

ALABAMA

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
Title 20. Food, Drugs, and Cosmetics; Chapter 2. Controlled Substances
- PROFESSIONAL PRACTICE ACT (*No provisions found*)
Title 34. Professions and Businesses; Chapter 24. Physicians and Other Practitioners of Healing Arts; Article 1. State Licensing Board for Healing Arts
- MEDICAL PRACTICE ACT
Title 34. Professions and Businesses; Chapter 24. Physicians and Other Practitioners of Healing Arts; Article 3. Physicians and Osteopaths

Title 34. Professions and Businesses; Chapter 24. Physicians and Other Practitioners of Healing Arts; Article 8. Licensing and Registration of Physicians and Osteopaths
- PHARMACY PRACTICE ACT (*No provisions found*)
Title 34. Professions and Businesses; Chapter 23. Pharmacists and Pharmacies
- INTRACTABLE PAIN TREATMENT ACT
No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*No provisions found*) (*Part of Pharmacy Board Regulations*)
Alabama Uniform Controlled Substances Regulations; Chapter 680-X-3.
- MEDICAL BOARD REGULATIONS
Alabama Board of Medical Examiners; Chapter 540-X.
- PHARMACY BOARD REGULATIONS (*No provisions found*)
Alabama Board of Pharmacy; Chapter 680-X.

OTHER GOVERNMENTAL POLICIES

No policies found

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

- HOSPICE SERVICES
State Health Planning and Development Agency; Alabama State Health Plan 2004 – 2007; Chapter 410-2-3: Specialty Services.



Provisions that may <i>ENHANCE</i> pain management								
Criteria	1	2	3	4	5	6	7	8
	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		•						
Pharmacy Practice Act ¹								
Intractable Pain Treatment Act ²								
REGULATIONS								
Controlled Substances ¹								
Medical Board		•	•	•	•	•	•	•
Pharmacy Board ¹								
OTHER GOVERNMENTAL POLICIES²								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Hospice Services								•

Note: A dot indicates that one or more provisions were identified
¹ No provisions were found in this policy, ² No policy found

Provisions that may <i>IMPEDE</i> pain management								
Criteria	9	10	11	12	13	14	15	16
	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								
Pharmacy Practice Act ¹								
Intractable Pain Treatment Act ²								
REGULATIONS								
Controlled Substances ¹								
Medical Board ¹								
Pharmacy Board ¹								
OTHER GOVERNMENTAL POLICIES²								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Hospice Services ¹								

Note: A dot indicates that one or more provisions were identified
¹ No provisions were found in this policy, ² No policy found



STATUTES

Controlled Substances Act

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

Code of Ala. § 20-2-2

§ 20-2-2. Definitions

When used in this chapter, the following words and phrases shall have the following meanings, respectively, unless the context clearly indicates otherwise:

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(20) Practitioner.

a. A physician, dentist, veterinarian, scientific investigator, 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.

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(+) CRITERION 3:
Opioids are part of professional practice

STATUTES

Medical Practice Act

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

Code of Ala. § 34-24-50

§ 34-24-50. "Practice of medicine or osteopathy" defined

The "practice of medicine or osteopathy" means:

(1) To diagnose, treat, correct, advise or prescribe for any human disease, ailment, injury, infirmity, deformity, pain or other condition, physical or mental, real or imaginary, by any means or instrumentality;

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(+) CRITERION 2:
Pain management is part of medical practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



REGULATIONS

Medical Board Regulations

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

§ 540-X-4-.08

540-X-4-.08 Guidelines for the Use of Controlled Substances for the Treatment of Pain

(1) Preamble.

(a) The Board recognizes that principles of quality medical practice dictate that the people of the State of Alabama 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 to 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.

(+) **CRITERION 2:**
Pain management is part of medical practice

(b) 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.

(+) **CRITERION 4:**
Encourages pain management

(c) 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. 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 pain (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.) and cancer-related pain (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). The medical management of pain should be based upon 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.

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

(d) The Board is obligated under the laws of the State of Alabama 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.

(e) 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.

(+) **CRITERION 5:**
Addresses fear of regulatory scrutiny

(+) **CRITERION 3:**
Opioids are part of professional practice

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



REGULATIONS

Medical Board Regulations

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

(+) **CRITERION 8:**
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.

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(f) 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 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.

(g) 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.

(2) Guidelines. The Board has adopted the following guidelines when evaluating the use of controlled substances for pain control:

(a) 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 should also document the presence of one or more recognized medical indications for the use of a controlled substance.

(b) 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.

(c) 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

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

(d) Periodic Review. At reasonable intervals based upon the individual circumstance 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 re-evaluate the appropriateness of continued treatment. The physician should monitor patient compliance in medication usage and related treatment plans.

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(+) **CRITERION 6:**
Prescription amount alone does not determine legitimacy

(+) **CRITERION 8:**
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.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



REGULATIONS

Medical Board Regulations

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

[CONTINUED]

(e) 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.

(f) Medical Records. The physician should keep accurate and complete records to include:

1. the medical history and physical examination;
2. diagnostic, therapeutic and laboratory results;
3. evaluations and consultations;
4. treatment objectives;
5. discussion of risks and benefits;
6. treatments;
7. medications (including date, type, dosage, and quantity prescribed);
8. instructions and agreements; and
9. periodic reviews.

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

(g) 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 applicable state regulations for rules governing controlled substances.

(3) Definitions. For the purposes of these guidelines, the following terms are defined as follows:

(a) 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.

(b) 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.

(c) 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.

(d) 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.

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

(f) 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.

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

(h) 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.

(i) 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.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Hospice Services

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

Ala. Admin. Code r. 410-2-3-.10

410-2-3-.10 In-Home Hospice Services.

(1) Discussion

(a) Hospice care is a choice you make to enhance life for a dying person. Hospice focuses on caring, not curing and, in most cases, care is provided in the patient's home. Hospice care also is provided in freestanding hospice centers, hospitals, and nursing homes and other long-term care facilities. Hospice services are available to patients of any age, religion, race, or illness. Hospice care is covered under Medicare, Medicaid, most private insurance plans, HMOs, and other managed care organizations.

(b) Members of the hospice staff make regular visits to assess the patient and provide additional care or other services. Hospice staff is on-call 24 hours a day, seven days a week. The hospice team develops a care plan that meets each patient's individual needs for pain management and symptom control. Emotional and spiritual support is also provided to meet the patient's needs and wishes as well as that of the family.

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(+) **CRITERION 8:**
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

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



Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

ALASKA

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
Title 17. Food and Drugs; Chapter 30. Controlled Substances
Title 11. Criminal Law; Chapter 71. Controlled Substances
- MEDICAL PRACTICE ACT (*No provisions found*)
Title 8. Businesses and Professions; Chapter 64. Medicine
- PHARMACY PRACTICE ACT
Title 8. Businesses and Professions; Chapter 80. Pharmacists and Pharmacies
- INTRACTABLE PAIN TREATMENT ACT
No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
No policy found
- MEDICAL BOARD REGULATIONS (*No provisions found*)
Title 12. Professional and Vocational Regulations; Part 1. Boards and Commissions Subject to Centralized Licensing; Chapter 40. State Medical Board
- PHARMACY BOARD REGULATIONS (*No provisions found*)
Title 12. Professional and Vocational Regulations; Part 1. Boards and Commissions Subject to Centralized Licensing; Chapter 52. Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

No policies found

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

No policies found



Provisions that may <i>ENHANCE</i> pain management								
Criteria	1	2	3	4	5	6	7	8
	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								
Controlled Substances ²								
Medical Board ¹								
Pharmacy Board ¹								
OTHER GOVERNMENTAL POLICIES²								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES²								

Note: A dot indicates that one or more provisions were identified
¹ No provisions were found in this policy, ² No policy found

Provisions that may <i>IMPEDE</i> pain management								
Criteria	9	10	11	12	13	14	15	16
	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 ²								
Medical Board ¹								
Pharmacy Board ¹								
OTHER GOVERNMENTAL POLICIES²								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES²								

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STATUTES

Controlled Substances Act

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

Alaska Stat. § 11.71.900

Sec. 11.71.900. Definitions

In this chapter, unless the context clearly requires otherwise,

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(19) "practitioner" means

(A) a physician, dentist, veterinarian, scientific investigator, or other person licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer or use in teaching or chemical analysis a controlled substance in the course of professional practice or research in the state;

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(+) **CRITERION 3:**
Opioids are part of professional practice

STATUTES

Pharmacy Practice Act

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

Alaska Stat. § 08.80.480

Sec. 08.80.480. Definitions

In this chapter, unless the context otherwise requires,

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(28) "practitioner" means an individual currently licensed, registered, or otherwise authorized by the jurisdiction in which the individual practices to prescribe and administer drugs in the course of professional practice;

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(+) **CRITERION 3:**
Opioids are part of professional practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

ARIZONA

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
Title 36. Public Health and Safety; Chapter 27. Uniform Controlled Substances Act
- MEDICAL PRACTICE ACT (*No provisions found*)
Title 32. Professions and Occupations; Chapter 13. Medicine and Surgery
- OSTEOPATHIC PRACTICE ACT (*No provisions found*)
Title 32. Professions and Occupations; Chapter 17. Osteopathic Physicians and Surgeons
- PHARMACY PRACTICE ACT
Title 32. Professions and Occupations; Chapter 18. Pharmacy
- INTRACTABLE PAIN TREATMENT ACT
No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
No policy found
- MEDICAL BOARD REGULATIONS (*No provisions found*)
Title 4. Professions and Occupations; Chapter 16. Arizona Medical Board
- OSTEOPATHIC BOARD REGULATIONS (*No provisions found*)
Title 4. Professions and Occupations; Chapter 22. Board of Osteopathic Examiners in Medicine and Surgery
- PHARMACY BOARD REGULATIONS (*No provisions found*)
Title 4. Professions and Occupations; Chapter 23. Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD POLICY STATEMENT
Arizona Medical Board. *Guidelines for the Use of Controlled Substances for the Treatment of Chronic Pain*. Agency Substantive Policy Statement #7. Adopted: June 2003.
- OSTEOPATHIC BOARD POLICY STATEMENT
Arizona Board of Osteopathic Examiners in Medicine and Surgery. *Guidelines: The Prescribing of Controlled Substances for the Treatment of Pain Management*. Adopted: January 22, 2000.



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

- HEALTH SERVICES

Title 9. Health Services; Chapter 10. Department of Health Services: Health Care Institutions: Licensing; Article 2. Hospitals

Title 9. Health Services; Chapter 20. Department of Health Services: Behavioral Health Service Agencies: Licensure; Article 10. Opioid Treatment



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

Controlled Substances ²								
Medical Board ¹								
Osteopathic Board ¹								
Pharmacy Board ¹								

OTHER GOVERNMENTAL POLICIES

Medical Board Policy Statement			•	•	•			•
Osteopathic Board Policy Statement		•	•	•	•	•	•	•

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

Health Services: Hospitals								•
Health Services: Opioid Treatment								•

Note: A dot indicates that one or more provisions were identified
¹ No provisions were found in this policy, ² No policy found

Provisions that may <i>IMPEDE</i> pain management								
Criteria	9	10	11	12	13	14	15	16
	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 ²								
Medical Board ¹								
Osteopathic Board ¹								
Pharmacy Board ¹								
OTHER GOVERNMENTAL POLICIES								
Medical Board Policy Statement	•	•		•				•
Osteopathic Board Policy Statement ¹								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Health Services: Hospitals ¹								
Health Services: Opioid Treatment ¹								

Note: A dot indicates that one or more provisions were identified
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STATUTES

Controlled Substances Act

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

A.R.S. § 36-2501

§ 36-2501. Definitions

A. In this chapter, unless the context otherwise requires:

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5. "Drug dependent person" means a person who is using a controlled substance and who is in a state of psychic or physical dependence, or both, arising from the use of that 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 continuing basis in order to experience its psychic effects or to avoid the discomfort caused by its absence.

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

STATUTES

Pharmacy Practice Act

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

A.R.S. § 32-1901

§ 32-1901. Definitions

In this chapter, unless the context otherwise requires:

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70. "Practitioner" means any physician, dentist, veterinarian, scientific investigator 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 professional practice or research in this state, or any pharmacy, hospital or other institution 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 this state.

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(+) **CRITERION 3:**
Opioids are part of professional practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Policy Statement

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

USE OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF CHRONIC PAIN

Guideline encourages effective pain management in Arizona, so that physicians reach a level of comfort about appropriate prescribing.

The Board strongly urges physicians to view effective pain management as a high priority in all patients, including children and the elderly. Pain should be assessed and treated promptly, effectively and for as long as pain persists. The medical management of pain should be based on up-to-date knowledge about pain, pain assessment and pain treatment. Pain treatment may involve the use of several drug and non-drug treatment modalities, often in combination. For some types of pain the use of drugs is emphasized and should be pursued vigorously; for other types, the use of drugs is better de-emphasized in favor of other therapeutic modalities. Physicians should have sufficient knowledge or consultation to make such judgments for their patients.

Drugs, in particular the opioid analgesics, are considered the cornerstone of treatment for pain associated with trauma, surgery, medical procedures and cancer. Physicians are referred to the U.S. Agency for Health Care Policy and Research Clinical Practice Guidelines as a sound yet flexible approach to the management of these types of pain.

The prescribing of opioid analgesics for other patients with intractable non-cancer pain also may be beneficial, especially when efforts to remove the cause of pain or to treat it with other modalities have been unsuccessful. For the purposes of these guidelines, intractable pain is defined as:

"A pain state in which the cause of the pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts including, but not limited to, evaluation by the attending physician and surgeon and one or more physicians and surgeons specializing in the treatment of the area, system, or organs of the body perceived as the source of the pain."

Therefore, these guidelines are an attempt to communicate to physicians who prescribe opioids for intractable pain not to fear disciplinary action from this Board for prescribing or administering controlled substances in the course of treatment of a person for intractable pain. Also, physicians should use sound clinical judgment, and care for their patients according to the following principles of responsible professional practice:

Statutory ability to develop guidelines

Pursuant to Arizona Revised Statutes §32-1403(A)(3), the Board may develop and recommend standards governing the profession in Arizona. In developing these guidelines, the Board reviewed 18 guidelines developed by other states and agencies.¹

Guidelines for Patient Care when prescribing controlled substances for chronic pain

A) Pain Assessment

Pain assessment should occur during initial evaluation, after each new report of pain, at appropriate intervals after each pharmacological intervention, and at regular intervals during treatment. Unless a patient is terminally ill and death is imminent (in which case the diagnosis is usually evident and diagnostic evaluations may be of little value and discomforting to the patient), the evaluation should include:

1. Medical history, including the presence of a recognized medical indication for the use of a controlled substances, the intensity and character of pain, and questions regarding substance abuse;

[CONTINUED ON NEXT PAGE]

(+) **CRITERION 4:**
Encourages pain management

(+) **CRITERION 3:**
Opioids are part of professional practice

(-) **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?

(-) **CRITERION 10:**
Implies opioids are not part of professional practice

(-) **CRITERION 12:**
Medical decisions are restricted

CATEGORY B:
Mandated consultation

(+) **CRITERION 5:**
Addresses fear of regulatory scrutiny

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



OTHER GOVERNMENTAL POLICY

Medical Board Policy Statement

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

(+) **CRITERION 8:**
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.

[CONTINUED]

2. Psycho-social assessment, which may include but is not limited to:

- a. The patient's understanding of the medical diagnosis, expectations about pain relief and pain management methods, concerns regarding the use of controlled substances, and coping mechanisms for pain;
- b. Changes in mood which have occurred secondary to pain (i.e., anxiety, depression); and
- c. The meaning of pain to the patient and his/her family.

3. Physical examination, including a neurologic evaluation and examination of the site of pain.

B) Treatment Plan

A treatment plan should be developed for the management of chronic pain and state objectives by which therapeutic success can be evaluated, including:

1. Pain relief;
2. Improved physical functioning;
3. Proposed diagnostic evaluations (i.e., blood tests, radiologic, psychological and social studies such as CAT and bone scans, MRI and neurophysiologic examinations such as electromyography); and
4. Analysis of inclusion and exclusion criteria for opioid management: Inclusion criteria include: a clear diagnosis has been made, consistent with symptoms; the exploration of all reasonable alternative therapies have been explored; the patient is reliable and communicates well; and there has been informed consent or a treatment agreement signed. Potential exclusion criteria include a history of chemical dependency, major psychiatric disorder, chaotic social situation, or a planned pregnancy.

