain. Accordingly, this *Model Policy* has been revised to emphasize the professional and ethical responsibility of the physician to assess patients' pain as well as to update references and definitions of key terms used in pain management.

The *Model Policy* is not intended to establish clinical practice guidelines nor is it intended to be inconsistent with controlled substance laws and regulations.

- As of January 2004, 22 of 70 state medical boards have policy, rules, regulations or statutes reflecting the Federation's Model Guidelines for the Use of Controlled Substances for the Treatment of Pain and two (2) states have formally endorsed the Model Guidelines.
- SUPPORT Study Principal Investigators. A controlled trial to improve care for seriously ill hospitalized patients: JAMA, 274(20) (1995): p. 1591-1598.
- 3. A.M. Gilson, D.E. Joranson, and M.A. Mauer, Improving Medical Board Policies: Influence of a Model, *J. of Law, Medicine, and Ethics*, 31 (2003): p. 128.

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(+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

<u>CATEGORY C:</u> Regulatory or policy issues

COMMENT: Identifies the possibility of restrictive policies as an important barrier to the appropriate use of opioid analgesics.



Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

CATEGORY A: Issues related to healthcare professionals

COMMENT: Recognizes that inadequate treatment of pain is subject to disciplinary action just as other substandard practices might be.

(+) <u>CRITERION 4:</u> Encourages pain management (CONTINUED)

Model Policy for the Use of Controlled Substances for the Treatment of Pain

Section I: Preamble

The (name of board) recognizes that principles of quality medical practice dictate that the people of the State of (name of state) 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. For the purposes of this policy, the inappropriate treatment of pain includes nontreatment, <u>undertreatment</u>, overtreatment, and the continued use of ineffective treatments

The diagnosis and treatment of pain is integral to the practice of medicine. The Board encourages physicians to 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. All physicians should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. Accordingly, this policy have been developed to clarify the Board's position on pain control, particularly as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

Inappropriate pain treatment may result from physicians' 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 physician'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 Board will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain. 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 physician. 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. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

The (name of board) is obligated under the laws of the State of (name of state) to protect the public health and safety. The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes 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, the Board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

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(+) <u>CRITERION 2:</u> Pain management is part of medical practice

(+) <u>CRITERION 7:</u> Physical dependence or analgesic tolerance are not confused with "addiction"



Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) <u>CRITERION 5:</u> Addresses fear of regulatory scrutiny

(+) <u>CRITERION 6:</u> Prescription amount alone does not determine legitimacy

(+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

<u>CATEGORY A:</u> Issues related to healthcare professionals

COMMENT:

Acknowledges need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

(CONTINUED)

Physicians 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 physician-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 physician'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 not take disciplinary action against a physician for deviating from this policy when contemporaneous medical records document reasonable cause for deviation. The physician'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.

Section II: Guidelines

The Board has adopted the following criteria when evaluating the physician's treatment of pain, including the use of controlled substances:

Evaluation of the Patient—A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

Treatment Plan—The written treatment plan should state 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. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

(CONTINUED ON NEXT PAGE)

(+) <u>CRITERION 3:</u> Opioids are part of professional practice

(+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

CATEGORY A: Issues related to healthcare professionals

COMMENT: Recognizes that the goals of pain treatment should extend beyond pain scores, to include improvements in patient functioning and quality of life.



Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

Informed Consent and Agreement for Treatment—The physician 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. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including

- o urine/serum medication levels screening when requested;
- o number and frequency of all prescription refills; and
- reasons for which drug therapy may be discontinued (e.g., violation of agreement).

Periodic Review—The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

Consultation—The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should 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 comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

Medical Records—The physician should keep accurate and complete records to include

- 1. the medical history and physical examination,
- diagnostic, therapeutic and laboratory results,
- 3. evaluations and consultations
- 4. treatment objectives,
- 5. discussion of risks and benefits
- informed consent,
- treatments,

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Medical Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

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- medications (including date, type, dosage and quantity prescribed),
- 9. instructions and agreements and
- 10. periodic reviews.

Records should remain current and be maintained in an accessible manner and readily available for review.

Compliance With Controlled Substances Laws and Regulations—To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and (any relevant documents issued by the state medical board) for specific rules governing controlled substances as well as applicable state regulations.

Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:

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.

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.

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.

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

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.

Pseudoaddiction—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.

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.

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.



REGULATIONS

Hospital Licensure

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

105 CMR 130.616

130.616: Administration and Staffing

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- (D) Patient Care Policies. Each maternal and newborn service shall develop and implement <u>written patient care policies</u> and procedures, supported by evidence based resources, which shall include provisions for the following:
- (1) Triage of patents presenting to the service to establish the diagnosis of labor, need for admission, transfer and/or other care management.
- (2) Communication and decision making responsibilities with specified chain of command.
- (3) Pain management, including the use of non pharmacological support techniques, analgesic medication and parenteral therapy. Routine standing orders shall not be permitted.

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(12) Care of the Newborn Such

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- (12) Care of the Newborn. Such policies shall provide for the following:
- (i) Comfort measures and reduction of pain and trauma during invasive procedures.