C) Informed Consent

The physician should advise the patient, guardian, or designated surrogate of the risks and benefits of the use of controlled substances. The patient should be counseled on the importance of regular visits, the impact of recreational drug use, the number of physicians and pharmacies used for prescriptions, taking medications as prescribed, etc.

D) Ongoing Assessment

The assessment and treatment of chronic pain mandates continuing evaluation, and if necessary, modification and/or discontinuation of opioid therapy. If clinical improvement does not occur, the physician should consider the appropriateness of continued opioid therapy, and consider a trial of alternative pharmacologic and nonpharmacologic modalities.

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(-) **CRITERION 9:**
Opioids are a last resort

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



OTHER GOVERNMENTAL POLICY

Medical Board Policy Statement

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

[CONTINUED]

E) Consultation

The physician should refer patients as necessary for additional evaluation to achieve treatment objectives. Physicians should recognize patients requiring individual attention, in particular, patients whose living situations pose a risk for misuse or diversion of controlled substances. In addition, the prescription of controlled substances to patients with a history of substance abuse requires extra care, monitoring, and documentation, and may also require consultation with an addiction medicine specialist. The physician may also consider the use of physician-patient agreements or contracts that specify the rules for medication use and the consequences of misuse or abuse.

F) Documentation

The physician must maintain adequate, accurate and timely records regarding items A-E from above. "Adequate Records," pursuant to A.R.S. §32-1401(2), "means legible records containing, at a minimum, sufficient information to identify the patient, support the diagnosis, justify the treatment, adequately document the results, indicate advice and cautionary warnings provided to the patient, and provide sufficient information for another practitioner to assume continuity of the patient's care at any point in the treatment." Specific to chronic pain patients, the documentation should include:

1. The medical history and physical examination;
2. Related evaluations and consultations, treatment plan and objectives;
3. Evidence of discussion regarding informed consent;
4. Prescribed medications and treatments;
5. Periodic reviews of treatments and patient response; and
6. Any physician-patient agreements or contracts.

Compliance with Laws and Regulations

To prescribe controlled substances, physicians must comply with all applicable laws, including the following:

1. Possess a valid current license to practice medicine in the State of Arizona;
2. Possess a valid and current controlled substances Drug Enforcement Administration registration for the schedules being prescribed;
3. If drugs are dispensed from the office, comply with Arizona Revised Statutes §32-1491 et. Seq., and AAC R4-16-201 through R4-16-205.
4. If controlled substances are provided for detoxification, comply with 22 CFR 1306.07(a).

¹ Statutes were reviewed from the Alabama, Delaware and Texas Medical Boards; Policies were reviewed from the California, Colorado, Florida, Idaho, Minnesota, New Mexico, North Carolina, Ohio, Oregon, Rhode Island, Tennessee, and Vermont Medical Boards, as well as the Agency on Health Care Policy and Research, American Academy of Pain Management and American Pain Society, and the Arizona Pain Society/American Society of Anesthesiologist Task Force.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



OTHER GOVERNMENTAL POLICY

Osteopathic Board Policy Statement

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

**ARIZONA BOARD OF OSTEOPATHIC EXAMINERS
IN MEDICINE AND SURGERY**

**GUIDELINES: THE PRESCRIBING OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN
MANAGEMENT**

INTRODUCTION:
The Arizona State Board of Osteopathic Examiners in Medicine and Surgery recognizes that Principles of quality medical practice dictate that the people of the State Of Arizona 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.

INTRODUCTION:
The Board encourages physicians to view effective pain management as part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for those patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about effective methods of pain relief as well as statutory requirements for Prescribing controlled substances.

Physicians should not fear disciplinary action from the Board or other state regulatory or Enforcement agencies for Prescribing, dispensing, or administering controlled substances, including opioid analgesics 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 and/or federal law.

The Board will judge the validity of prescribing based on the physician's treatment of the patient and on the available documentation. 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 the complete or best practice, but rather to communicate what the Board considers to be within the boundaries of professional practice.

PURPOSE:
The purpose of these guidelines regarding the prescribing of controlled substances for the treatment of pain is to establish criteria to be considered by the Board in consideration of allegations of unprofessional conduct. The Board's objective is for these Guidelines to recognize but to not interfere with the medical use of controlled substances for pain relief, while continuing to address the issue of prescribing that may contribute to drug abuse and diversion. These guidelines are general recommendations. Each case involving the prescription of controlled substances for pain management will be judged on all factors related to that patient. These guidelines were created to provide the Board and the Licensed osteopathic medical community a basis in which to provide quality medical care to the citizens of the State of Arizona.

Guidelines:

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

1. Pain Assessment:

A. Medical History

A comprehensive history should include a review of pertinent lab and diagnostic test that have already been performed. The initial evaluation of the pain complaint should include characteristics such as intensity, character, frequency, location, duration, and precipitating and relieving factors, underlying or co-existing diseases or conditions.

[CONTINUED ON NEXT PAGE]

(+) **CRITERION 2:**
Pain management is part of medical practice

(+) **CRITERION 5:**
Addresses fear of regulatory scrutiny

(+) **CRITERION 6:**
Prescription amount alone does not determine legitimacy

(+) **CRITERION 8:**
Other provisions that may enhance pain management

CATEGORY C:
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.

(+) **CRITERION 4:**
Encourages pain management

(+) **CRITERION 3:**
Opioids are part of professional practice

(+) **CRITERION 8:**
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.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



OTHER GOVERNMENTAL POLICY

Osteopathic Board Policy Statement

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

[CONTINUED]

It should also include a thorough analgesic medication history, including current and previous prescription medications, over-the-counter medications, natural remedies and illicit drug use.

It should also include an evaluation of physical function. This should focus on pain associated disabilities, including activities of daily living.

B. Psycho-social Assessment

Evaluation should also include assessment of the patient's mood with particular concern regarding anxiety or depression. The physician should assess whether the patient understands the diagnosis. One should also evaluate the patient's expectations about pain relief and pain management methods. The patient may have reservations about the use of controlled substances. The physician should question the patient about their coping mechanisms for pain. This also includes assessment of the patient's social networks, including any dysfunctional family relationships.

C. Physical Exam

Physical exams should focus on the neuromuscular system, search for neurological impairment, weakness, hyperalgesia, allodynia, or parathesias.

One should assess the musculoskeletal system with attention to the palpation of tenderness, inflammation, deformity, trigger points, and physical function.

2. Treatment Plan:

A. Pain Relief

A treatment plan should be developed for the management of chronic pain. Consideration should also 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. The assessment of pain should occur, not only during the initial exam, but also after each new reportive pain, at the appropriate intervals, after each pharmacological intervention and at regular intervals during treatment.

B. Improved Physical Functioning

A quantitative assessment of pain should be recorded by the use of a standard pain scale and pain log. Patients with chronic pain and their caregivers should be instructed on the use of the pain log with regular intervals for pain intensity, medication use, response to treatment, and associated activities.

A qualitative assessment of the treatment plan should include the evaluation of the patient's ability to function productively in society.

3. Informed Consent:

Advise the chronic pain patient or guardian of the risks and the benefits of the use of controlled substances as well as alternatives to that treatment. They should be counseled on the importance of regular visits, the impact of recreational drug use, avoiding the use of multiple pharmacies and physicians for prescriptions and taking medication as directed. A contract should be signed outlining the patient's responsibilities, if appropriate.

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OTHER GOVERNMENTAL POLICY

Osteopathic Board Policy Statement

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

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4. On-going Assessment:

Patients with chronic pain should be re-assessed regularly. The frequency of follow-up should be a function of the pain syndrome and potential for adverse effects of treatment. The physician may consider discontinuing the use or modifying medications if the patient is experiencing side effects that are not tolerable, if clinical improvement does not occur, or if the physician notes non-compliance. The clinician should watch for signs of narcotic use for inappropriate indications like anxiety or depression. Requests for early refills should prompt an evaluation of tolerance to the medication, progression of disease or inappropriate behavioral factors.

5. Consultation and Referral – Optimal Treatment requires a team approach

Psychiatrists, psychologists, pain management specialists are available and should be part of the treatment team specifically in the more complex patient.

6. Documentation:

Documentation is essential for supporting the evaluation. The clinician should include the reason for prescribing controlled substances. The clinician should also document the overall pain management treatment plan, any consultations received, and a periodic review of the status of the patient. The clinician should also include medications and treatments including the date, type, dosage and quantity prescribed.

7. Medical Record – in accordance with A.R.S. § 32-1800 (2) and A.R.S. § 12-2291(4)

Physician should develop and maintain complete records to include:

Medical history and physical examination
Diagnostic, therapeutic, and lab results;
Evaluations and consultations;
Treatment objectives;
Discussion of risks and benefits;
Treatment;
Medication (include date, type, dose and quantity)
Instructions and agreements; and
Periodic reviews

Records should be accessible and ready for review.

COMPLIANCE WITH LAWS AND REGULATIONS:

Treating physician must possess a valid and current license to practice medicine in the State of Arizona.

A. Possess a Valid and current controlled substances drug enforcement registration for the schedules being prescribed.

B. If drugs are dispensed from the office, the physician must comply with the Arizona State Statutes.

C. If controlled substances are provided for detoxification, the physician should comply with the Arizona State Statutes.

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(+) **CRITERION 8:**
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.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



OTHER GOVERNMENTAL POLICY

Osteopathic Board Policy Statement

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

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Definitions

For the purpose 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, mechanical or neurological 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 result in psychological dependence on the use of substances for the 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 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.

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.

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

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



REGULATIONS

Health Services: Hospitals

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

(+) **CRITERION 8:**
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (documentation in medical records) for hospitals to ensure that pain management is an essential part of patient care.

A.A.C. § R9-10-217

R9-10-217. Pharmaceutical Services

An administrator shall require that:

14. If pain medication is administered to a patient, documentation in the patient's medical record includes:

a. An assessment of the patient's pain before administering the medication; and

b. The effect of the pain medication administered;

REGULATIONS

Health Services: Opioid Treatment

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

(+) **CRITERION 8:**
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (written policies and procedures) for OTP staff to refer opioid-maintained patients who have chronic pain for treatment of their pain.

A.A.C. § R9-20-1002

R9-20-1002. Administration

A program sponsor shall ensure that:

1. The program sponsor designates a physician to serve as medical director and to have authority over all medical aspects of opioid treatment;

2. Written policies and procedures are developed, implemented, complied with, and maintained at the agency and include:

g. A requirement that a client who is physiologically dependent as a result of chronic pain receives consultation with or a referral for consultation with a medical practitioner who specializes in chronic pain;

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

ARKANSAS

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
Title 5. Criminal Offenses; Subtitle 6. Offenses Against Public Health, Safety, or Welfare; Chapter 64. Controlled Substances

Title 20. Public Health and Welfare; Subtitle 4. Food, Drugs, and Cosmetics; Chapter 64. Alcohol and Drug Abuse; Subchapter 2. Uniform Narcotic Drug Act
- MEDICAL PRACTICE ACT (*No provisions found*)
Title 17. Professions, Occupations, and Businesses; Subtitle 3. Medical Professions; Chapter 95. Physicians and Surgeons
- INTRACTABLE PAIN TREATMENT ACT (*Part of Medical Practice Act*)
Title 17. Professions, Occupations, and Businesses; Subtitle 3. Medical Professions; Chapter 95. Physicians and Surgeons; Subchapter 7. Treatment of Chronic Intractable Pain
- OSTEOPATHIC PRACTICE ACT (*No provisions found*)
Title 17. Professions, Occupations, and Businesses; Subtitle 3. Medical Professions; Chapter 91. Osteopaths
- PHARMACY PRACTICE ACT (*No provisions found*)
Title 17. Professions, Occupations, and Businesses; Subtitle 3. Medical Professions; Chapter 92. Pharmacists and Pharmacies

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
007 Department of Health; 07 Pharmacy Services and Drug Control (Bureau of Health Resources)
- MEDICAL BOARD REGULATIONS
060 State Medical Board
- OSTEOPATHIC BOARD REGULATIONS
No policy found
- PHARMACY BOARD REGULATIONS (*No provisions found*)
070 Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

No policies found



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

- HOMICIDE
Title 5. Criminal Offenses; Subtitle 2. Offenses Against the Person; Chapter 10. Homicide
- HEALTH FACILITY SERVICES
007. Department of Health; 05. Health Facility Services



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								
Intractable Pain Treatment Act		•	•	•	•	•		•
Osteopathic Practice Act ¹								
Pharmacy Practice Act ¹								
REGULATIONS								
Controlled Substances			•					
Medical Board		•	•					•
Osteopathic Board ¹								
Pharmacy Board ¹								
OTHER GOVERNMENTAL POLICIES²								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Homicide								•
Health Facility Services								•

Note: A dot indicates that one or more provisions were identified
¹ No provisions were found in this policy, ² No policy found

Provisions that may *IMPEDE* pain management

Criteria	9	10	11	12	13	14	15	16
	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								
Intractable Pain Treatment Act				•				•
Osteopathic Practice Act ¹								
Pharmacy Practice Act ¹								
REGULATIONS								
Controlled Substances ¹								
Medical Board								•
Osteopathic Board ¹								
Pharmacy Board ¹								
OTHER GOVERNMENTAL POLICIES²								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Homicide ¹								
Health Facility Services ¹								

Note: A dot indicates that one or more provisions were identified
¹ No provisions were found in this policy, ² No policy found

STATUTES

Controlled Substances Act

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

A.C.A. § 5-64-101

§ 5-64-101. Definitions

As used in this chapter:

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(21) "Practitioner" means:

(A) A physician, dentist, veterinarian, scientific investigator, 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;

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(+) CRITERION 3:
Opioids are part of professional practice

STATUTES

Uniform Narcotic Drug Act

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

Ark. Stat. Ann. § 20-64-207

§ 20-64-207. Professional use of narcotic drugs

(1) Physicians and Dentists. A physician or a dentist, in good faith and in the course of his professional practice only, may prescribe, administer, and dispense narcotic drugs, or he may cause the same to be administered by a nurse or intern under his direction and supervision.

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(+) CRITERION 3:
Opioids are part of professional practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



STATUTES

Intractable Pain Treatment Act

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

A.C.A. § 17-95-701 – § 17-95-707

§ 17-95-701. Title

This subchapter shall be known and may be cited as the "Chronic Intractable Pain Treatment Act".

§ 17-95-702. Findings

The General Assembly finds that:

(1) Pain management plays an important role in good medical practice.

(2) Physicians should recognize the need to make pain relief accessible to all patients with chronic intractable pain; and

(3) Physicians should view pain management as a regular part of their medical practice for all patients with chronic intractable pain.

§ 17-95-703. Definitions

As used in this subchapter:

(1) "Board" means the Arkansas State Medical Board;

(2) "Chronic intractable pain" means a pain state for which the cause of the pain cannot be removed or otherwise treated and for which no relief or cure has been found after reasonable efforts by a physician.

(3) (A) "Dangerous or controlled drugs" means drugs used for pain relief, including, but not limited to:

(i) Opioids; and

(ii) Other drugs classified under schedules II, III, IV, or V by the United States Food and Drug Administration.

(B) "Dangerous or controlled drugs" does not include any substance the prescription of which is illegal under federal law;

(4) "Disciplinary action" means any remedial or punitive sanctions imposed on a licensed physician by the board;

(5) "Patient" means a person seeking medical diagnosis and treatment; and

(6) "Physician" means a licensee of the Arkansas State Medical Board.

[CONTINUED ON NEXT PAGE]

(+) **CRITERION 4:**
Pain management is encouraged

(+) **CRITERION 2:**
Pain management is part of medical practice

(-) **CRITERION 16:**
Provisions that are ambiguous

CATEGORY B: *Unclear intent leading to possible misinterpretation*

COMMENT: Suggests that physicians would not qualify for immunity and relief from concerns about regulatory scrutiny if they prescribe opioids as a treatment of first choice for patients who present initially with severe pain, such as those with sickle-cell anemia.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



STATUTES

Intractable Pain Treatment Act

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

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§ 17-95-704. Arkansas State Medical Board -- Treatment -- Prohibitions

(a) (1) A physician shall not be subject to disciplinary action by the Arkansas State Medical Board solely for prescribing dangerous or controlled drugs for the relief of chronic intractable pain.