COMMENT: Establishes a mechanism (written policies) for hospitals to ensure that pain management is an

essential part of patient

(+) CRITERION 8:

management

CATEGORY C:

Other provisions that

may enhance pain

Regulatory or policy

care.

issues



REGULATIONS

Hospice Licensure

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

105 CMR 141.204

141.204: Required Patient Care Services

- (1) Each hospice shall designate a physician to serve as Medical Director. The Medical Director shall have overall responsibility for the medical component of patient care and for ensuring achievement and maintenance of quality standards of professional medical care.
 - (2) The duties of the medical director shall include but need not be limited to:
- (k) Participating in establishing <u>written programmatic guidelines</u> for symptom control (e.g., pain, nausea, vomiting, or other symptoms.)
 - (H) Inpatient Care.
- (1) The hospice shall provide or arrange for short-term inpatient care for the control of pain and management of acute and severe clinical problems that cannot be managed in a home setting.

(+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

CATEGORY C: Regulatory or policy

COMMENT: Establishes a mechanism (written programmatic guidelines) for hospices to ensure that pain management is an essential part of patient care.

MICHIGAN

Citations for Policies Evaluated

STATUTES

Controlled Substances Act

Chapter 333. Health; Public Health Code; Article 7. Controlled Substances

PROFESSIONAL PRACTICE ACT (No provisions found)

Chapter 333. Health; Public Health Code; Article 15. Occupations; Part 161. General Provisions

Medical Practice Act

Chapter 333. Health; Public Health Code; Article 15. Occupations; Part 170. Medicine

OSTEOPATHIC PRACTICE ACT

Chapter 333. Health; Public Health Code; Article 15. Occupations; Part 175. Osteopathic Medicine and Surgery

PHARMACY PRACTICE ACT

Chapter 333. Health; Public Health Code; Article 15. Occupations; Part 177. Pharmacy Practice and Drug Control

 Intractable Pain Treatment Act No policy found

REGULATIONS

Controlled Substances Regulations

Department of Community Health. Director's Office. Controlled Substances

Medical Board Regulations (No provisions found)

Department of Community Health. Director's Office. Medicine - General Rules

OSTEOPATHIC BOARD REGULATIONS (No provisions found)

Department of Community Health. Director's Office. Osteopathic Medicine and Surgery – General Rules

PHARMACY BOARD REGULATIONS (No provisions found)

Department of Community Health. Director's Office. Board of Pharmacy. General Rules



JOINT BOARD GUIDELINE

Michigan Boards of Medicine and Osteopathic Medicine & Surgery. *Michigan Guidelines for the Use of Controlled Substances for the Treatment of Pain.* Adopted: Late 2003.

PHARMACY BOARD GUIDELINE

Michigan Board of Pharmacy. *Michigan Board of Pharmacy Guidelines for the Use of Controlled Substances for the Treatment of Pain.* Adopted: ND.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

END-OF-LIFE CARE

Chapter 333. Health; Public Health Code; Article 5. Prevention and Control of Diseases and Disabilities; Part 56A. End-of-Life Care

FACILITIES AND AGENCIES

Chapter 333. Health; Public Health Code; Article 17. Facilities and Agencies

Assisted Suicide

Chapter 752. Assistance to Suicide



Provisions that may ENHANCE pain management										
	1	2	3	4	5	6	7	8		
Criteria	Controlled substances are necessary for public health	Pain management is part of medical practice	Opioids are part of professional practice	Encourages pain management	Addresses fear of regulatory scrutiny	Prescription amount alone does not determine legitimacy	Physical dependence or analgesic tolerance are not confused with "addiction"	Other provisions that may enhance pain management		
STATUTES										
Controlled Substances Act			•					•		
Professional Practice Act ¹										
Medical Practice Act		•	•	•				•		
Osteopathic Practice Act								•		
Pharmacy Practice Act								•		
Intractable Pain Treatment Act ²										
REGULATION	S									
Controlled Substances			•							
Medical Board ¹										
Osteopathic Board ¹										
Pharmacy Board ¹										
OTHER GOVE	RNMENTA	L POLICIES								
Joint Board Guideline		•	•	•	•	•	•	•		
Pharmacy Board Guideline		•	•	•	•		•	•		
RELEVANT PC	LICIES OR	PROVISIO	NS IDENTIF	IED BY BOC	LEAN (KE	Y WORD)	SEARCHES			
End-of-life care		•			•					
Facilities and Agencies								•		
Assisted Suicide								•		

Provisions that may IMPEDE pain management										
	9	10	11	12	13	14	15	16		
Criteria	Opioids are a last resort	Implies opioids are not part of professional practice	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Undue prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous		
STATUTES										
Controlled Substances Act ¹										
Professional Practice Act ¹										
Medical Practice Act ¹										
Osteopathic Practice Act ¹										
Pharmacy Practice Act ¹										
Intractable Pain Treatment Act ²										
REGULATIONS	S									
Controlled Substances ¹										
Medical Board ¹										
Osteopathic Board ¹										
Pharmacy Board ¹										
OTHER GOVE	RNMENT	AL POLIC	IES							
Joint Board Guideline ¹										
Pharmacy Board Guideline ¹										
RELEVANT PO	LICIES C	R PROVIS	SIONS IDEN	NTIFIED BY	/ BOOLE	AN (KEY W	ORD) SEAF	RCHES		
End-of-life care ¹										
Facilities and Agencies ¹										
Assisted Suicide ¹										



Controlled Substances Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

MCL § 333.7109

§ 333.7109. Definitions; P to U.

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(+) <u>CRITERION 3:</u> Opioids are part of professional practice (3) "Practitioner" means:

(a) A prescriber or pharmacist, a scientific investigator as defined by rule of the administrator, or other person licensed, registered, or otherwise permitted to <u>distribute</u>, <u>dispense</u>, <u>conduct research with respect to</u>, <u>or administer a controlled substance in the course of professional practice</u> or research in this state, including an individual in charge of a dog pound or animal shelter licensed or registered by the department of agriculture pursuant to 1969 PA 287, MCL 287.331 to 287.340, or a class B dealer licensed by the United States department of agriculture pursuant to the animal welfare act, Public Law 89-544, 7 U.S.C. 2131 to 2147, 2149, and 2151 to 2159 and the department of agriculture pursuant to 1969 PA 224, MCL 287.381 to 287.395, for the limited purpose of buying, possessing, and administering a commercially prepared, premixed solution of sodium pentobarbital to practice euthanasia on animals.

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MCL§ 333.7333a

§ 333.7333a. Electronic monitoring system.

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(+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

<u>CATEGORY C:</u> Regulatory or policy issues

COMMENT: Recognizes characteristics of prescription monitoring programs that are believed to impede the appropriate medical use of Schedule II controlled substances.

(7) The department, in consultation with the controlled substances advisory commission, the Michigan board of pharmacy, the Michigan board of medicine, the Michigan board of osteopathic medicine and surgery, the Michigan state police, and appropriate medical professional associations, shall examine the need for and may promulgate rules for the production of a prescription form on paper that minimizes the potential for forgery. The rules shall not include any requirement that sequential numbers, bar codes, or symbols be affixed, printed, or written on a prescription form or that the prescription form be a state produced prescription form. In examining the need for rules for the production of a prescription form on paper that minimizes the potential for forgery, the department shall consider and identify the following:

- (a) Cost, benefits, and barriers.
- (b) Overall cost-benefit analysis.
- (c) Compatibility with the electronic monitoring system required under this section.



Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

<u>CATEGORY C:</u> Regulatory or policy issues

COMMENT: Establishes a mechanism (Mandatory continuing education) to provide practitioners information/education about pain management

MCL § 333.16204

§ 333.16204. Completion of courses in pain and symptom management as condition for license renewal; applicability.

Sec. 16204. (1) Effective for the renewal of licenses or registrations issued under this article and expiring after January 1, 1997 if the completion of continuing education is a condition for renewal, the appropriate board shall by rule require an applicant for renewal to complete an appropriate number of hours or courses in pain and symptom management. Rules promulgated by a board under section 16205(2) for continuing education in pain and symptom management shall cover both course length and content and shall take into consideration the recommendation for that health care profession by the interdisciplinary advisory committee created in section 16204a. A board shall submit the notice of public hearing for the rules as required under section 42 of the administrative procedures act of 1969, being section 24.242 of the Michigan Compiled Laws, not later than 90 days after the first interdisciplinary advisory committee makes its initial recommendations and shall promulgate the rules as expeditiously as possible.

MCL § 333.16204a

§ 333.16204a. Advisory committee on pain and symptom management; creation; members; compensation; expenses; terms; duties; review of guidelines.

(4) The <u>advisory committee</u> shall do all of the following, as necessary:

- (a) At least once annually consult with all of the following boards to develop an integrated approach to understanding and applying pain and symptom management techniques:
- (i) All licensure boards created under this article, except the Michigan board of veterinary medicine.
 - (ii) The Michigan board of social work created in section 18505
- (b) Hold a public hearing in the same manner as provided for a public hearing held under the administrative procedures act of 1969, within 90 days after the members of the advisory committee are appointed under subsection (1) to gather information from the general public on issues pertaining to pain and symptom management.
- (c) Develop and encourage the implementation of model core curricula on pain and symptom management.
- (d) Develop recommendations to the licensing and registration boards and the task force created under this article on integrating pain and symptom management into the customary practice of health care professionals and identifying the role and responsibilities of the various health care professionals in pain and symptom management.
- (e) Advise the licensing and registration boards created under this article on the duration and content of continuing education requirements for pain and symptom management.
- (f) Annually report on the activities of the advisory committee and make recommendations on the following issues to the director of the department of consumer and industry services and to the director of the department of community health:
- (i) Pain management educational curricula and continuing educational requirements of institutions providing health care education.
- (ii) Information about the impact and effectiveness of previous recommendations, if any, that have been implemented, including, but not limited to, recommendations made under subdivision (d).
- (iii) Activities undertaken by the advisory committee in complying with the duties imposed under subdivisions (c) and (d).
- (g) Beginning in January of 2000, annually review any changes occurring in pain and symptom management.

(+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

<u>CATEGORY C:</u> Regulatory or policy issues

COMMENT: Establishes a mechanism (advisory committee) to improve pain management.



Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

MCL § 333.16204b

§ 333.16204b. Treatment of pain; enactment of legislation.

Sec. 16204b. The legislature finds that the treatment of pain is an appropriate issue for the legislature to consider, and that the citizens of this state would be well served by the enactment of legislation that accomplishes all of the following:

- (a) Provides more and better information to health care consumers regarding the medical treatment of pain, health care coverage and benefits for the treatment of pain, and the education of health professionals in pain and symptom management.
- (b) Provides for the appointment of an advisory body to study and make recommendations on model core curricula on pain and symptom management for the institutions in this state providing health care education, continuing education for health professionals on pain and symptom management, and the integration of pain and symptom management into the customary practice of health care.
- (c) Educates health professionals about the disciplinary process for state licensees and registrants, including, but not limited to, how the department of consumer and industry services processes allegations of wrongdoing against licensees and registrants.