(2) (A) (i) Any allegation of improper prescribing determined to require a board hearing shall be referred to the Pain Management Review Committee before any board hearing or action.

(ii) (a) However, in exceptional limited substantive instances requiring immediate action to protect the public health, an emergency action under § 25-15-211(c) may be implemented.

(b) The implementation of an emergency action under § 25-15-211(c) shall in no way be used by the board to circumvent, void, supplant, or otherwise limit the role of the committee as provided in this subchapter.

(B) The board shall provide the committee all necessary documentation for the review process in a timely manner.

(3) The board shall direct the committee to use the criteria under subsections (d) and (e) of this section to review a physician's conduct in regard to prescribing, administering, ordering, or dispensing pain medications and other drugs necessary to treat chronic intractable pain.

(4) (A) If the board determines that an allegation or a question regarding a physician's prescribing does not justify a board hearing, in lieu of a board hearing, the board may refer a physician to the committee for review and recommendations to the board.

(B) The review and recommendations under subdivision (a)(4)(A) of this section shall not adversely affect the physician's license or licensure status.

(b) The board shall:

(1) Make reasonable efforts to notify health care providers under its jurisdiction of the existence of this subchapter;

(2) Inform any health care provider licensed by the board and investigated regarding the provider's practices in the management of pain of the existence of this subchapter; and

(3) (A) In a disciplinary hearing, present opinion evidence from a full-time active practice physician in direct patient care who is knowledgeable in pain management.

(B) The physician has the right to present testimony from a full-time active practice physician in direct patient care who is knowledgeable in pain management.

(c) (1) In lieu of a finding of gross and ignorant malpractice, the board after a hearing may incrementally impose sanctions as follows:

(A) Monitor prescribing habits of the physician not to exceed six (6) months;

(B) Require the physician to voluntarily surrender his or her United States Drug Enforcement Agency license to the board for a specified period of time not to exceed three (3) months;

(C) Suspend the physician's license, stay the suspension, and require monitoring of prescribing habits;

(D) Revoke the physician's license, stay revocation, and require monitoring of the physician's prescribing habits for a specified time; and

(E) Revoke the physician's license for serious violations of statutes and regulations.

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(+) **CRITERION 5:**
Practitioners' concerns about regulatory scrutiny are addressed

(+) **CRITERION 8:**
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility to communicate to practitioners about immunity from board discipline for pain management prescribing practices.

(+) **CRITERION 8:**
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (Pain Management Review Committee) to review allegations of improper prescribing against physicians for treating intractable pain before disciplinary determinations are made.

(+) **CRITERION 8:**
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (using opinions from physicians involved in direct care of patients with pain) to decide allegations against physicians for treating intractable pain.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Intractable Pain Treatment Act

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

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(2) With a finding of severe violation of statutes and regulations, the board may initially impose the more severe sanctions.

(3) At any level of sanction, the board may require continuing medical education hours in proper prescribing habits.

(d) Based upon evaluation and management of a patient's individual needs, a physician may:

(1) Treat a patient who develops chronic intractable pain with a dangerous or controlled drug to relieve the patient's pain;

(2) Continue to treat the patient for as long as the pain persists;

(3) Treat the pain by managing it with dangerous or controlled drugs in amounts or combinations that may not be appropriate for treating another medical condition;

(4) Administer large doses of dangerous or controlled drugs for pain management if the benefit of relief outweighs the risk of the large dose; and

(5) Administer a large dose of a dangerous or controlled drug even if its use may increase the risk of death if the purpose is not to cause or assist in a patient's death.

(e) A physician may not:

(1) Prescribe or administer dangerous or controlled drugs intended to manage chronic intractable pain to treat a patient for chemical dependency on drugs or controlled substances;

(2) Prescribe or administer dangerous or controlled drugs to a person the physician knows to be using drugs for nontherapeutic purposes;

(3) Prescribe or administer dangerous or controlled drugs to a person for other than legitimate medical purposes; or

(4) (A) Cause or assist in causing the suicide, euthanasia, or mercy killing of any individual.

(B) However, causing or assisting in causing the suicide, euthanasia, or mercy killing of any individual does not include prescribing, dispensing, or administering medical treatment for the purpose of alleviating pain or discomfort even if that use may increase the risk of death so long as the treatment is not furnished for the purpose of causing or assisting in causing the death of the individual.

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(+) **CRITERION 3:**
Opioids are part of professional practice

(+) **CRITERION 8:**
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 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.

(+) **CRITERION 6:**
Prescription amount alone does not determine legitimacy

(-) **CRITERION 12:**
Medical decisions are restricted

CATEGORY A:
Restrictions based on patient characteristics

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



STATUTES

Intractable Pain Treatment Act

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

[CONTINUED]

§ 17-95-705. Pain Management Review Committee -- Membership -- Duties

(a) There is created the Pain Management Review Committee, appointed by the Arkansas State Medical Board.

(b) The committee shall consist of five (5) members who are full-time active physicians in direct patient care, two (2) of whom may be board-certified pain management specialists and three (3) of whom may be physicians with significant pain management in their practices or with a degree in pharmacy, appointed by the board from a list provided by the Arkansas Osteopathic Medical Association, the Arkansas Medical Society, and the Arkansas Pain Society.

(c) The committee shall:

(1) Have committee representation from the Arkansas Osteopathic Medical Association, the Arkansas Medical Society, and the Arkansas Pain Society to develop guidelines for investigations of complaints regarding conduct in violation of this subchapter;

(2) Review complaints on an individual patient-needs basis regarding physicians treating chronic intractable pain in violation of this subchapter; and

(3) (A) Provide an objective critique to the board for board determination in a timely manner and if so determined, before the board's disciplinary hearing.

(B) In order to ensure a fair, impartial, and objective board hearing, no board member shall be:

- (i) Present while the committee reviews allegations of improper prescribing; or
- (ii) Involved in any way in the committee's deliberations.

§ 17-95-706. Scope

This subchapter does not condone, authorize, or approve mercy killing or euthanasia, and no treatment authorized by this subchapter may be used for mercy killing or euthanasia.

§ 17-95-707. Immunity -- Criminal prosecution

No physician shall be subject to criminal prosecution for prescribing or administering controlled substances under appropriate criteria in the course of treatment of a person for chronic intractable pain.

(+) **CRITERION 8:**
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (Pain Management Review Committee) to review allegations of improper prescribing against physicians for treating intractable pain based on the individual clinical needs of the patient.

(+) **CRITERION 8:**
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (immunity) to protect physicians treating intractable pain from criminal prosecution.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



REGULATIONS

Controlled Substances Regulations

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

007 07 CARR 009

009 Rules and Regulations Pertaining to Controlled Substances

SECTION 1. REGISTRATION

Every Practitioner as defined as follows shall obtain a registration from the Federal Drug Enforcement Administration, Department of Justice unless exempted by Law.

A. A physician, podiatric physician, osteopathic physician, dentist, veterinarian, optometrist, scientific investigator, researcher, mid-level practitioner, or other persons licensed, registered, or otherwise permitted to prescribe, dispense, distribute, administer or conduct research with respect to controlled substances in the course of professional practice or research in Arkansas:

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(+) **CRITERION 3:**
Opioids are part of professional practice

REGULATIONS

Medical Board Regulations

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

060 00 CARR 001

001 Arkansas Medical Practices Regulations REGULATION NO. 2

The Arkansas Medical Practices Act authorizes the Arkansas State Medical Board to revoke or suspend the license issued by the Board to practice medicine if the holder thereof has been found guilty of grossly negligent or ignorant malpractice.

"Malpractice" includes any professional misconduct, unreasonable lack of skill or fidelity in professional duties, evil practice, or illegal or immoral conduct in the practice of medicine and surgery.

It shall include, among other things, but not limited to:

1. Violation of laws, regulations, and procedures governing payment to physicians for medical services for eligible public assistance recipients and/or other third party payment programs.
2. Participation in any plan, agreement, or arrangement which compromises the quality or extent of professional medical services or facilities at the expense of the public health, safety, and welfare.
3. Practicing fraud, deceit, or misrepresentation in the practice of medicine.
4. The prescribing of excessive amounts of controlled substances to a patient including the writing of an excessive number of prescriptions for an addicting or potentially harmful drug to a patient.
5. The prescribing of Schedule II controlled substances by a physician for his own use or for the use of his immediate family.
6. The treatment of pain with dangerous drugs and controlled substances is a legitimate medical purpose when done in the usual course of medical practice. If the provisions as set out below in this Resolution are met, and if all drug treatment is properly documented, the Board will consider such practices as prescribing in a therapeutic manner, and prescribing and practicing medicine in a manner consistent with public health and welfare.

[CONTINUED ON NEXT PAGE]

(-) **CRITERION 16:**
Provisions that are ambiguous

CATEGORY A: *Arbitrary standards for legitimate prescribing*

COMMENT: "Excessive" implies there is a limit, but the limit is not specified and who determines the limit?

(+) **CRITERION 2:**
Pain management is part of medical practice

(+) **CRITERION 3:**
Opioids are part of professional practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



REGULATIONS

Medical Board Regulations

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

[CONTINUED]

However, a physician who prescribes **narcotic agents Schedule 2, 3, 4, and 5, excluding Schedule 4 Propoxyphene products and to include the schedule drugs Talwin, Stadol, and Nubain, on a long term basis (more than six (6) months) for a patient with pain not associated with malignant or terminal illness will be considered exhibiting gross negligence or ignorant malpractice unless he or she has complied with the following:

a. The physician will keep accurate records to include the medical history, physical examination, other evaluations and consultations, treatment plan objective, informed consent noted in the patient record, treatment, medications given, agreements with the patient and periodic reviews.

b. The physician will periodically review the course of schedule drug treatment of the patient and any new information about etiology of the pain. If the patient has not improved, the physician should assess the appropriateness of continued prescribing of scheduled medications or dangerous drugs, or trial of other modalities.

c. The physician will obtain written informed consent from those patients he or she is concerned may abuse controlled substances and discuss the risks and benefits of the use of controlled substances with the patient, his or her guardian, or authorized representatives.

d. The physician will be licensed appropriately in Arkansas and have a valid controlled substance registration and comply with the Federal and State regulations for the issuing of controlled substances and prescriptions, more especially the regulations as set forth in 21 Code of Federal Regulations Section 1300, et sequence.

7. A licensed physician engaging in sexual contact, sexual relations or romantic relationship with a patient concurrent with the physician-patient relationship; or a licensed physician engaging in the same conduct with a former patient, if the physician uses or exploits trust, knowledge, emotions or influence derived from the previous professional relationship, shows a lack of fidelity of professional duties and immoral conduct, thus exhibiting gross negligence and ignorant malpractice. A patient's consent to, initiation of, or participation in sexual relationship or conduct with a physician does not change the nature of the conduct nor the prohibition.

8. **Requiring minimum standards for establishing physician/patient relationships. A physician exhibits gross negligence if he provides and/or recommends any form of treatment, including prescribing legend drugs, without first establishing a proper physician/patient relationship.

A. For purposes of this regulation, a proper physician/patient relationship, at a minimum requires that:

1. The physician performs a history and physical examination of the patient adequate to establish a diagnosis and identify underlying conditions and/or contraindications to the treatment recommended/provided, OR personally knows the patient and the patient's general health status through an "ongoing" personal or professional relationship, AND THAT

2. Appropriate follow-up be provided, when necessary, at medically necessary intervals.

B. For the purposes of this regulation, a proper physician/patient relationship is deemed to exist in the following situations:

1. When treatment is provided in consultation with, or upon referral by, another physician who has an ongoing relationship with the patient, and who has agreed to supervise the patient's treatment, including follow up care and the use of any prescribed medications.

2. On-call or cross-coverage situations.

C. Exceptions – Recognizing a physician's duty to adhere to the applicable standard of care, the following situations are hereby excluded from the requirement of this regulation:

1. Emergency situations where the life or health of the patient is in danger or imminent danger.

2. Simply providing information of a generic nature not meant to be specific to an individual patient.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



REGULATIONS

Medical Board Regulations

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

060 00 CARR 001

001 Arkansas Medical Practices Regulations

REGULATION NO. 19. PAIN MANAGEMENT PROGRAMS

A. Physicians operating a pain management program for specific syndromes...that is headache, low back pain, pain associated with malignancies, or temporomandibular joint dysfunctions...are expected to meet the standards set forth in this section or in fact be in violation of the Medical Practice Act by exhibiting gross negligence or ignorant malpractice.

B. Definitions:

1. Chronic Pain Syndrome: Any set of verbal and/or nonverbal behaviors that: (1) involves the complaint of enduring pain, (2) differs significantly from a person's premorbid status, (3) has not responded to previous appropriate medical and/or surgical treatment, and (4) interferes with a person's physical, psychological and social and/or vocational functioning.

2. Chronic Pain Management Program provides coordinated, goal-oriented, interdisciplinary team services to reduce pain, improving functioning, and decrease the dependence on the health care system of persons with chronic pain syndrome.

C. The following standards apply to both inpatient and outpatient programs and the physician should conform to the same.

1. There should be medical supervision of physician prescribed services.

2. A licensee should obtain a history and conduct a physical examination prior to or immediately following admission of a person to the Chronic Pain Management Program.

3. At the time of admission to the program, the patient and the physician should enter into a written contract stating the following:

- a. The presenting problems of the person served.
- b. The goals and expected benefits of admission.
- c. The initial estimated time frame for goal accomplishment.
- d. Services needed.

[CONTINUED ON NEXT PAGE]

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



REGULATIONS

Medical Board Regulations

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

(+) **CRITERION 8:**
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.

[CONTINUED]

D. In order to provide a safe pain program, the scope and intensity of medical services should relate to the medical care needs of the person served. The treating physician of the patient should be available for medical services. Services for the patient in a Chronic Pain Management Program can be provided by a coordinated interdisciplinary team of professionals other than physicians. The members of the core team, though each may not serve every person should include:

- a. A Physician.
- b. A clinical psychologist or psychiatrist.
- c. An occupational therapist.
- d. A physical therapist.
- e. A rehabilitation nurse.

E. A physician managing a Chronic Pain Management Program to a patient should meet the following criteria:

1. Three years experience in the interdisciplinary management of persons with chronic pain.
2. Participation in active education on pain management at a local or national level.
3. Board certification in a medical specialty or completion of training sufficient to qualify for examinations by members of the American Board of Medical Specialties.
4. Two years experience in the medical direction of an interdisciplinary Chronic Pain Program or at least six (6) months of pain fellowship in an interdisciplinary Chronic Pain Program.

The Physician must have completed and maintained at least one (1) of the following:

5. Attendance at one (1) meeting per year of a regional and national pain society.
6. Presentation of an abstract to a regional national pain society.
7. Publication on a pain topic in a peer review journal.
8. Membership in a pain society at a regional or national level.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



STATUTES

Homicide

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

Ark. Stat. Ann. § 5-10-106

§ 5-10-106. Physician-assisted suicide

(a) (1) For purposes of this section, "physician-assisted suicide" means a physician or health care provider participating in a medical procedure or willfully prescribing any drug, compound, or substance for the express purpose of assisting a patient to intentionally end his or her life.

(2) Provided, however, this term shall not apply to a person participating in the execution of a person sentenced by a court to death by lethal injection.

(b) It shall be unlawful for any physician or health care provider to commit the offense of physician-assisted suicide by:

(1) Prescribing any drug, compound, or substance to a patient with the express purpose of assisting the patient to intentionally end his or her life; or

(2) Assisting in any medical procedure for the express purpose of assisting a patient to intentionally end his or her life.

(c) Any physician or health care provider violating the provisions of subsection (b) of this section shall be deemed guilty of a Class C felony.

(d) Nothing in this section shall prohibit physicians or health care providers from carrying out advanced directives or living wills, nor shall this section prohibit physicians from prescribing any drug, compound, or substance for the specific purpose of pain relief.

(+) **CRITERION 8:**
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 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.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



REGULATIONS

Health Facility Services

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

007 05 CARR 007

007 Rules and Regulations for Hospice in Arkansas

PREFACE

These rules and regulations have been prepared for the purpose of establishing a criterion for minimum standards for the certification, operation and maintenance of hospices in Arkansas that is consistent with current trends in patient care practices. By necessity they are of a regulatory nature but are considered to be practical minimal design and operational standards for these facilities. These standards are not static and are subject to periodic revisions in the future as new knowledge and changes in patient care trends become apparent. However, it is expected that facilities will exceed these minimum requirements and that they will not be dependent upon future revisions in these standards as a necessary prerequisite for improved services. Hospices have a strong moral responsibility for providing optimum patient care and treatment for the terminally ill and their families.

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SHORT-TERM INPATIENT CARE

Inpatient care must be available for pain control, symptom management, and respite purposes, and must be provided in licensed facilities, as stated below:

(a) Inpatient care for symptom control. Inpatient care for pain control and symptom management must be provided in one of the following:

(1) A hospice that meets the requirements for providing inpatient care directly as specified in the section, "Free Standing Hospices Providing Inpatient Care Directly".

(2) A hospital or a Skilled Nursing Facility (SNF) that also meets the requirements specified for nursing service and patient areas. (See paragraphs (a) twenty-four (24) hour nursing services, and (f) patient areas, under "Freestanding Hospices Providing Inpatient Care Directly".)

(b) Inpatient care for respite purposes. Inpatient care for respite purposes must be provided by one of the following:

(1) A provider specified in paragraph (a) of this section.

(2) An Intermediate Care Facility (ICF) that also meets the requirements specified under "Free Standing Hospices Providing Inpatient Care Directly" paragraphs (a) and (f) regarding twenty-four (24) hour nursing service and patient areas.

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(+) **CRITERION 8:**
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

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

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

CALIFORNIA

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
Health and Safety Code; Division 10. Uniform Controlled Substances Act
- PROFESSIONAL PRACTICE ACT
Business and Professions Code; Division 2. Healing Arts; Chapter 1. General Provisions
- MEDICAL PRACTICE ACT
Business and Professions Code; Division 2. Healing Arts; Chapter 5. Medicine
- INTRACTABLE PAIN TREATMENT ACT (*Part of Medical Practice Act*)
Business and Professions Code; Division 2. Healing Arts; Chapter 5. Medicine; Section 2241.5
- PHARMACY PRACTICE ACT
Business and Professions Code; Division 2. Healing Arts; Chapter 9. Pharmacy
- PAIN PATIENT'S BILL OF RIGHTS
Health and Safety Code; Division 106. Personal Health Care; Part 4.5
- EFFECT ON INTRACTABLE PAIN TREATMENT ACT; BILL OF RIGHTS
Health and Safety Code; Division 106. Personal Health Care; Part 4.5

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*Part of Pharmacy Board Regulations*) (*No provisions found*)
Title 16. Professional and Vocational Regulations; Division 17. California State Board of Pharmacy; *Article 6. Dangerous Drugs*
- MEDICAL BOARD REGULATIONS (*No provisions found*)
Title 16. Professional and Vocational Regulations; Division 13. Medical Board of California
- PHARMACY BOARD REGULATIONS (*No provisions found*)
Title 16. Professional and Vocational Regulations; Division 17. California State Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD POLICY STATEMENT
California Medical Board. "A Statement by the Medical Board." *Action Report*. Vol. 50, pp. 4-5. July 1994.



- MEDICAL BOARD GUIDELINE
California Medical Board. "Guideline for Prescribing Controlled Substances for Intractable Pain." *Action Report*. Vol. 87, pp. 1, 4-6. October 2003. Adopted: August 2, 2003.
- PHARMACY BOARD POLICY STATEMENT
California Pharmacy Board. "Dispensing Controlled Substances for Pain." *Health Notes - Pain Management*. Vol. 1, No. 1. 1996.

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

- HEALTH FACILITY LICENSING
Health and Safety Code; Division 2. Licensing Provisions; Chapter 2. Health Facilities; Article 1. General
- HOSPICE SERVICES
Title 28. Managed Health Care; Division 1. The Department of Managed Health Care; Chapter 2. Health Care Service Plans; Article 8. Self-Policing Procedures

Note: California's Uniform Controlled Substances Act continues to reference the triplicate prescription program that was repealed in 2005; although not considered a barrier to practice, efforts should be made to remove from state law all references to this vestigial policy.



Provisions that may <i>ENHANCE</i> pain management								
Criteria	1	2	3	4	5	6	7	8
	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					•			•
Intractable Pain Treatment Act		•	•		•			
Pharmacy Practice Act ¹								
Pain Patient's Bill of Rights		•		•				•
Effect on IPTA: Bill of Rights								•
REGULATIONS								
Controlled Substances ¹								
Medical Board ¹								
Pharmacy Board ¹								
OTHER GOVERNMENTAL POLICIES								
Medical Board Policy Statement		•	•	•	•	•	•	•
Medical Board Guideline		•	•	•	•	•		•
Pharmacy Board Policy Statement			•	•		•	•	
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Health Facility Licensing				•				•
Hospice Services								•

Note: A dot indicates that one or more provisions were identified
¹ No provisions were found in this policy, ² No policy found

Provisions that may <i>IMPEDE</i> pain management								
Criteria	9	10	11	12	13	14	15	16
	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				•			•	
Professional Practice Act								•
Medical Practice Act				•				
Intractable Pain Treatment Act		•		•				•
Pharmacy Practice Act								•
Pain Patient's Bill of Rights ¹								
Effect on IPTA; Bill of Rights								•
REGULATIONS								
Controlled Substances ¹								
Medical Board ¹								
Pharmacy Board ¹								
OTHER GOVERNMENTAL POLICIES								
Medical Board Policy Statement ¹								
Medical Board Guideline ¹								
Pharmacy Board Policy Statement ¹								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Health and Safety Code ¹								
Hospice Services ¹								

Note: A dot indicates that one or more provisions were identified
¹ No provisions were found in this policy, ² No policy found



STATUTES

Controlled Substances Act

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

(-) CRITERION 12:
Medical decisions are restricted

CATEGORY A:
Restrictions based on patient characteristics

Cal Health & Saf Code § 11156

§ 11156. Prohibited prescription for, or dispensation to, addict, etc.

No person shall prescribe for or administer, or dispense a controlled substance to an addict or habitual user, or to any person representing himself as such, except as permitted by this division.

Cal Health & Saf Code § 11159.2

§ 11159.2. Prescriptions for terminally ill patients

(a) Notwithstanding any other provision of law, a prescription for a Schedule II controlled substance for use by a patient who has a terminal illness shall not be subject to Section 11164.

(b) (1) The prescription shall be signed and dated by the prescriber and shall contain the name of the person for whom the controlled substance is prescribed, the name and quantity of the controlled substance prescribed, and directions for use. The signature, date, and information required by this paragraph shall be wholly written in ink or indelible pencil in the handwriting of the prescriber.

(2) The prescription shall also contain the address of the person for whom the controlled substance is prescribed, as provided in paragraph (3) of subdivision (b) of Section 11164, and shall contain the name, address, telephone number, category of professional licensure, and federal controlled substance registration number of the prescriber, as provided in paragraph (2) of subdivision (b) of Section 11164.

(3) The prescription shall also indicate that the prescriber has certified that the patient is terminally ill by the words "11159.2 exemption."

(c) A pharmacist may fill a prescription pursuant to this section when there is a technical error in the certification required by paragraph (3) of subdivision (b), provided that he or she has personal knowledge of the patient's terminal illness, and subsequently returns the prescription to the prescriber for correction within 72 hours.

(d) For purposes of this section, "terminally ill" means a patient who meets all of the following conditions:

(1) In the reasonable medical judgment of the prescribing physician, the patient has been determined to be suffering from an illness that is incurable and irreversible.

(2) In the reasonable medical judgment of the prescribing physician, the patient's illness will, if the illness takes its normal course, bring about the death of the patient within a period of one year.

(3) The patient's treatment by the physician prescribing a Schedule II controlled substance pursuant to this section primarily is for the control of pain, symptom management, or both, rather than for cure of the illness.

(+) CRITERION 8:
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Exemption of these patients nevertheless continues the prescribing restriction for all other patients with an addictive disease or history of addiction.

(+) CRITERION 8:
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: The exemption of these patients from special prescription requirements nevertheless continues those requirements for all other patients.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



STATUTES

Controlled Substances Act

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

Cal Health & Saf Code § 11210

§ 11210. Permitted prescribing, furnishing, or administering controlled substances by practitioners

A physician, surgeon, dentist, veterinarian, naturopathic doctor acting pursuant to Section 3640.7 of the Business and Professions Code, or podiatrist, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or registered nurse acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or naturopathic doctor acting within the scope of Section 3640.5 of the Business and Professions Code, or an optometrist acting within the scope of Section 3041 of the Business and Professions Code may prescribe for, furnish to, or administer controlled substances to his or her patient when the patient is suffering from a disease, ailment, injury, or infirmities attendant upon old age, other than addiction to a controlled substance.

Cal Health & Saf Code § 11453

§ 11453. Department physician; Interviews and reports; Violation

The Department of Justice may employ a physician to interview and examine any patient for whom any controlled substance classified in Schedule I, II, or III has been prescribed or to whom any such controlled substance has been furnished or administered, or who is an habitual user of such a controlled substance, or who has a previous addiction record to a substance listed as a controlled substance classified in Schedule I, II, or III.

The patient shall submit to the interview and examination and shall not in any manner hinder or impede it.

The physician employed by the Department of Justice to conduct the interview and examination shall report the results of the examination and interview to the department.

The physician so employed may testify in any action brought under this division or in any administrative hearing conducted under the Medical Practice Act or the Osteopathic Act and his or her testimony is not privileged.

Every person who violates any provision of this section is guilty of a misdemeanor.

(+) **CRITERION 3:**
Opioids are part of professional practice

(-) **CRITERION 15:**
Other provisions that may impede pain management

COMMENT: Authorizing a Department of Justice-assigned physician to examine any California patient who is prescribed a controlled substance, who may be a "habitual user," or who has an "addiction record," and allows a misdemeanor charge to be brought against a patient for not submitting, appears arbitrary, falls well outside the accepted framework of law regarding controlled substances, medical practice and patient confidentiality, and if implemented could subject patients to undue scrutiny and seriously disrupt legitimate medical practice and patient care.

STATUTES

Professional Practice Act

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

Cal Bus & Prof Code § 725

§ 725. Excessive prescribing or treatment; Treatment for intractable pain

Repeated acts of clearly excessive prescribing or administering of drugs or treatment, repeated acts of clearly excessive use of diagnostic procedures, or repeated acts of clearly excessive use of diagnostic or treatment facilities as determined by the standard of the community of licensees is unprofessional conduct for a physician and surgeon, dentist, podiatrist, psychologist, physical therapist, chiropractor, or optometrist. However, pursuant to Section 2241.5, no physician and surgeon in compliance with the California Intractable Pain Treatment Act shall be subject to disciplinary action for lawfully prescribing or administering controlled substances in the course of treatment of a person for intractable pain.

(-) **CRITERION 16:**
Provisions that are ambiguous

CATEGORY A:
Arbitrary standards for legitimate prescribing

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

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



STATUTES

Medical Practice Act

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

(+) **CRITERION 8:**
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility to communicate to practitioners about existing pain management standards.

Cal Bus & Prof Code § 2025

§ 2025. Pain management guidelines

The board through its regular mailing shall notify all licensees of the existence of pain management guidelines published by the Agency for Health Care Policy and Research of the Public Health Service within the United States Department of Health and Human Services, and shall provide the published guidelines to licensees upon request.

Cal Bus & Prof Code § 2190.5

§ 2190.5. Mandatory continuing education course in pain management and treatment of terminally ill and dying patients; Deadline for completion of course; Exemptions; Application

(a) All physicians and surgeons shall complete a mandatory continuing education course in the subjects of pain management and the treatment of terminally ill and dying patients. For the purposes of this section, this course shall be a one-time requirement of 12 credit hours within the required minimum established by regulation, to be completed by December 31, 2006. All physicians and surgeons licensed on and after January 1, 2002, shall complete this requirement within four years of their initial license or by their second renewal date, whichever occurs first. The board may verify completion of this requirement on the renewal application form.

Cal Bus & Prof Code § 2196.2

§ 2196.2. Information on pain management

The board shall periodically develop and disseminate information and educational material regarding pain management techniques and procedures to each licensed physician and surgeon and to each general acute care hospital in this state. The board shall consult with the State Department of Health Services in developing the materials to be distributed pursuant to this section.

(+) **CRITERION 8:**
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 and palliative care.

(+) **CRITERION 8:**
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility to communicate to practitioners about acceptable practices governing pain management.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Medical Practice Act

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

Cal Bus & Prof Code § 2220.05

§ 2220.05. Prioritization of allegations

(a) In order to ensure that its resources are maximized for the protection of the public, the Medical Board of California shall prioritize its investigative and prosecutorial resources to ensure that physicians and surgeons representing the greatest threat of harm are identified and disciplined expeditiously. Cases involving any of the following allegations shall be handled on a priority basis, as follows, with the highest priority being given to cases in the first paragraph:

(3) Repeated acts of clearly excessive prescribing, furnishing, or administering of controlled substances, or repeated acts of prescribing, dispensing, or furnishing of controlled substances without a good faith prior examination of the patient and medical reason therefore. However, in no event shall a physician and surgeon prescribing, furnishing, or administering controlled substances for intractable pain consistent with lawful prescribing, including, but not limited to, Sections 725, 2241.5, and 2241.6 of this code and Sections 11159.2 and 124961 of the Health and Safety Code, be prosecuted for excessive prescribing and prompt review of the applicability of these provisions shall be made in any complaint that may implicate these provisions.

(+) CRITERION 5:
Addresses fear of regulatory scrutiny

Cal Bus & Prof Code § 2241

§ 2241. Furnishing drugs to addict

Unless otherwise provided by this section, the prescribing, selling, furnishing, giving away, or administering or offering to prescribe, sell, furnish, give away, or administer any of the drugs or compounds mentioned in Section 2239 to an addict or habitue constitutes unprofessional conduct.

If the drugs or compounds are administered or applied by a licensed physician and surgeon or by a registered nurse acting under his or her instruction and supervision, this section shall not apply to any of the following cases:

- (a) Emergency treatment of a patient whose addiction is complicated by the presence of incurable disease, serious accident or injury, or the infirmities attendant upon age.
- (b) Treatment of addicts or habitues in state licensed institutions where the patient is kept under restraint and control, or in city or county jails or state prisons.
- (c) Treatment of addicts as provided for by Section 11217.5 of the Health and Safety Code.

(-) CRITERION 12:
Medical decisions are restricted

CATEGORY A:
Restrictions based on patient characteristics

(+) CRITERION 8:
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Exemption of these patients nevertheless continues the prescribing restriction for all other patients with an addictive disease or history of addiction.

(+) CRITERION 8:
Other provisions that may enhance pain management

CATEGORY C: *Regulatory or policy issues*

COMMENT: Establishes a mechanism (written standards) to ensure competent review of pain management disciplinary cases, which recognizes that inadequate treatment of pain is subject to disciplinary action just as other substandard practices might be.

Cal Bus & Prof Code § 2241.6

§ 2241.6. Development of standards for review of cases concerning management of a patient's pain

The Division of Medical Quality shall develop standards before June 1, 2002, to assure the competent review in cases concerning the management, including, but not limited to, the undertreatment, undermedication, and overmedication of a patient's pain. The division may consult with entities such as the American Pain Society, the American Academy of Pain Medicine, the California Society of Anesthesiologists, the California Chapter of the American College of Emergency Physicians, and any other medical entity specializing in pain control therapies to develop the standards utilizing, to the extent they are applicable, current authoritative clinical practice guidelines.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



STATUTES

Intractable Pain Treatment Act

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

Cal Bus & Prof Code § 2241.5

§ 2241.5. Administration of controlled substances to person experiencing "intractable pain"

(a) Notwithstanding any other provision of law, a physician and surgeon may prescribe or administer controlled substances to a person in the course of the physician and surgeon's treatment of that person for a diagnosed condition causing intractable pain.

(b) "Intractable pain," as used in this section, means a pain state in which the cause of the pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts including, but not limited to, evaluation by the attending physician and surgeon and one or more physicians and surgeons specializing in the treatment of the area, system, or organ of the body perceived as the source of the pain.

(c) No physician and surgeon shall be subject to disciplinary action by the board for prescribing or administering controlled substances in the course of treatment of a person for intractable pain.

(d) This section shall not apply to those persons being treated by the physician and surgeon for chemical dependency because of their use of drugs or controlled substances.

(e) This section shall not authorize a physician and surgeon to prescribe or administer controlled substances to a person the physician and surgeon knows to be using drugs or substances for nontherapeutic purposes.