MCL § 333.16204c

§ 333.16204c. Medical treatment of pain; use of controlled substances; legislative findings; treatment by licensed health professionals; electronic monitoring system; "controlled substance" defined.

Sec. 16204c. (1) The legislature finds that the use of controlled substances is appropriate in the medical treatment of certain forms of pain, and that efforts to control diversion or improper administration of controlled substances should not interfere with the legitimate, medically recognized use of those controlled substances to relieve pain and suffering.

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(+) <u>CRITERION 4:</u> Encourages pain management

(+) CRITERION 3:

Opioids are part of

professional practice

(+) CRITERION 2:

of medical practice

Pain management is part

(3) It is the intent of the legislature to permit and facilitate adequate treatment for pain by licensed health professionals, including, but not limited to, the prescription or dispensing of controlled substances included in schedule 2 under section 7214, when medically appropriate, and to enable regulatory and law enforcement agencies to prevent the abuse and diversion of controlled substances by creating an electronic monitoring system.

(+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

<u>CATEGORY C:</u> Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.



Medical Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

MCL§ 333.16204d

§ 333.16204d. Information booklet on pain; development by department of consumer and industry services; educational program for health professionals.

Sec. 16204d. (1) The department of consumer and industry services, in consultation with the department of community health, shall develop, publish, and distribute an <u>informational booklet</u> on pain. The department of consumer and industry services shall include at least all of the following in the informational booklet:

- (a) Pain management educational curricula and continuing educational requirements of institutions providing health care education recommended by the advisory committee on pain and symptom management under section 16204a.
- (b) Other information considered relevant or useful by the department of consumer and industry services.
- (2) The department of consumer and industry services, in conjunction with the controlled substances advisory commission created in article 7, shall develop and conduct an <u>educational program</u> for health professionals who are licensed under part 73 to prescribe or dispense, or both, controlled substances. The department of consumer and industry services shall include, at a minimum, all of the following in the educational program:
- (a) Information on how the department of consumer and industry services processes allegations of wrongdoing against licensees under this article and article 17, including, but not limited to, how the permanent historical record is maintained for each licensee, how and why a review of the permanent historical record is done, and how the decision is made to issue a formal complaint against a licensee.
- (b) Information on the disciplinary process, including a licensee's rights and duties if an allegation of wrongdoing is filed against the licensee or if some other circumstance occurs that causes or requires the department of consumer and industry services to review a licensee's permanent historical record.
- (c) Other information considered relevant or useful by the department of consumer and industry services or the controlled substances advisory commission, especially information that would address the findings and statements of intent contained in section 16204c.

MCL § 333.17033

§ 333.17033. Renewal of license; continuing education requirements.

Sec. 17033. (1) Notwithstanding the requirements of part 161, the board may require a licensee seeking renewal of a license to furnish the board with satisfactory evidence that during the 3 years immediately preceding application for renewal the licensee has attended continuing education courses or programs approved by the board totaling not less than 150 hours in subjects related to the practice of medicine including, but not limited to, medical ethics and designed to further educate licensees.

(2) As required under section 16204, the board shall promulgate rules requiring each applicant for license renewal to complete as part of the <u>continuing education</u> requirement of subsection (1) an appropriate number of hours or courses in pain and symptom management.

(+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

<u>CATEGORY C:</u> Regulatory or policy issues

COMMENT: Establishes a mechanism (educational program) to provide practitioners information/education about the disciplinary process regarding the treatment of pain.

(+) <u>CRITERION 8:</u>

Other provisions that

may enhance pain

(+) CRITERION 8:

management

CATEGORY C:

issues

Other provisions that

may enhance pain

Regulatory or policy

COMMENT: Establishes a

mechanism (information

information/education

booklet) to provide

practitioners

about pain

management.

management

<u>CATEGORY C:</u>

Regulatory or policy

issues

COMMENT: Establishes a mechanism (mandatory continuing education) to provide practitioners information/education about pain management.



Osteopathic Practice Act

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

CATEGORY C: Regulatory or policy issues

COMMENT: Establishes a mechanism (mandatory continuing education) to provide practitioners information/education about pain management.

MCL § 333.17533

§ 333.17533. Renewal of license; continuing education requirements.

Sec. 17533. (1) Notwithstanding the requirements of part 161, the board may require a licensee seeking renewal of a license to furnish the board with satisfactory evidence that during the 3 years immediately preceding an application for renewal the licensee has attended continuing education courses or programs approved by the board and totaling not less than 150 hours in subjects related to the practice of osteopathic medicine and surgery and designed to further educate licensees.

(2) As required under section 16204, the board shall promulgate rules requiring each applicant for license renewal to complete as part of the <u>continuing education</u> requirement of subsection (1) an appropriate number of hours or courses in pain and symptom management.

STATUTES

Pharmacy Practice Act

- For complete reference to this policy, see "Citations" for Policies Evaluated" at the beginning of this State Profile -

(+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

<u>CATEGORY C:</u> Regulatory or policy issues

COMMENT: Establishes a mechanism (mandatory continuing education) to provide practitioners information/education about pain management. MCL§ 333.17731

§ 333.17731. Renewal of license; continuing education requirements.