(f) This section shall not affect the power of the board to deny, revoke, or suspend the license of any physician and surgeon who does any of the following:

(1) Prescribes or administers a controlled substance or treatment that is nontherapeutic in nature or nontherapeutic in the manner the controlled substance or treatment is administered or prescribed or is for a nontherapeutic purpose in a nontherapeutic manner.

(2) Fails to keep complete and accurate records of purchases and disposals of substances listed in the California Controlled Substances Act, or of controlled substances scheduled in, or pursuant to, the federal Comprehensive Drug Abuse Prevention and Control Act of 1970. A physician and surgeon shall keep records of his or her purchases and disposals of these drugs, including the date of purchase, the date and records of the sale or disposal of the drugs by the physician and surgeon, the name and address of the person receiving the drugs, and the reason for the disposal of or the dispensing of the drugs to the person and shall otherwise comply with all state recordkeeping requirements for controlled substances.

(3) Writes false or fictitious prescriptions for controlled substances listed in the California Controlled Substances Act or scheduled in the federal Comprehensive Drug Abuse Prevention and Control Act of 1970.

(4) Prescribes, administers, or dispenses in a manner not consistent with public health and welfare controlled substances listed in the California Controlled Substance Act or scheduled in the federal Comprehensive Drug Abuse Prevention and Control Act of 1970.

(5) Prescribes, administers, or dispenses in violation of either Chapter 4 (commencing with Section 11150) or Chapter 5 (commencing with Section 11210) of Division 10 of the Health and Safety Code or this chapter.

(g) Nothing in this section shall be construed to prohibit the governing body of a hospital from taking disciplinary actions against a physician and surgeon, as authorized pursuant to Sections 809.05, 809.4, and 809.5.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

(+) CRITERION 2:
Pain management is part of medical practice

(-) CRITERION 16:
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: Suggests that physicians would not qualify for immunity and relief from concerns about regulatory scrutiny if they prescribe opioids as a treatment of first choice for patients who present initially with severe pain, such as those with sickle-cell anemia.

(-) CRITERION 12:
Medical decisions are restricted

CATEGORY A:
Restrictions based on patient characteristics

(+) CRITERION 3:
Opioids are part of professional practice

(-) CRITERION 10:
Implies opioids are not part of professional practice

(-) CRITERION 12:
Medical decisions are restricted

CATEGORY B:
Mandated consultation

(+) CRITERION 5:
Addresses fear of regulatory scrutiny



STATUTES

Pharmacy Practice Act

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

Cal Bus & Prof Code § 4301

§ 4301. Unprofessional conduct, procuring license by fraud or misrepresentation, or issuance of license by mistake

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

- (a) Gross immorality.
- (b) Incompetence.
- (c) Gross negligence.
- (d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

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(-) **CRITERION 16:**
Provisions that are ambiguous

CATEGORY A:
Arbitrary standards for legitimate prescribing

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

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



STATUTES

Pain Patient's Bill of Rights

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

California Health & Safety Code §124960

§ 124960. Legislative findings and declarations

The Legislature finds and declares all of the following:

(a) The state has a right and duty to control the illegal use of opiate drugs.

(b) Inadequate treatment of acute and chronic pain originating from cancer or noncancerous conditions is a significant health problem.

(c) For some patients, pain management is the single most important treatment a physician can provide.

(d) A patient suffering from severe chronic intractable pain should have access to proper treatment of his or her pain.

(e) Due to the complexity of their problems, many patients suffering from severe chronic intractable pain may require referral to a physician with expertise in the treatment of severe chronic intractable pain. In some cases, severe chronic intractable pain is best treated by a team of clinicians in order to address the associated physical, psychological, social, and vocational issues.

(f) In the hands of knowledgeable, ethical, and experienced pain management practitioners, opiates administered for severe acute and severe chronic intractable pain can be safe.

(g) Opiates can be an accepted treatment for patients in severe chronic intractable pain who have not obtained relief from any other means of treatment.

(h) A patient suffering from severe chronic intractable pain has the option to request or reject the use of any or all modalities to relieve his or her severe chronic intractable pain.

(i) A physician treating a patient who suffers from severe chronic intractable pain may prescribe a dosage deemed medically necessary to relieve severe chronic intractable pain as long as the prescribing is in conformance with the provisions of the California Intractable Pain Treatment Act, Section 2241.5 of the Business and Professions Code.

(j) A patient who suffers from severe chronic intractable pain has the option to choose opiate medication for the treatment of the severe chronic intractable pain as long as the prescribing is in conformance with the provisions of the California Intractable Pain Treatment Act, Section 2241.5 of the Business and Professions Code.

(k) The patient's physician may refuse to prescribe opiate medication for a patient who requests the treatment for severe chronic intractable pain. However, that physician shall inform the patient that there are physicians who specialize in the treatment of severe chronic intractable pain with methods that include the use of opiates.

(+) **CRITERION 2:**
Pain management is part of medical practice

(+) **CRITERION 8:**
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.

(+) **CRITERION 4:**
Encourages pain management

(+) **CRITERION 8:**
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.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

**Effect on Intractable Pain Treatment Act;
Bill of Rights**

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

(+) **CRITERION 8:**
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Sections (a) and (b) recognize the patient's right to choose or refuse different types of treatments.

California Health & Safety Code §124961

§ 124961. Effect on Intractable Pain Treatment Act; Bill of Rights

Nothing in this section shall be construed to alter any of the provisions set forth in the California Intractable Pain Treatment Act, Section 2241.5 of the Business and Professions Code. This section shall be known as the Pain Patient's Bill of Rights.

(a) A patient suffering from severe chronic intractable pain has the option to request or reject the use of any or all modalities in order to relieve his or her severe chronic intractable pain.

(b) A patient who suffers from severe chronic intractable pain has the option to choose opiate medications to relieve severe chronic intractable pain without first having to submit to an invasive medical procedure, which is defined as surgery, destruction of a nerve or other body tissue by manipulation, or the implantation of a drug delivery system or device, as long as the prescribing physician acts in conformance with the provisions of the California Intractable Pain Treatment Act, Section 2241.5 of the Business and Professions Code.

(c) The patient's physician may refuse to prescribe opiate medication for the patient who requests a treatment for severe chronic intractable pain. However, that physician shall inform the patient that there are physicians who specialize in the treatment of severe chronic intractable pain with methods that include the use of opiates.

(d) A physician who uses opiate therapy to relieve severe chronic intractable pain may prescribe a dosage deemed medically necessary to relieve severe chronic intractable pain, as long as that prescribing is in conformance with the California Intractable Pain Treatment Act, Section 2241.5 of the Business and Professions Code.

(e) A patient may voluntarily request that his or her physician provide an identifying notice of the prescription for purposes of emergency treatment or law enforcement identification.

(f) Nothing in this section shall do either of the following:

(1) Limit any reporting or disciplinary provisions applicable to licensed physicians and surgeons who violate prescribing practices or other provisions set forth in the Medical Practice Act, Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code, or the regulations adopted thereunder.

(2) Limit the applicability of any federal statute or federal regulation or any of the other statutes or regulations of this state that regulate dangerous drugs or controlled substances.

(-) **CRITERION 16:**
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: The phrase "severe chronic intractable pain" is used throughout this policy. The intended result of such elaborate and unconventional medical terminology is unclear, but appears to limit the patient population which should be given access to "proper treatment" of pain, including the use of opioids, and which is given the option to request or reject any treatments. What is the effect of this law on patients with pain that is not severe, chronic, or intractable? Is there a greater risk of discipline for a physician who would prescribe opioids to a patient with pain which was not severe

(-) **CRITERION 16:**
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: The Pain Patient's Bill of Rights requires that all opiate treatment for patients with "severe chronic intractable pain," must be according to the IPTA, thus requiring an evaluation by a second physician in every case, and excluding certain patient populations. Also, is it legal for a physician to prescribe medically necessary dosages of opioids for patients with severe chronic pain who are not qualified under the IPTA?

(-) **CRITERION 16:**
Provisions that are ambiguous

CATEGORY C:
Conflicting or inconsistent policies or provisions

COMMENT: This provision may be confusing, and even in conflict, when considered in conjunction with provision §124960(g) which states that patients qualify for opiate treatment after "other means of treatment;" in §124961(b), the patient does not have to "submit" to certain treatments.

(-) **CRITERION 16:**
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: Allowing a physician to refuse to prescribe opioid medications would appear to conflict with criteria that recognize that opioids are necessary for public health and are part of medical practice. Furthermore, how does this qualify as a "Pain Patient's Bill of Rights" if a physician may refuse to provide opioid analgesics to a patient in pain?

Without commenting on the concept of patients' bills of rights, this language would fall short of providing any rights and thus may establish a false expectation for adequate pain management.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



OTHER GOVERNMENTAL POLICY

Medical Board Statement

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

A STATEMENT BY THE MEDICAL BOARD

INTRODUCTION

The 1993 report of the Medical Board to the Governor signaled a new beginning in the history of medical regulation in California. An important part of this initiative is implementation of the recommendations made by the Board's Task Force on Appropriate Prescribing, chaired by Jacqueline Trestrail, M.D.

The Task Force was established to look into "malprescribing," one of the fastest growing categories of physician discipline. The Board continues to be concerned that controlled substances are subject to abuse by individuals who seek them for their mood altering and other psychological effects, rather than for legitimate medical purposes.

The Board is also concerned about effective pain management and the appropriate medical use of controlled substances. During the Task Force's public meetings, the members heard testimony that some physicians avoid prescribing controlled substances, including the "triplicate" drugs, for patients with intractable pain for fear of discipline by the Board. The Task Force recommended that the Board take a pro-active approach to emphasize to all California physicians that it supports prescribing of opioid analgesics (narcotics) and other controlled substances when medically indicated for the treatment of pain, including intractable pain. After careful review of this matter, the Board concurs with the following statement.

This statement is consistent with good medical practice, protection of public health and consumer interests, with international treaties, federal and California law, including the California Intractable Pain Treatment Act.

THE PAIN PROBLEM

The Board recognizes that pain, whether due to trauma, surgery, cancer and other diseases, is often undertreated. Minorities, women, children, the elderly and people with HIV/AIDS are at particular risk for under treatment of their pain. Unrelieved pain has a harsh and sometimes disastrous impact on the quality of life of people and their families.

While some progress is being made to improve pain and symptom management, the Board is concerned that a number of factors continue to interfere with effective pain management. These include the low priority of pain management in our health care system, incomplete integration of current knowledge into medical education and clinical practice, lack of knowledge among consumers about pain management, exaggerated fears of opioid side effects and addiction, and fear of legal consequences when controlled substances are used.

PAIN MANAGEMENT SHOULD BE A HIGH PRIORITY IN CALIFORNIA

Principles of quality medical practice dictate that citizens of California who suffer from pain should be able to obtain the relief that is currently available. The Board believes that the appropriate application of current knowledge and treatments would greatly improve the quality of life for many California citizens, and could also reduce the morbidity and the costs that are associated with uncontrolled pain.

In addition to making this statement, the Board will take a number of steps to help make effective pain management a reality in California. The Board has provided information to all state physicians about new clinical practice guidelines for pain management that have been prepared by a panel of experts supported by the Agency for Health Care Policy and Research. The Board also co-sponsored and participated in the March 18, 1994 Pain Management and Appropriate Prescribing Summit in conjunction with the Department of Consumer Affairs on removing impediments to appropriate prescribing of controlled substances for effective pain management. Further, the Board will develop guidelines to help physicians avoid investigation if they appropriately prescribe controlled substances for pain management.

(CONTINUED ON NEXT PAGE)

(+) CRITERION 4:
Encourages pain management

(+) CRITERION 3:
Opioids are part of professional practice

(+) CRITERION 2:
Pain management is part of medical practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



OTHER GOVERNMENTAL POLICY

Medical Board Statement

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

(CONTINUED)

Prescribing Controlled Substances for Pain

THE APPROPRIATE ROLE OF OPIOID ANALGESICS

There are numerous drug and non-drug treatments that are used for the management of pain and other symptoms. The proper treatment of any patient's pain depends upon a careful diagnosis of the etiology of the pain, selection of appropriate and cost-effective treatments, and ongoing evaluation of the results of treatment. Opioid analgesics and other controlled substances are useful for the treatment of pain, and are considered the cornerstone of treatment of acute pain due to trauma, surgery and chronic pain due to progressive diseases such as cancer. Large doses may be necessary to control pain if it is severe. Extended therapy may be necessary if the pain is chronic.

The Board recognizes that opioid analgesics can also be useful in the treatment of patients with intractable non-malignant pain especially where efforts to remove the cause of pain or to treat it with other modalities have failed. The pain of such patients may have a number of different etiologies and may require several treatment modalities. In addition, the extent to which pain is associated with physical and psychosocial impairment varies greatly. Therefore, the selection of a patient for a trial of opioid therapy should be based upon a careful assessment of the pain as well as the disability experienced by the patient. Continuation of opioid therapy should be based on the physician's evaluation of the results of treatment, including the degree of pain relief, changes in physical and psychological functioning, and appropriate utilization of health care resources. Physicians should not hesitate to obtain consultation from legitimate practitioners who specialize in pain management.

The Board recommends that physicians pay particular attention to those patients who misuse their prescriptions, particularly when the patient or family have a history of substance abuse that could complicate pain management. The management of pain in such patients requires extra care and monitoring, as well as consultation with medical specialists whose area of expertise is substance abuse or pain management.

The Board believes that addiction should be placed into proper perspective. Physical dependence and tolerance are normal physiologic consequences of extended opioid therapy and are not the same as addiction. Addiction is a behavioral syndrome characterized by psychological dependence and aberrant drug-related behaviors. Addicts compulsively use drugs for non-medical purposes despite harmful effects; a person who is addicted may also be physically dependent or tolerant. Patients with chronic pain should not be considered addicts or habitues merely because they are being treated with opioids.

PAIN MANAGEMENT, CONTROLLED SUBSTANCES AND THE LAW

The laws and regulations of the federal government and the State of California impose special requirements for the prescribing of controlled substances, including requirements as to the form of the prescription document, so as to prevent harm to the public health that is caused when prescription drugs are diverted to non-medical uses. For example, it is illegal to prescribe controlled substances solely to maintain narcotic addiction. However, federal and California law clearly recognize that it is a legitimate medical practice for physicians to prescribe controlled substances for the treatment of pain, including intractable pain.

The Medical Board will work with the Drug Enforcement Administration, the Bureau of Narcotic Enforcement, the Office of the Attorney General, the Board of Pharmacy and its own investigators in an attempt to develop policy and guidelines based on the physician's diagnosis and treatment program rather than amounts of drugs prescribed.

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(+) **CRITERION 8:**
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.

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

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



OTHER GOVERNMENTAL POLICY

Medical Board Statement

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

(CONTINUED)

Concerns about regulatory scrutiny should not make physicians who follow appropriate guidelines reluctant to prescribe or administer controlled substances, including Schedule II drugs, for patients with a legitimate medical need for them. A physician is not subject to Board action when prescribing in the regular course of his or her profession to one under the physician's treatment for a pathology or condition and where the prescription is issued after a good faith examination and where there is medical indication for the drug. Good faith prescribing requires an equally good faith history, physical examination and documentation.

(+) **CRITERION 5:**
Addresses fear of regulatory scrutiny

The Medical Board may identify a pattern of controlled substance use that merits further examination. A private, courteous and professional inquiry can usually determine whether the physician is in good faith appropriately prescribing for patients, or whether an investigation is necessary. The Board will judge the validity of prescribing based on the physician's diagnosis and treatment of the patient and whether the drugs prescribed by the physician are appropriate for that condition, and will not act on the basis of predetermined numerical limits on dosages or length of drug therapy.

(+) **CRITERION 6:**
Prescription amount alone does not determine legitimacy

The Board hopes to replace practitioners' perception of inappropriate regulatory scrutiny with recognition of the Board's commitment to enhance the quality of life of patients by improving pain management while, at the same time, preventing the diversion and abuse of controlled substances.

(+) **CRITERION 8:**
Other provisions that may enhance pain management

CATEGORY C:
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.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

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

Text of "Guideline for Prescribing Controlled Substances for Intractable Pain"
Adopted Unanimously by the Board in 1994 and Recently Revised

"No physician and surgeon shall be subject to disciplinary action by the board for prescribing or administering controlled substances in the course of treatment of a person for intractable pain." -Business and Professions Code §2241.5(c)

PREAMBLE

In 1994, the Medical Board of California formally adopted a policy statement titled, "Prescribing Controlled Substances for Pain." The statement outlined the Board's proactive approach to improving appropriate prescribing for effective pain management in California, while preventing drug diversion and abuse. The policy statement was the product of a year of research, hearings and discussions. California physicians and surgeons are encouraged to consult the policy statement and these guidelines, which can be found at www.medbd.ca.gov or obtained from the Medical Board of California.

In May 2002, as a result of AB 487, a task force was established to review the 1994 Guidelines and to assist the Division of Medical Quality to "develop standards to assure the competent review in cases concerning the management, including, but not limited to, the under treatment, under medication, and over medication of a patient's pain." The task force expanded the scope of the Guidelines, from intractable pain patients to all patients with pain.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



OTHER GOVERNMENTAL POLICY

Medical Board Guideline

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

(+) **CRITERION 8:**
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.

(+) **CRITERION 2:**
Pain management is part of medical practice

(+) **CRITERION 3:**
Opioids are part of professional practice

(CONTINUED)

Inappropriate prescribing of controlled substances, including opioids, can lead to drug abuse or diversion and can also lead to ineffective management of pain, unnecessary suffering of patients, and increased health costs. The Medical Board recognizes that some physicians do not treat pain appropriately due to a lack of knowledge or concern about pain, and others may fail to treat pain properly due to fear of discipline by the Medical Board. These Guidelines are intended to improve effective pain management in California, by avoiding under treatment, over treatment, or other inappropriate treatment of a patient's pain and by clarifying the principles of professional practice that are endorsed by the Medical Board so that physicians have a higher level of comfort in using controlled substances, including opioids, in the treatment of pain. These Guidelines are intended to promote improved pain management for all forms of pain and for all patients in pain.

A HIGH PRIORITY

The Board strongly urges physicians and surgeons to view effective pain management as a high priority in all patients, including children, the elderly, and patients who are terminally ill. Pain should be assessed and treated promptly, effectively and for as long as pain persists. The medical management of pain should be based on up-to-date knowledge about pain, pain assessment and pain treatment. Pain treatment may involve the use of several medications and non-pharmacological treatment modalities, often in combination. For some types of pain, the use of medications is emphasized and should be pursued vigorously; for other types, the use of medications is better de-emphasized in favor of other therapeutic modalities. Physicians and surgeons should have sufficient knowledge or utilize consultations to make such judgments for their patients.

Medications, in particular opioid analgesics, are considered the cornerstone of treatment for pain associated with trauma, surgery, medical procedures, or cancer. A number of medical organizations have developed guidelines for acute and chronic pain management. Links to these references may be found on the Medical Board of California's Web site at ww.medbd.ca.gov.

The prescribing of opioid analgesics for patients with pain, may also be beneficial, especially when efforts to alleviate the pain with other modalities have been unsuccessful.

Intractable pain is defined by law in California as: "a pain state in which the cause of the pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts including, but not limited to, evaluation by the attending physician and surgeon and one or more physicians and surgeons specializing in the treatment of the area, system, or organ of the body perceived as the source of the pain." (Section 2241.5(b) of the California Business and Professions Code)

Physicians and surgeons who prescribe opioids either for acute or persistent pain should not fear disciplinary or other action from California law enforcement or regulatory agencies for the mere fact of having prescribed opioids. The appropriate use of opioids in the treatment of intractable pain has long been recognized in California's Intractable Pain Treatment Act, which provides that "No physician and surgeon shall be subject to disciplinary action by the Medical Board for prescribing or administering controlled substances in the course of treatment of a person for intractable pain." (Section 2241.5(c) of the California Business and Professions Code) The Medical Board expects physicians and surgeons to follow the standard of care in managing pain patients.

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(+) **CRITERION 4:**
Encourages pain management

(+) **CRITERION 5:**
Addresses fear of regulatory scrutiny

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

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)

GUIDELINES

- History/Physical Examination A medical history and physical examination must be accomplished. This includes an assessment of the pain, physical and psychological function; a substance abuse history; history of prior pain treatment; an assessment of underlying or coexisting diseases or conditions; and documentation of the presence of a recognized medical indication for the use of a controlled substance.

Annotation One: The prescribing of controlled substances for pain may require referral to one or more consulting physicians.

Annotation Two: The complexity of the history and physical examination may vary based on the practice location. In the emergency department, the operating room, at night or on the weekends, the physician and surgeon may not always be able to verify the patient's history and past medical treatment. In continuing care situations for chronic pain management, the physician and surgeon should have a more extensive evaluation of the history, past treatment, diagnostic tests and physical exam.

- Treatment Plan, Objectives The treatment plan should state objectives by which the treatment plan can be evaluated, such as pain relief and/or improved physical and psychosocial function, and indicate if any further diagnostic evaluations or other treatments are planned. The physician and surgeon should tailor pharmacological therapy to the individual medical needs of each patient. Multiple treatment modalities and/or a rehabilitation program may be necessary if the pain is complex or is associated with physical and psychosocial impairment.

Annotation One: Physicians and surgeons may use control of pain, increase in function, and improved quality of life as criteria to evaluate the treatment plan.

Annotation Two: When the patient is requesting opioid medications for their pain and inconsistencies are identified in the history, presentation, behaviors or physical findings, physicians and surgeons who make a clinical decision to withhold opioid medications should document the basis for their decision.

- Informed Consent The physician and surgeon should discuss the risks and benefits of the use of controlled substances and other treatment modalities with the patient, caregiver or guardian.

Annotation: A written consent or pain agreement for chronic use is not required but may make it easier for the physician and surgeon to document patient education, the treatment plan, and the informed consent. Patient, guardian, and caregiver attitudes about medicines may influence the patient's use of medications for relief from pain.

- Periodic Review The physician and surgeon should periodically review the course of pain treatment of the patient 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. If the patient's progress is unsatisfactory, the physician and surgeon should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

Annotation One: Patients with pain who are managed with controlled substances should be seen monthly, quarterly, or semiannually as required by the standard of care.

Annotation Two: Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment.

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(+) **CRITERION 8:**
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.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

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)

- **Consultation** The physician and surgeon should consider referring the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Complex pain problems may require consultation with a pain medicine specialist.

In addition, physicians should give special attention to those pain patients who are at risk for misusing their medications including those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse requires extra care, monitoring, documentation and consultation with addiction medicine specialists, and may entail the use of agreements between the provider and the patient that specify the rules for medication use and consequences for misuse.

Annotation One: Coordination of care in prescribing chronic analgesics is of paramount importance.

Annotation Two: In situations where there is dual diagnosis of opioid dependence and intractable pain, both of which are being treated with controlled substances, protections apply to physicians and surgeons who prescribe controlled substances for intractable pain provided the physician complies with the requirements of the general standard of care and California Business and Professions Code section 2241.5.

- **Records** The physician and surgeon should keep accurate and complete records according to items above, including the medical history and physical examination, other evaluations and consultations, treatment plan objectives, informed consent, treatments, medications, rationale for changes in the treatment plan or medications, agreements with the patient, and periodic reviews of the treatment plan.

Annotation One: Documentation of the periodic reviews should be done at least annually or more frequently as warranted.

Annotation Two: Pain levels, levels of function, and quality of life should be documented. Medical documentation should include both subjective complaints of patient and caregiver, and objective findings by the physician.

- **Compliance with Controlled Substances Laws and Regulations** To prescribe controlled substances, the physician and surgeon must be appropriately licensed in California, have a valid controlled substances registration and comply with federal and state regulations for issuing controlled substances prescriptions. Physicians and surgeons are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and the Medical Board's Guidebook to Laws Governing the Practice of Medicine by Physicians and Surgeons for specific rules governing issuance of controlled substances prescriptions.

Annotation One: There is not a minimum or maximum number of medications which can be prescribed to the patient under either federal or California law.

Annotation Two: Physicians and surgeons who supervise Physician Assistants (PA's) or Nurse Practitioners (NP's) should carefully review the respective supervision requirements.

Additional information on PA supervision requirements is available at www.physicianassistant.ca.gov.

PA's are able to obtain their own DEA number to use when writing prescriptions for drug orders for controlled substances. Current law permits physician assistants to write and sign prescription drug orders when authorized to do so by their supervising physician for Schedule II-IV. Further, a PA may only administer, provide or transmit a drug order for

(CONTINUED ON NEXT PAGE)

(+) **CRITERION 6:**
Prescription amount
alone does not
determine legitimacy

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

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)

To ensure that a PA's actions involving the prescribing, administration, or dispensing of drugs is in strict accordance with the directions of the physician, every time a PA administers or dispenses a drug or transmits a drug order, the physician supervisor must sign and date the patient's medical record or drug chart within seven days. (Section 1399.545(f) of the California Code of Regulations)

NP's are allowed to furnish Schedule III-V controlled substances under written protocols.

POSTSCRIPT

While it is lawful under both federal and California law to prescribe controlled substances for the treatment of pain, there are limitations on the prescribing of controlled substances to or for patients for the treatment of chemical dependency (see Sections 11215-11222 of the California Health and Safety Code). The California Intractable Pain Treatment Act (CIPTA) does not apply to those persons being treated by the physician and surgeon only for chemical dependency because of use of drugs or controlled substances (Section 2241.5(d)). The CIPTA does not authorize a physician and surgeon to prescribe, dispense, or administer controlled substances to a person the practitioner knows to be using the prescribed drugs or controlled substances for non-therapeutic purposes (Section 2241.5(e)). At the same time, California law permits the prescribing, furnishing, or administering of controlled substances to or for a patient who is suffering from disease, ailments, injury, or infirmities attendant on old age, other than addiction (Section 11210 of the California Health and Safety Code) and the CIPTA does apply to "a practitioner who is prescribing controlled substances for intractable pain, and as long as that practitioner is not also treating the patient for chemical dependency."

The Medical Board emphasizes the above issues, both to ensure physicians and surgeons know that a patient in pain who is also chemically dependent should not be deprived of appropriate pain relief, and to recognize the special issues and difficulties associated with patients who suffer both from drug addiction and pain. The Medical Board expects that the acute pain from trauma or surgery will be addressed regardless of the patient's current or prior history of substance abuse. This postscript should not be interpreted as a deterrent for appropriate treatment of pain.

(+) CRITERION 8:
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Recognizes that a patient's prior history or current status of drug abuse does not contraindicate appropriate pain management.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



OTHER GOVERNMENTAL POLICY

Pharmacy Board Policy Statement

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

DISPENSING CONTROLLED SUBSTANCES FOR PAIN

INTRODUCTION

Healthcare leaders and patient advocates from throughout California met at the Summit on Effective Pain Management: Removing Impediments to Appropriate Prescribing in Los Angeles in 1994 to discuss the effective management of pain. Summit participants concurred that effective pain management, including the use of controlled substance medications, is essential to the health and welfare of Californians experiencing pain. It was also concluded that inappropriate or undertreatment of pain is serious and wide spread.

In response to these findings, the California State Board of Pharmacy is taking a leadership role in promoting the effective management of pain for the state's citizens. The Board's objectives include educating pharmacists on advances in appropriate pain management and taking active roles in providing this therapy. The Board is working to computerize the triplicate prescription program; is encouraging the timely availability of opioids in different healthcare settings such as hospitals, patient's homes and pharmacies; and is encouraging better knowledge and attitudes of patients, the public and other licensed healthcare professionals in the use of pain medications-all with the goal of positively influencing the care of patients in pain.

The Board of Pharmacy must ensure that laws, regulations, policies, and practices promote the availability and use of controlled substance drugs to patients for legitimate pain management. The Board encourages programs to help educate patients, the public, and licensed healthcare professionals about the effective use of medications in the treatment of various types of pain. The Board also recognizes that, with proper assessment, therapeutic planning, and follow up, medications should be available and used when needed.

The pharmacist's role (as educator and manager) in providing drug therapy for patients in pain is extensive. If pharmacists are to provide complete pain management services, they must fulfill their responsibilities to:

1. Facilitate the dispensing of legitimate prescriptions;
2. Understand and learn about the effective uses of all pain medications, especially opioids and other controlled substances, in the management of pain;
3. Carefully explain dosage regimens, and discuss potential side effects of pain medications;
4. Monitor and assess the patient for effective pain therapy outcomes, evaluate compliance, assess for tolerance to opioids, and ensure subsequent dosage adjustments as needed;
5. Obtain, retain, and update appropriate information documenting the course of, and need for, on-going opioid therapy;
6. Encourage patients to talk with their pharmacist about their medications, the benefits and problems;
7. Discuss and allay patients' possible fear of addiction with the use of narcotics where this is a factor;

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(+) CRITERION 4:
*Encourages pain
management*

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



OTHER GOVERNMENTAL POLICY

Pharmacy Board Policy Statement

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

(CONTINUED)

8. Watch for patients who misuse their prescriptions and be especially aware of a patient or family history of substance abuse that might complicate pain management and act accordingly;
9. Assess the patient for adverse drug reactions from the pain therapy regimen and take action to minimize or eliminate them;
10. Be aware of and recommend non-medication treatments for pain or refer patients for such when appropriate;
11. Evaluate OTC, prescription drugs, and alcohol taken with pain medications for potential drug interactions;
12. Recognize that patients and caregivers are important sources of information in assessing the patient's pain therapy;
13. Act as a liaison between patients and other healthcare providers, ensuring that there is open communication and understanding about the drugs patients are taking to reduce pain; and
14. Optimize pain management so patients can reach their highest level of functioning and quality of life.

ROLE OF OPIOIDS IN PAIN MANAGEMENT

Many patients with cancer or chronic medical conditions experience moderate to severe pain that is often inappropriately treated or undermedicated. Pain can have a negative effect on the patient's health and quality of life resulting in needless suffering, emotional distress, loss of productivity and possibly slower recovery from illness, injury, and disease.

Although there have been significant advances in knowledge about pain and the use of opioids and other medications in pain management, many licensed healthcare professionals prescribe, dispense, or administer these medications suboptimally. There is a misconception by patients, the public, and some licensed healthcare providers that opioids are "bad" drugs because opioids are often associated with drug abuse, addiction, and criminal activity. Studies have shown that opioids used appropriately for pain management have an extremely low potential for abuse.

The Board understands that the ongoing use of opioids for cancer, post-surgical, and chronic pain is not what causes addiction or a patient's desire for higher doses of pain medication. Patients suffering from extreme pain or progression of disease may require increased doses of medication; the appropriate dose is that which is required to adequately treat the pain, even if the dose is higher than usually expected. In addition, with long-term treatment of pain with opioids, patients may develop a tolerance to the drug or a dependence on the drug. These occurrences are considered "normal" and "to be expected" - they should not be confused by the licensed healthcare professional with drug addiction or be mislabeled as "drug seeking."

The Board understands that an important part of effective pain management is ensuring that patients do not have difficulty obtaining adequate medication for pain relief. The Board recognizes that it is the professional responsibility of the pharmacist to recommend that patients in pain receive appropriate, timely, and adequate drug therapy to reduce their pain.

CONCLUSION

Recognition of the utility of opioids and other controlled substance drugs for the treatment of pain resulting from a variety of conditions is well established. The need for regulators and practitioners to understand this use, and to adopt laws, policies, and practices is self-evident if patients are to receive relief from pain which is now medically possible. In addition, pharmacists must understand their role in the on-going monitoring and assessment of patients' pain management. Working cooperatively, the Board of Pharmacy and the profession can ensure that opioids and other controlled substance drugs are used appropriately and effectively.

(+) **CRITERION 6:**
Prescription amount alone does not determine legitimacy



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



(+) **CRITERION 3:**
Opioids are part of professional practice



Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



STATUTES

Health Facility Licensing

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

Cal Health & Saf Code § 1254.7

§ 1254.7. Pain assessment

(a) It is the intent of the Legislature that pain be assessed and treated promptly, effectively, and for as long as pain persists.

(b) Every health facility licensed pursuant to this chapter shall, as a condition of licensure, include pain as an item to be assessed at the same time as vital signs are taken. The health facility shall ensure that pain assessment is performed in a consistent manner that is appropriate to the patient. The pain assessment shall be noted in the patient's chart in a manner consistent with other vital signs.