Sec. 17731. (1) Notwithstanding the requirements of part 161, the board may require a licensee seeking renewal of a pharmacist's license to furnish the board with satisfactory evidence that during the 2 years immediately preceding application for renewal the applicant has attended continuing education courses or programs, approved by the board, totaling not less than 30 hours or the satisfactory completion of a proficiency examination according to rules promulgated by the board.

(2) As required under section 16204, the board shall promulgate rules requiring each applicant for license renewal to complete as part of the <u>continuing education</u> or proficiency examination requirement of subsection (1) an appropriate number of hours or courses in pain and symptom management.



REGULATIONS

Controlled Substances Regulations

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Mich. Admin. Code R 338.3170

R 338.3170 Dispensing and administering controlled substances by prescribers.

(+) <u>CRITERION 3:</u> Opioids are part of professional practice Rule 70. (1) A prescriber in the course of his or her professional practice only, may dispense or administer, or both, a controlled substance listed in schedules 2 to 5 or he or she may cause them to be administered by an assistant under personal charge supervision.



Joint Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Michigan Guidelines for the Use of Controlled Substances for the Treatment of Pain

Section I: Preamble

The Michigan Boards of Medicine and Osteopathic Medicine & Surgery recognize that principles of quality medical practice dictate that the people of the State of Michigan have access to appropriate and effective pain relief. The appropriate application of upto-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 Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

Inadequate pain control may result from physicians' lack of knowledge about pain management or an inadequate understanding of addiction. Fears of investigation or sanction by federal, state and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients. Accordingly, these guidelines have been developed to clarify the Boards' position on pain control, specifically as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

The Boards recognize 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. Physicians are referred to the U.S. Agency for Health Care and Research Clinical Practice Guidelines for a sound approach to the management of acute (1) and cancer-related pain (2). The medical management of pain should be based on current knowledge and research and include the use of both pharmacologic and non-pharmacologic modalities. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.

The Boards are obligated under the laws of the State of Michigan to protect the public health and safety. The Boards recognize that 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. Physicians should be diligent in preventing the diversion of drugs for illegitimate purposes.

- 1. Acute Pain Management Guideline Panel. Acute Pain Management: Operative or Medical Procedures and Trauma. Clinical Practice Guideline. AHCPR Publication No. 92-0032. Rockville, Md. Agency for Health Care Policy and Research. U.S. Department of Health and Human Resources, Public Health Service. February 1992.
- 2. Jacox A, Carr DB, Payne R, et al. Management of Cancer Pain. Clinical Practice Guideline No. 9. AHCPR Publication No. 94-0592. Rockville, Md. Agency for Health Care Policy and Research. U.S. Department of Health and Human Resources, Public Health Service. March 1994.

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(+) <u>CRITERION 2:</u>
Pain management is part of medical practice

(+) <u>CRITERION 4:</u> Encourages pain management

(+) CRITERION 7: Physical dependence or analgesic tolerance are not confused with "addiction"



Joint Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(+) <u>CRITERION 5:</u> Practitioners' concerns about regulatory scrutiny are addressed

(+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

<u>CATEGORY A:</u> Issues related to healthcare professionals

COMMENT:

Acknowledges need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

(CONTINUED)

Physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agency for prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice. The Board will consider prescribing, ordering, administering or dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be based on clear documentation of unrelieved pain and in compliance with applicable state or federal law.

Each case of prescribing for pain will be evaluated on an individual basis. The board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these quidelines, if good cause is shown for such deviation. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs—including any improvement in functioning—and recognizing that some types of pain cannot be completely relieved.

The Boards will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors. The following guidelines are not intended to define complete or best practice, but rather to communicate what the Boards consider to be within the boundaries of professional practice.

Section II: Guidelines

The Boards have adopted the following guidelines when evaluating the use of controlled substances for pain control:

1. Evaluation of the Patient

A complete medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

2. Treatment Plan

The written treatment plan should state 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. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

(CONTINUED ON NEXT PAGE)

(+) <u>CRITERION 3:</u> Opioids are part of professional practice

(+) <u>CRITERION 6:</u> Prescription amount alone does not determine legitimacy

(+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

CATEGORY A: Issues related to healthcare professionals

COMMENT: Recognizes that the goals of pain treatment should extend beyond pain scores, to include improvements in patient functioning and quality of life.



Joint Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

3. Informed Consent and Agreement for Treatment

The physician 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 incompetent. The patient should receive prescriptions from one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician may employ the use of a written agreement between physician and patient outlining patient responsibilities, including

o urine/serum medication levels screening when requested;

o number and frequency of all prescription refills; and

o reasons for which drug therapy may be discontinued (i.e., violation of agreement).

4. Periodic Review

At reasonable intervals based on the individual circumstances of the patient, the physician should review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy should depend on the physician's evaluation of progress toward stated treatment objectives, such as improvement in patient's pain intensity and improved physical and/or psychosocial function, i.e., ability to work, need of health care resources, activities of daily living and quality of social life. If treatment goals are not being achieved, despite medication adjustments, the physician should reevaluate the appropriateness of continued treatment. The physician should monitor patient compliance in medication usage and related treatment plans.

5. Consultation

The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangement pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

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Joint Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

6. Medical Records

The physician should keep accurate and complete records to include

- o the medical history and physical examination;
- o diagnostic, therapeutic and laboratory results;
- o evaluations and consultations;
- o treatment objectives;
- o discussion of risks and benefits:
- o treatments;
- o medications (including date, type, dosage and quantity prescribed);
- o instructions and agreements; and
- o periodic reviews.

Records should remain current and be maintained in an accessible manner and readily available for review.

7. Compliance With Controlled Substances Laws and Regulations To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and (any relevant documents issued by the state medical board) for specific rules governing controlled substances as well as applicable state regulations.

Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:

Acute Pair

Acute pain is the normal, predicted physiological response to an adverse chemical, thermal or mechanical stimulus and is associated with surgery, trauma and acute illness. It is generally time-limited and is responsive to opioid therapy, among other therapies.

Addiction

Addiction is a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as "drug dependence" and "psychological dependence." Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

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Joint Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

Analgesic Tolerance

Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Chronic Pair

A pain state which is persistent and in which the cause of the pain cannot be removed or otherwise treated. Chronic pain may be associated with a long-term incurable or intractable medical condition or disease.

Pair

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

Physical Dependence

Physical dependence on a controlled substance is a physiologic state of neuro-adaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction

Pseudoaddiction

Pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

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.

Tolerance

Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect, or a reduced effect is observed with a constant dose.



Pharmacy Board Guideline

For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

Michigan Guidelines for the Use of Controlled Substances for the Treatment of Pain

Michigan Board of Pharmacy Guidelines for the Use of Controlled Substances for the Treatment of Pain

Section I: Preamble

The Michigan Board of Pharmacy recognizes that principles of quality pharmacy practice dictate that the people of the State of Michigan 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 Board encourages pharmacists to view effective pain management as a part of quality health care for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal lilness. All pharmacists should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing and dispensing controlled substances.

Inadequate pain control may result from a health care provider's lack of knowledge about pain management or from an inadequate understanding of addiction. Fears of investigation or sanction by federal, state and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients. Accordingly, these guidelines have been developed to clarify the position of the Board on pain control, specifically as related to the use of controlled substances, in order to alleviate uncertainty of pharmacists and to encourage better pain management.

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 be based on current knowledge and research and include the use of both pharmacologic and non-pharmacologic modalities. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Pharmacists should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction. Pharmacists should also be aware that pseudoaddiction may develop as a direct consequence of inadequate pain management.

The Board is obligated under the laws of the State of Michigan to protect the public health and safety. The Board recognizes that inappropriate prescribing and dispensing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Pharmacists should be diligent in preventing the diversion of drugs for illegitimate purposes.

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(+) <u>CRITERION 4:</u> Pain management is encouraged

(+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

<u>CATEGORY A:</u> Issues related to healthcare professionals

COMMENT: Identifies pseudoaddiction as an important barrier to the appropriate use of opioids analgesics.

(+) <u>CRITERION 7:</u> Physical dependence or analgesic tolerance are not confused with "addiction"

(+) CRITERION 2:

of medical practice

Pain management is part



Pharmacy Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

The following are reference sources that provide sound approaches to the management of pain:

- 1. Acute Pain Management Guideline Panel. Acute Pain Management: Operative or Medical Procedures and Trauma. *Clinical Practice Guideline*. AHCPR Publication No. 92-0032. Rockville, Md. Agency for Health Care Policy and Research. U.S. Department of Health and Human Resources, Public Health Service. February 1992.
- 2. Jacox A, Carr DB, Payne R, et al. Management of Cancer Pain. *Clinical Practice Guideline No. 9.* AHCPR Publication No. 94-0592. Rockville, Md. Agency for Health Care Policy and Research. U.S. Department of Health and Human Resources, Public Health Service. March 1994.
- 3. Lipman AG, *Pain Management for Primary Care Clinicians*. 1 st ed. American Society of Health System Pharmacists: Bethesda. 2004.

Pharmacists should not fear disciplinary action from the Board or other state regulatory or enforcement agency for dispensing controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice. The Board will consider control of patients' pain to constitute a legitimate medical purpose when the prescribing and dispensing of controlled substances is based on accepted scientific knowledge of the treatment of pain and/or when based on sound clinical grounds.

The Board will not take disciplinary action against a pharmacist for failing to adhere strictly to the provisions of these guidelines, if good cause is shown for such deviation. In each case, the conduct of the pharmacist will be evaluated to a great extent by patient outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the patient's condition. In addition, the pharmacist will have taken steps in good faith to assure safe and effective medication use and to prevent possible drug diversion.

Section II: Guidelines

The following guidelines are not intended to define complete or best practices, but rather to communicate what the Board considers to be minimum standards of practice for pharmacists caring for patients requiring pain control and presenting with prescriptions for controlled substances.

Review of the Prescription

The pharmacist should exercise due diligence to verify that each prescription for a controlled substance has been issued for a legitimate medical purpose. The review should include, but not necessarily be limited to, a careful review of the prescription document for evidence of forgery or alteration, a discussion with the patient regarding the signs and symptoms of the disorder or disease and the diagnosis, a review of the patient's prescription records, and/or a discussion with the prescriber. The pharmacist may also determine that a query to the Michigan Automated Prescription System (MAPS) is warranted if fraud is suspected. Each of these and/or other steps taken to assure the validity of a prescription should be documented and filed in a readily retrievable manner.

(CONTINUED ON NEXT PAGE)

(+) CRITERION 3:

Medical use of opioids is recognized as legitimate professional practice

(+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

<u>CATEGORY C:</u> Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that efforts to reduce the abuse and diversion of controlled substances should not interfere with legitimate medical use.