(+) **CRITERION 4:**
Encourages pain management

(+) **CRITERION 8:**
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

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

Cal Health & Saf Code § 1262.6

§ 1262.6. Patient's rights information requirements provided by hospital

(a) Each hospital shall provide each patient, upon admission or as soon thereafter as reasonably practical, written information regarding the patient's right to the following:

(1) To be informed of continuing health care requirements following discharge from the hospital.

(2) To be informed that, if the patient so authorizes, that a friend or family member may be provided information about the patient's continuing health care requirements following discharge from the hospital.

(3) Participate actively in decisions regarding medical care. To the extent permitted by law, participation shall include the right to refuse treatment.

(4) Appropriate pain assessment and treatment consistent with Sections 124960 and 124961.

(b) A hospital may include the information required by this section with other notices to the patient regarding patient rights. If a hospital chooses to include this information along with existing notices to the patient regarding patient rights, this information shall be provided when the hospital exhausts its existing inventory of written materials and prints new written materials.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Hospice Services

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

28 CCR 1300.68.2

§ 1300.68.2. Hospice Services

(a) For purposes of this section, the following definitions shall apply:

(2) "Hospice service" or "hospice program" means a specialized form of interdisciplinary health care that is designed to provide palliative care, alleviate the physical, emotional, social and spiritual discomforts of an enrollee who is experiencing the last phases of life due to the existence of a terminal disease, to provide supportive care to the primary care giver and the family of the hospice patient, and which meets all of the following criteria:

(C) Requires the interdisciplinary team to develop an overall plan of care and to provide coordinated care which emphasizes supportive services, including, but not limited to, home care, pain control, and short-term inpatient services. Short-term inpatient services are intended to ensure both continuity of care and appropriateness of services for those enrollees who cannot be managed at home because of acute complications or the temporary absence of a capable primary caregiver.

(D) Provides for the palliative medical treatment of pain and other symptoms associated with a terminal disease, but does not provide for efforts to cure the disease.

(7) "Medical direction" means those services provided by a licensed physician and surgeon who is charged with the responsibility of acting as a consultant to the interdisciplinary team, a consultant to the enrollee's attending physician and surgeon, as requested, with regard to pain and symptom management, and liaison with physicians and surgeons in the community. For purposes of this section, the person providing these services shall be referred to as the "medical director."

(+) CRITERION 8:
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes mechanisms for hospices to ensure that pain management is an essential part of patient care.



Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

COLORADO

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
Title 18. Criminal Code; Article 18. Uniform Controlled Substances Act of 1992
- MEDICAL PRACTICE ACT
Title 12. Professions and Occupations; Health Care; Article 36. Medical Practice
- INTRACTABLE PAIN TREATMENT ACT (*Part of Medical Practice Act*)
Title 12. Professions and Occupations; Health Care; Article 36. Medical Practice; Part 1. General Provisions
- PHARMACY PRACTICE ACT
Title 12. Professions and Occupations; General; Article 22. Pharmaceuticals and Pharmacists

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
No policy found
- MEDICAL BOARD REGULATIONS (*No provisions found*)
Department of Regulatory Agencies; Board of Medical Examiners
- PHARMACY BOARD REGULATIONS (*No provisions found*)
Department of Regulatory Agencies; State Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
Colorado State Board of Medical Examiners. *Policy for the Use of Controlled Substances for the Treatment of Pain*. Adopted: November 18, 2004.

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

- STANDARDS FOR HOSPITALS AND HEALTH FACILITIES
Department of Public Health and Environment; Health Facilities and Emergency Medical Services Division



Provisions that may <i>ENHANCE</i> pain management								
Criteria	1	2	3	4	5	6	7	8
	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		•						
Intractable Pain Treatment Act					•			
Pharmacy Practice Act ¹								
REGULATIONS								
Controlled Substances ²								
Medical Board ¹								
Pharmacy Board ¹								
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline		•	•	•	•	•	•	•
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Standards for Hospitals and Health Facilities								•

Note: A dot indicates that one or more provisions were identified
¹ No provisions were found in this policy, ² No policy found

Provisions that may <i>IMPEDE</i> pain management								
Criteria	9	10	11	12	13	14	15	16
	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								
Intractable Pain Treatment Act		•		•				•
Pharmacy Practice Act			•					
REGULATIONS								
Controlled Substances ²								
Medical Board ¹								
Pharmacy Board ¹								
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline ¹								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Standards for Hospitals and Health Facilities ⁷								

Note: A dot indicates that one or more provisions were identified
¹ No provisions were found in this policy, ² No policy found

STATUTES

Controlled Substances Act

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

C.R.S. 18-18-102

18-18-102. Definitions

As used in this article:

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(29) "Practitioner" means a physician, podiatrist, dentist, optometrist, veterinarian, researcher, pharmacist, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by this state, to distribute, dispense, conduct research with respect to, administer, or to use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

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. .

C.R.S. 18-18-308

18-18-308. Prescriptions

(1) As used in this section, "medical treatment" includes dispensing or administering a narcotic drug for pain, including intractable pain.

(2) Except as provided in section 18-18-414, a person may dispense a controlled substance only as provided in this section.

(3) Except when dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, a substance included in schedule II may not be dispensed without the written prescription of a practitioner.

(4) Except when dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, a substance included in schedule III, IV, or V may not be dispensed without a written or oral prescription order of a practitioner. The prescription order must not be filled or refilled more than six months after the date thereof or be refilled more than five times.

(5) A practitioner may dispense or deliver a controlled substance to or for an individual or animal only for medical treatment or authorized research in the ordinary course of that practitioner's profession.

(6) No civil or criminal liability or administrative sanction may be imposed on a pharmacist for action taken in reliance on a reasonable belief that an order purporting to be a prescription was issued by a practitioner in the usual course of professional

(+) CRITERION 3:
Opioids are part of professional practice

(+) CRITERION 2:
Pain management is part of medical practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Medical Practice Act

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

C.R.S. 12-36-106

12-36-106. Practice of medicine defined - exemptions from licensing requirements - repeal

(1) For the purpose of this article, "practice of medicine" means:

(a) Holding out one's self to the public within this state as being able to diagnose, treat, prescribe for, palliate, or prevent any human disease, ailment, pain, injury, deformity, or physical or mental condition, whether by the use of drugs, surgery, manipulation, electricity, telemedicine, the interpretation of tests, including primary diagnosis of pathology specimens, images, or photographs, or any physical, mechanical, or other means whatsoever.

(+) CRITERION 2: Pain management is part of medical practice

STATUTES

Intractable Pain Treatment Act

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

C.R.S. 12-36-117

12-36-117. Unprofessional conduct

(1) "Unprofessional conduct" as used in this article means:

- (hh) Advertising in a manner that is misleading, deceptive, or false;

(ii) Entering into or continuing a collaborative agreement pursuant to sections 12-38-111.6 (4) (d) (IV) and 12-36-106.3 that fails to meet generally acceptable standards of medical practice.

(1.5) (a) A physician shall not be subject to disciplinary action by the board solely for prescribing controlled substances for the relief of intractable pain.

(b) For the purposes of this subsection (1.5), "intractable pain" means a pain state in which the cause of the pain cannot be removed and which in the generally accepted course of medical practice no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts including, but not limited to, evaluation by the attending physician and one or more physicians specializing in the treatment of the area, system, or organ of the body perceived as the source of the pain.

(-) CRITERION 16: Provisions that are ambiguous

CATEGORY B: Unclear intent leading to possible misinterpretation

COMMENT: Suggests that physicians would not qualify for immunity and relief from concerns about regulatory scrutiny if they prescribe opioids as a treatment of first choice for patients who present initially with severe pain, such as those with sickle-cell anemia.

(+) CRITERION 5: Addresses fear of regulatory scrutiny

(-) CRITERION 10: Implies opioids are not part of professional

(-) CRITERION 12: Medical decisions are restricted

CATEGORY B: Mandated consultation

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

STATUTES

Pharmacy Practice Act

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

C.R.S. 12-22-303

12-22-303. Definitions

As used in this part 3, unless the context otherwise requires:

(1) "Addict" means a person who has a physical or psychological dependence on a controlled substance, which dependence develops following the use of the controlled substance on a periodic or continuing basis and is demonstrated by appropriate observation and tests by a person licensed to practice medicine pursuant to article 36 of this title.

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

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY
Medical Board Guideline
- For complete reference to this policy, see "Citations for Policies Evaluated" at the beginning of this State Profile -

**COLORADO STATE BOARD OF MEDICAL EXAMINERS
POLICY FOR THE USE OF CONTROLLED SUBSTANCES
FOR THE TREATMENT OF PAIN**

Section I: Preamble

The Colorado State Board of Medical Examiners ("Board") recognizes that principles of quality medical practice dictate that the people of the State of Colorado 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, undertreatment, 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, these guidelines 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 just as diligently as it would allegations of other misconduct relating to prescribing practices, 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 Board is obligated under the laws of the State of Colorado 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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(+) **CRITERION 2:**
Pain management is part of medical practice

(+) **CRITERION 4:**
Encourages pain management

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

(+) **CRITERION 8:**
Other provisions that may enhance pain treatment

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.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

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)

(+) **CRITERION 5:**
Addresses fear of regulatory scrutiny

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 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. 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. 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.

(+) **CRITERION 3:**
Opioids are part of professional practice

(+) **CRITERION 6:**
Prescription amount alone does not determine legitimacy

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.

(+) **CRITERION 8:**
Other provisions that may enhance pain treatment

CATEGORY A:
Issues related to healthcare professionals

(+) **CRITERION 8:**
Other provisions that may enhance pain management

CATEGORY A:
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.

Allegations of inappropriate pain management will be evaluated on an individual basis. The board will not take disciplinary action against a physician for not adhering strictly to 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.

Section II: Guidelines

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

1. 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.

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.

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 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

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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 -

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

4. 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.

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 patients with pain who are at 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.

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 risks and benefits;
- informed consent;
- treatments;
- medications (including date, type, dosage and quantity prescribed);
- instructions and agreements; and
- periodic reviews.

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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)

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 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.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Standards for Hospitals and Health Facilities

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

6 CCR 1011-1

6 CCR 1011-1. STANDARDS FOR HOSPITALS AND HEALTH FACILITIES

6. POLICIES AND PROCEDURES

6.1 Under the supervision and direction of the Governing Body, the hospice shall develop and implement written policies to coordinate a program for home and inpatient hospice care services.

6.1.1 These policies and procedures shall be reviewed and approved by the Governing Body annually.

6.1.2 The policies and procedures shall include but not be limited to:

- a) pain and other symptoms.
- b) physical components of care.
- c) financial needs.
- d) contractual services.

(+) CRITERION 8:
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

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



Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

CONNECTICUT

Citations for Policies Evaluated

STATUTES

- UNIFORM CONTROLLED SUBSTANCES ACT
Title 21a. Consumer Protection; Chapter 420b. Dependency-Producing Drugs
- MEDICAL PRACTICE ACT (*No provisions found*)
Title 20. Professional and Occupational Licensing; Certification, Title Protection and Registration; Examining Boards; Chapter 370. Medicine and Surgery
- PHARMACY PRACTICE ACT (*No provisions found*)
Title 20. Professional and Occupational Licensing; Certification, Title Protection and Registration; Examining Boards; Chapter 400j. Pharmacy
- INTRACTABLE PAIN TREATMENT ACT
No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
Title 21a Consumer Protection; Department of Consumer Protection; Designation of Controlled Drugs
- MEDICAL BOARD REGULATIONS
Title 20 Professional Licenses; Connecticut Medical Examining Board
- Pharmacy Board Regulations (*No provisions found*)
Title 20 Professional Licenses; Commission of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
Connecticut Medical Examining Board. *Statement of the Connecticut Medical Examining Board on the Use of Controlled Substances for the Treatment of Pain.* Adopted: June 21, 2005.

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

- LICENSURE OF HOME HEALTH CARE AGENCIES
Title 19. Health and Safety; Department of Public Health and Addiction Services; The Public Health Code of the State of Connecticut; Chapter IV. Hospitals, Child Day Care Centers, Other Institutions and Children's Licensure of Home Health Care Agencies.



Provisions that may <i>ENHANCE</i> pain management								
Criteria	1	2	3	4	5	6	7	8
	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								
Controlled Substances			•					
Medical Board ¹								
Pharmacy Board ¹								
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline		•	•	•		•	•	•
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Licensure of Home Health Care Agencies								•

Note: A dot indicates that one or more provisions were identified
¹ No provisions were found in this policy, ² No policy found

Provisions that may <i>IMPEDE</i> pain management								
Criteria	9	10	11	12	13	14	15	16
	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 GOVERNMENTAL POLICIES								
Medical Board Guidelines ¹								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Licensure of Home Health Care Agencies ¹								

Note: A dot indicates that one or more provisions were identified
¹ No provisions were found in this policy, ² No policy found

STATUTES

Controlled Substances Act

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

Conn. Gen. Stat. § 21a-240

§ 21a-240. (Formerly Sec. 19-443). Definitions.

The following words and phrases, as used in this chapter, shall have the following meanings, unless the context otherwise requires:

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(43) "Practitioner" means: (A) A physician, dentist, veterinarian, podiatrist, scientific investigator 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; (B) a pharmacy, hospital or other institution 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;

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Conn. Gen. Stat. § 21a-251

§ 21a-251. (Formerly Sec. 19-459). Dispensing of controlled substances by hospitals, infirmaries or clinics.

(a) No controlled substances shall be dispensed or administered by hospitals, infirmaries or clinics except upon written order signed or initialed by the prescribing practitioner or upon an oral order of a prescribing practitioner which shall be confirmed by a written order which shall be signed or initialed by such prescribing practitioner within twenty-four hours after the giving of such oral order for schedule II controlled substances and within seventy-two hours after the giving of such oral order for other controlled substances.

(b) Original and continuing orders for schedule II controlled substances shall be limited to a period not exceeding seven days from the time the order is entered, but may be extended for additional periods of seven days each by the signing or initialing of the order by a prescribing practitioner.

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(+) CRITERION 3:
Opioids are part of professional practice



(-) CRITERION 14:
Undue prescription requirements

COMMENT: Stop-orders for controlled substances typically are found in institutional policy, but this establishes a specific requirement under the Connecticut Controlled Substances Act, which is largely a criminal statute. Is such a policy appropriate in a state CSA?



Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Controlled Substances Regulations

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

Regs., Conn. State Agencies § 21a-326-1

Sec. 21a-326-1. Definitions

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(c) "Course of Professional Practice" means the limitation of prescribing, dispensing, or administering of controlled substances for professional treatment authorized pursuant to regulations and/or statutes of the appropriate state licensing authority under which situations there must be a bona fide practitioner-patient relationship. The prescribing or dispensing of controlled substances for patients, friends, relatives, associates, and/or employees wherein a bona fide practitioner-patient relationship does not exist or wherein the practitioner has not medically evaluated the need for controlled substances shall not be considered to be in the "course of professional practice."

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(+) CRITERION 3:
Opioids are part of professional practice

REGULATIONS

Medical Board Regulations

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

Connecticut Regulations § 21a-326-1

Sec. 21a-326-1. Definitions

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(e) "Therapeutic or Other Proper Medical or Scientific Purposes" means the following:
(1) The prescribing, dispensing, or administering of a controlled substance for treatment of a specific disease or medical condition, recognized by medical consensus and/or stated in the literature of the manufacturers of the controlled substances as being the purposes for which the controlled substance is intended.

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(-) CRITERION 12:
Medical decisions are restricted

CATEGORY D:
Undue prescription limitations

COMMENT: Under Federal law, physicians are not restricted to FDA approved indications listed in the manufacturer's literature. Because prescribing for other than (e) is considered unprofessional conduct, it appears that "off label" prescribing of controlled substances would be unprofessional conduct. Also, what constitutes a "medical consensus" and who determines this?

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

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

Statement of the Connecticut Medical Examining Board on the Use of Controlled Substances for the Treatment of Pain

Section I: Preamble

The Connecticut Medical Examining Board (Board) recognizes that principles of quality medical practice dictate that the people of the State of Connecticut have access to appropriate and effective pain relief. The purpose of this statement is to express the Board's support for the development and implementation of practices to assure the appropriate application of up-to-date knowledge and treatment modalities which 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 Statement, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine. Therefore, 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 in conjunction with terminal illness. All physicians and health care professionals should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory and regulatory requirements for prescribing controlled substances. Accordingly this Statement has been developed to encourage physicians to consider the importance of pain control, particularly as related to the use of controlled substances and to encourage comprehensive pain management.