(+) <u>CRITERION 5:</u> Addresses fear of regulatory scrutiny

(+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

<u>CATEGORY A:</u> Issues related to healthcare professionals

COMMENT.

Acknowledges need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.



Pharmacy Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

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Fictitious or Possibly Fictitious Prescriptions

When a pharmacist is reasonably certain that a prescription is fictitious, he/she should contact the appropriate law enforcement agency. In cases where the pharmacist suspects, but cannot be certain, that a prescription is fictitious, he/she should take necessary steps to help assure that a patient's symptoms are managed during the time it takes to confirm the validity of the prescription. In these cases, the pharmacist should also be certain to obtain positive patient identification in case the event must later be reported to enforcement agencies. The pharmacist may also determine that a query to the Michigan Automated Prescription System (MAPS) is warranted.

Prescription Refills

The pharmacist should evaluate the patient at each refill of a controlled substance to help assure that positive, intended outcomes are achieved and that the patient is not experiencing untoward effects. This evaluation should include but not necessarily be limited to, a discussion with the patient regarding signs and symptoms of the condition being treated, a review of signs and symptoms of untoward effects, a review of the patient's prescription records, and/or a discussion with the prescriber regarding the need for continuation or modification of therapy.

Special attention should be given to those pain patients who are at risk for misusing their medications. The management of pain in patients with a history of substance abuse or with a co-morbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

The steps undertaken in the process of evaluation should be documented and filed in a readily retrievable manner.

Patient Referral

When a patient presents with a prescription for a controlled substance that is not stocked in the pharmacy, the pharmacist should make every effort to refer the patient to another proper source of care to help assure the patient finds access to medication required for symptom relief.

Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:

Acute Pain

Acute pain is the normal, predicted physiological response to an adverse chemical, thermal or mechanical stimulus and is associated with surgery, trauma and acute illness. It is generally time-limited and is responsive to opioid therapy, among other therapies.

Addiction

Addiction is a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as "drug dependence" and "psychological dependence." Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

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Pharmacy Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

(CONTINUED)

Analgesic Tolerance

Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Chronic Pair

A state of pain which is persistent and in which the cause of the pain cannot be removed or otherwise treated. Chronic pain may be associated with a long-term incurable or intractable medical condition or disease.

Controlled Substance

A controlled substance is a drug, substance, or immediate precursor included in schedules 1 to 5 of Article 7, part 72, of Public Act 368 of 1978 as amended (the Michigan Public Health Code).

Dispense

Dispense means to deliver or issue a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including prescribing, administering, or compounding necessary to prepare the substance for the delivery or issuance.

Dispenser

Dispenser means a practitioner that dispenses.

Good Faith

The prescribing or dispensing of a controlled substance by a practitioner licensed under section 333.7303 of the Michigan Public Health Code, in the regular course of professional treatment to, or for, an individual who is under treatment by a practitioner for a pathology or condition other than that individual's physical or psychological dependence upon or addiction to a controlled substance, except as provided in this article. Application of good faith to a pharmacist is the dispensing of a controlled substance pursuant to a prescriber's order that, in the professional judgment of the pharmacist, is lawful. The pharmacist shall be guided by nationally accepted professional standards including, but not limited to, all of the following, in making the judgment:

- (a) Lack of consistency in the doctor-patient relationship
- (b) Frequency of prescriptions for the same drug by one prescriber for larger numbers of patients
- (c) Quantities beyond those normally prescribed for the same drug
- (d) Unusual dosages
- (e) Unusual geographic distances between patient, pharmacist, and prescriber.

Pair

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

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Pharmacy Board Guideline

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

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Pharmacy Practice

Pharmacy practice means a health service, the clinical application of which includes the encouragement of safety and efficacy in the prescribing, dispensing, administering, and use of drugs and related articles for the prevention of illness, and the maintenance and management of health. Professional functions associated with the practice of pharmacy include:

- (a) The interpretation and evaluation of the prescription
- (b) Drug product selection
- (c) The compounding, dispensing, safe storage, and distribution of drugs and devices.

Physical Dependence

Physical dependence on a controlled substance is a physiologic state of neuro-adaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.

Positive Identification

Positive identification means identification that includes a photograph of an individual in addition to his or her date of birth. Positive identification shall include an identification card issued by a governmental agency provided the ID card meets these requirements.

Practitioner

A prescriber or pharmacist, a scientific investigator as defined by rule or the administrator, or other person, licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to or administer a controlled substance in the course of the professional practice or research in this state.

A pharmacy, hospital, or other institution or place of professional practice licensed, registered, or otherwise permitted to distribute, prescribe, dispense, conduct research with respect to, administer a controlled substance in the course of professional practice or research in this state.

Pseudoaddiction

Pseudoaddiction is the term that describes patient drug-seeking behaviors that may develop as a direct consequence of inadequate pain management. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated.

MICHIGAN

STATUTES

End-of-Life Care

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

MCL § 333.5655

§ 333.5655. Recommended medical treatment for advanced illness; duty of physician to inform orally and in writing; requirements.

Sec. 5655. In addition to the requirements of section 5654, a physician who has diagnosed a patient as having a reduced life expectancy due to an advanced illness and is recommending medical treatment for the patient shall, both orally and in writing, inform the patient, the patient's patient surrogate, or, if the patient has designated a patient advocate and is unable to participate in medical treatment decisions, the patient advocate, of all of the following:

(d) <u>That the patient or the patient's surrogate or patient advocate acting on behalf of the patient may choose adequate and appropriate pain and symptom management as a basic and essential element of medical treatment.</u>

MCL § 333.5658

 \S 14.15(5658). Prescription of controlled substance; immunity from administrative and civil liability.

Sec. 5658. A physician who, as part of a medical treatment plan for a terminally ill patient, prescribes for the terminally ill patient a controlled substance that is included in schedules 2 to 5 under part 72 and that is a narcotic drug is immune from administrative and civil liability based on prescribing the controlled substance if the prescription is given in good faith and with the intention to treat a patient with a terminal illness or alleviate the patient's pain, or both, and all of the following are met:

- (a) The prescription is for a legitimate legal and professionally recognized therapeutic
- (b) Prescribing the controlled substance is within the scope of practice of the physician.
- (c) The physician holds a valid license under article 7 to prescribe controlled substances.

(+) <u>CRITERION 2:</u> Pain management is part of medical practice

(+) <u>CRITERION 5:</u> Addresses fear of regulatory scrutiny

Comment: The immunity provision is valid only for physicians who prescribe for pain patients according to prognosis.



Facilities and Agencies

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

MCL § 333.20155

§ 333.20155. Visits to health facilities and agencies, clinical laboratories, nursing homes, hospices, and hospitals; purposes; waiver; confidentiality of accreditation information; limitation and effect; consultation engineering survey; summary of substantial noncompliance or deficiencies and hospital response; investigations or inspections; prior notice; misdemeanor; consultation visits; record; periodic reports; access to documents; confidentiality; disclosure; delegation of functions; voluntary inspections; forwarding evidence of violation to licensing agency; reports; clarification of terms; clinical process guidelines; clinical advisory committee; definitions.

(18) Subject to subsection (19), the department, in consultation with the clarification work group appointed under subsection (16), shall <u>develop and adopt clinical process quidelines</u> that shall be used in applying the terms set forth in subsection (16). The department shall establish and adopt clinical process guidelines and compliance protocols with outcome measures for all of the following areas and for other topics where the department determines that clarification will benefit providers and consumers of long-term care:

(f) Pain management

MCL § 333.20201

§ 333.20201. Policy describing rights and responsibilities of patients or residents; adoption; posting and distribution; contents; additional requirements; discharging, harassing, retaliating, or discriminating against patient exercising protected right; exercise of rights by patient's representative; informing patient or resident of policy; designation of person to exercise rights and responsibilities; additional patients' rights; definitions.

Sec. 20201. (1) A health facility or agency that provides services directly to patients or residents and is licensed under this article shall <u>adopt a policy describing the rights and responsibilities of patients or residents</u> admitted to the health facility or agency. Except for a licensed health maintenance organization which shall comply with chapter 35 of the insurance code of 1956, 1956 PA 218, MCL 500.3501 to 500.3580, the policy shall be posted at a public place in the health facility or agency and shall be provided to each member of the health facility or agency staff. Patients or residents shall be treated in accordance with the policy.

(2) The policy describing the rights and responsibilities of patients or residents required under subsection (1) shall include, as a minimum, all of the following:

(o) <u>A patient or resident is entitled to adequate and appropriate pain and symptom management as a basic and essential element of his or her medical treatment.</u>

MCL § 333.21521

§ 333.21521. Hospital to meet minimum standards and rules; protection of health and safety; preventive function.

Sec. 21521. A hospital shall meet the minimum standards and rules authorized by this article and shall endeavor to carry out practices that will further protect the public health and safety, prevent the spread of disease, <u>alleviate pain</u> and disability, and prevent premature death.

(+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

<u>CATEGORY C:</u> Regulatory or policy issues

COMMENT: Establishes a responsibility for hospitals to ensure that pain management is an essential part of patient care.

(+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

<u>CATEGORY C:</u> Regulatory or policy issues

COMMENT: Establishes mechanisms for health facilities or agencies to ensure that pain management is an essential part of patient care.



Assisted Suicide

- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

MCL § 752.1027

(+) <u>CRITERION 8:</u> Other provisions that may enhance pain management

<u>CATEGORY A:</u> Issues related to healthcare professionals

COMMENT: Clarifies for physicians that there is an important distinction between physicianassisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment.

§ 28.547(127). Prohibited acts; violation; penalties; applicability of subsection (1); exceptions; effective date of section; repeal of section.

Sec. 7. (1) A person who has knowledge that another person intends to commit or attempt to commit suicide and who intentionally does either of the following is guilty of criminal assistance to suicide, a felony punishable by imprisonment for not more than 4 years or by a fine of not more than \$2,000.00, or both:

- (a) Provides the physical means by which the other person attempts or commits suicide.
- (b) Participates in a physical act by which the other person attempts or commits suicide.

Exception; withholding or withdrawing medical treatment. (2) Subsection (1) shall not apply to withholding or withdrawing medical treatment.

Exception; medications and procedures not intended to cause death. (3) Subsection (1) does not apply to prescribing, dispensing, or administering medications or procedures if the intent is to relieve pain or discomfort and not to cause death, even if the medication or procedure may hasten or increase the risk of death.

Effective date. (4) This section shall take effect February 25, 1993.

Prospective repeal. (5) This section is repealed effective 6 months after the date the commission makes its recommendations to the legislature pursuant to section 4.