The Board recognizes that applicable standards of care permit the use of controlled substances including opioid analgesics in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The Board also believes that physicians should be able to prescribe, dispense or administer controlled substances, including opioid analgesics, when done for a legitimate medical purpose and in accord with applicable standards of care and applicable law. The Board recognizes that the aim of current practice guidelines 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. Current practice guidelines accept that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not pathognomonic of addiction.

The Board acknowledges the medical community's view that the goals of effective pain management include (i) pain is to be assessed and treated promptly; (ii) the amount of medication and frequency of dosing adjusted according to the intensity, duration of the pain, and treatment outcomes; (iii) consideration of current clinical knowledge and scientific research; and (iv) the use of pharmacologic and non-pharmacologic modalities.

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(+) **CRITERION 8:**
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 standardized practices might be.

(+) **CRITERION 3:**
Opioids are part of professional practice

(+) **CRITERION 8:**
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.

(+) **CRITERION 2:**
Pain management is part of medical practice

(+) **CRITERION 4:**
Encourages pain management

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

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

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)

The Board is obligated under the laws of the State of Connecticut to protect the public health and safety. Connecticut law reflects the public policy that the use of opioid analgesics for other than legitimate medical purposes poses 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, current practice guidelines also note that effective pain management incorporates safeguards into the practice to minimize the potential for the abuse and diversion of controlled substances such as periodic reviews and written agreements outlining patient responsibility. However, physicians may face serious questions as to the legitimate medical purpose of a prescription where no physician-patient relationship exists or the prescription is not based on a diagnosis and clear documentation of pain.

As in all proceedings, matters involving issues of pain management will be reviewed and decided on a case-by-case basis. The Board may consider clinical practice guidelines, expert opinions, witness testimony, medical records and other relevant evidence. In accord with its case-by-case approach to such cases, the Board may not judge the validity of treatment solely on the quantity and duration of medication administration; may take into account whether the drug used is appropriate for the diagnosis as well as the outcome of pain treatment including improvement in patient functioning and/or quality of life; and will not assume that all types of pain can be completely relieved.

(+) **CRITERION 6:**
Prescription amount
alone does not
determine legitimacy

Section II: Treatment of Pain Practices

The Board recognizes that the medical community has encouraged the following practices as appropriate for the treatment of pain, including the use of controlled substances:

1. 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.

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.

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 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

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

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

OTHER GOVERNMENTAL POLICY

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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4. 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 may 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.

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 patients with pain who are at 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.

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 risks and benefits;
- informed consent;
- treatments;
- patient response to treatments;
- medications (including date, type, dosage and quantity prescribed);
- instructions and agreements; and
- 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 Connecticut and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration for specific rules governing controlled substances as well as applicable state statutes and regulations.

Section III: Definitions

For the purposes of this statement, the following terms are defined as follows:

(CONTINUED ON NEXT PAGE)

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

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)

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.

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.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Licensure of Home Health Care Agencies

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

Regs., Conn. State Agencies § 19-13-D72

Sec. 19-13-D72. Patient care policies

(a) General Program Policies. An agency shall have written policies governing referrals received, admission of patients to agency services, delivery of such services and discharge of patients. Such policies shall cover all services provided by the agency, directly or under contract. A copy shall be readily available to patients and staff and shall include but not be limited to:

(B) An agency shall develop and implement written policies and procedures for all hospice services provided which include:

(iii) Procedures for the provision of care and services to the patient family including advising the patient or legal representative of the nature of the palliative care offered. Palliative care includes pain control, symptom management, quality of life enhancement and spiritual and emotional comfort for patients and their caregivers; the patient's needs are continuously assessed and all treatment options are explored and evaluated in the context of the patient's values and symptoms;

(vii) For hospice employees, six hours of the annual in-service education requirements in accordance with Section 19-13-D71(a)(2) of these regulations shall address topics related to hospice care. The agency shall ensure, as part of its coordination of inpatient care agreement with an inpatient setting, that all direct service staff receive in-service education including two hours specific to hospice care. The in-service education shall include current information regarding drugs and treatments, specific service procedures and techniques, pain and symptom management, psychosocial and spiritual aspects of care, interdisciplinary team approach to care, bereavement care, acceptable professional standards, and criteria and classification of clients served;

(iii) The medical director's responsibilities shall include, but not be limited to:

II. Consultation with attending physicians regarding pain and symptom control and medical management as appropriate.

(+) **CRITERION 8:**
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes mechanisms for hospices to ensure that pain management is an essential part of patient care.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

DELAWARE

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
Title 16. Health and Safety; Part IV. Food and Drugs; Chapter 47. Uniform Controlled Substances Act
- MEDICAL PRACTICE ACT
Title 24. Professions and Occupations; Chapter 17. Medical Practice Act
- PHARMACY PRACTICE ACT
Title 24. Professions and Occupations; Chapter 25. Pharmacy
- INTRACTABLE PAIN TREATMENT ACT
No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
Agency 16. Department of Health and Social Services; Sub-Agency 4000. Division of Public Health; Chapter 4426. Controlled Substances Act Regulations Health System Protection
- MEDICAL BOARD REGULATIONS (*No provisions found*)
Agency 24. Department of Administrative Services; Division of Professional Regulation. Sub-Agency 1700. Board of Medical Practice; Rules and Regulations
- PHARMACY BOARD REGULATIONS (*No provisions found*)
Agency 24. Department of Administrative Services; Division of Professional Regulation. Sub-Agency 2500. Board of Pharmacy; Rules and Regulations

OTHER GOVERNMENTAL POLICIES

No policies found

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

- DELIVERY OF HOSPICE SERVICES
Agency 16. Department of Health and Social Services; Sub-Agency 4000. Division of Public Health; Chapter 4468. Delivery of Hospice Services; Health Systems Protection



Provisions that may <i>ENHANCE</i> pain management								
Criteria	1	2	3	4	5	6	7	8
	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			•					
Intractable Pain Treatment Act ²								
REGULATIONS								
Controlled Substances			•					•
Medical Board ¹								
Pharmacy Board ¹								
OTHER GOVERNMENTAL POLICIES²								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Delivery of Hospice Services								•

Note: A dot indicates that one or more provisions were identified
¹ No provisions were found in this policy, ² No policy found



Provisions that may <i>IMPEDE</i> pain management								
Criteria	9	10	11	12	13	14	15	16
	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				•	•			
Medical Board ¹								
Pharmacy Board ¹								
OTHER GOVERNMENTAL POLICIES²								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Delivery of Hospice Services ¹								

Note: A dot indicates that one or more provisions were identified
¹ No provisions were found in this policy, ² No policy found



STATUTES

Controlled Substances Act

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

16 Del. C. § 4701

§ 4701. Definitions

As used in this chapter:

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(31) "Practitioner" means:

a. A physician, dentist, veterinarian, scientific investigator 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.

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(+) CRITERION 3:
Opioids are part of professional practice

STATUTES

Medical Practice Act

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

24 Del. C. § 1702

§ 1702. Definitions

The following definitions apply to this chapter unless otherwise expressly stated or implied by the context.

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(9) "Practice of medicine" or "practice medicine" includes:

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c. Offering or undertaking to prevent or to diagnose, correct, and/or treat in any manner or by any means, methods, or devices a disease, illness, pain, wound, fracture, infirmity, defect, or abnormal physical or mental condition of another person, including the management of pregnancy and parturition;

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(+) CRITERION 2:
Pain management is part of medical practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



STATUTES

Pharmacy Practice Act

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

24 Del. C. § 2502

§ 2502. Definitions as used in this chapter

As used in this chapter:

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(n) "Practitioner" means any person who is authorized by law to prescribe drugs in the course of professional practice or research in this State.

(+) CRITERION 3:
Opioids are part of professional practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



REGULATIONS

Controlled Substances Regulations

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

CDR 16-4000-4426

4.0 Prescriptions

4.1 Definitions. As used in this section:

"Individual Practitioner" means physician, dentist, veterinarian, or other individual, licensed, registered, or otherwise permitted, by the United States or the State of Delaware to dispense a controlled substance in the course of professional practice but does not include a pharmacist, a pharmacy, or an institutional practitioner.

(+) **CRITERION 3:**
Opioids are part of professional practice

CDR 16-4000-4426

4.8 Expiration of Prescription.

4.8.1 Prescriptions for controlled substances in Schedules II and III will become void unless dispensed within seven (7) days of the original date of the prescription or if the original prescriber authorizes the prescription past the seven (7) days period. Such prescriptions cannot be written nor dispensed for more than 100 dosage units or a 31 day supply whatever is the greater at one time. As an exception to dosage limitations set forth in this subparagraph, and in accordance with 21 C.F.R. Section 1306.1(b), prescriptions for controlled substances in Schedule II for patients either having a medically documented terminal illness or patients in Long Term Facilities (LTCF), may be filled in partial quantities, to include individual dosage units. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed and the identification of the dispensing pharmacist. The total quantity of Schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed.

4.8.2 Schedule II prescriptions for terminally ill or LTCF patients, shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of the medication.

(-) **CRITERION 13:**
Length of prescription validity is restricted

(-) **CRITERION 12:**
Medical decisions are restricted

CATEGORY C:
Restrictions regarding quantity prescribed or dispensed

(+) **CRITERION 8:**
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Exemption of these patients nevertheless continues the prescribing restriction for all other patients.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

REGULATIONS

Delivery of Hospice Services

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

CDR 16-4000-4468

16 4000 4468. DELIVERY OF HOSPICE SERVICES

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3.0 Hospice Care

3.1 Hospice is an option for care which utilizes an interdisciplinary team of the patient's choice. The team shall consist of at least a physician, nurse, social worker, clergy, trained volunteer, and the patient/family.

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3.3 The interdisciplinary team shall have the following responsibilities:

3.3.1 Perform an admission history which includes medical, social, spiritual, emotional aspects of the patient/family.

3.3.2 Develop the care plan for each patient/family. The patient care coordinator will be responsible for assuring the implementation and ongoing review of the care plan.

3.3.3 Hold an interdisciplinary care team meeting at least semimonthly or more often if needed to review and update the care plan.

3.3.4 Emphasize prevention and control of pain and other distressing symptoms.

3.3.5 Make provision for 24 hours per day, seven days a week coverage.

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(+) **CRITERION 8:**
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

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

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

DISTRICT OF COLUMBIA

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT (*No provisions found*)
Title 48. Food and Drugs; Subtitle II. Prescription Drugs
- MEDICAL PRACTICE ACT (*No provisions found*)
Title 3. District of Columbia Boards and Commissions; Subtitle 1. General; Chapter 12. Health Occupations Boards; Unit A. General
- PHARMACY PRACTICE ACT (*No provisions found*)
Title 3. District of Columbia Boards and Commissions; Subtitle 1. General; Chapter 12. Health Occupations Boards; Unit A. General
- INTRACTABLE PAIN TREATMENT ACT
No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
Title 22. Public Health and Medicine; Chapter 13. Prescriptions and Distribution
- MEDICAL BOARD REGULATIONS
Title 17. Business, Occupations, and Professions. Chapter 46. Medicine
- PHARMACY BOARD REGULATIONS (*No provisions found*)
Title 17. Business, Occupations, and Professions. Chapter 65. Pharmacists

OTHER GOVERNMENTAL POLICIES

No policies found

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

No policies found



Provisions that may <i>ENHANCE</i> pain management								
Criteria	1	2	3	4	5	6	7	8
	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								
Controlled Substances ¹								
Medical Board		•	•				•	•
Pharmacy Board ¹								
OTHER GOVERNMENTAL POLICIES²								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES²								

Note: A dot indicates that one or more provisions were identified
¹ No provisions were found in this policy, ² No policy found

Provisions that may <i>IMPEDE</i> pain management								
Criteria	9	10	11	12	13	14	15	16
	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								•
Medical Board				•				
Pharmacy Board ¹								
OTHER GOVERNMENTAL POLICIES²								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES²								

Note: A dot indicates that one or more provisions were identified
¹ No provisions were found in this policy, ² No policy found



REGULATIONS

Controlled Substances Regulations

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

D.C. Admin. Code § 22-1304.4

§ 22-1304.4 Administering or Dispensing of Narcotic Drugs

The rules of this chapter are not intended to impose any limitations on a physician or authorized hospital staff to administer or dispense narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction, or to administer or dispense narcotic drugs to persons 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?

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



REGULATIONS

Medical Board Regulations

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

CDCR 17-4614

Section 17-4614. Standards for the Use of Controlled Substances for the Treatment of Pain

4614.1 A licensed physician shall prescribe, order, administer, or dispense controlled substances for pain only for a legitimate medical purpose based on accepted scientific knowledge of the treatment of pain or based on sound clinical grounds. All such prescribing shall be based on clear documentation of unrelieved pain and in compliance with applicable District or federal law.

4614.2 A licensed physician shall employ up-to-date treatment modalities in order to improve the quality of life for patients who suffer from pain as well as to reduce the morbidity and costs incurred by patients associated with untreated or inappropriately treated pain. For purposes of this section, "inappropriately treated pain" includes the following:

- (a) Non-treatment;
- (b) Under-treatment;
- (c) Over-treatment; and
- (d) The continued use of ineffective treatments.

4614.3 A licensed physician shall perform an evaluation of the patient by taking a complete medical history and performing a physical examination. The medical history and physical examination shall be documented in the medical record. The medical record shall contain a description of the following:

- (a) The nature and intensity of the patient's pain;
- (b) The patient's current and past treatments for pain;
- (c) The patient's underlying or coexisting diseases or conditions;
- (d) The effect of the pain on the patient's physical and psychological function;
- (e) A history of the patient's substance abuse if applicable; and
- (f) The presence of one or more recognized medical indications in the patient for the use of a controlled substance.

4614.4 A licensed physician shall maintain a written treatment plan which states the objectives used to determine treatment success, such as pain relief and improved physical and psychosocial function

4614.5 The treatment plan shall indicate if any further diagnostic evaluations or other treatments are planned.

4614.6 The physician shall adjust drug therapy to the individual medical needs of each patient after treatment begins.

4614.7 The physician shall consider other treatment modalities or a rehabilitation program if necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

4614.8 The physician shall discuss the risks and benefits of the use of controlled substances with the patient, person(s) designated by the patient, or with the patient's surrogate or guardian if the patient is incompetent.

(CONTINUED ON NEXT PAGE)

(+) **CRITERION 2:**
Pain management is part of medical practice

(+) **CRITERION 3:**
Opioids are part of professional practice

(+) **CRITERION 8:**
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.

(+) **CRITERION 8:**
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.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



REGULATIONS

Medical Board Regulations

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

(CONTINUED)

4614.9 If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician shall employ the use of a written agreement between the physician and patient outlining the patient's responsibilities, including, but not limited to:

- (a) Urine/serum medication levels screening when requested;
- (b) Number and frequency of all prescription refills; and
- (c) Reasons for which drug therapy may be discontinued, such as violation of an agreement.

4614.10 The physician shall do the following:

- (a) Review the course of treatment and any new information about the etiology of the pain at reasonable intervals based on the individual circumstances of the patient;
- (b) Continue or modify the pain therapy depending on the physician's evaluation of the patient's progress;
- (c) Reevaluate the appropriateness of continued treatment if treatment goals are not being achieved despite medication adjustments; and
- (d) Monitor the patient's compliance in medication usage and and related treatment plans.

4614.11 The physician shall refer the patient, as necessary, to another physician for additional evaluation and treatment in order to achieve treatment objectives. Special attention shall 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.

4614.12 The physician shall consult with or refer to an expert for management the following types of patients:

- (a) Patients with a history of substance abuse; or
- (b) Patients with comorbid psychiatric disorders that require extra care, monitoring, and documentation.

4614.13 The physician shall recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

4614.14 The physician shall keep accurate and complete records that include, but are not limited to:

- (a) The medical history and physical examination, including history of drug abuse or dependence, as appropriate;
- (b) Diagnostic, therapeutic, and laboratory results;
- (c) Evaluations and consultations;
- (c) Treatment objectives;
- (d) Discussion of risks and benefits;
- (e) Treatments;
- (f) Medications including date, type, dosage, and quantity prescribed;
- (g) Instructions and agreements; and
- (h) Periodic reviews.

(-) **CRITERION 12:**
Medical decisions are restricted

CATEGORY B:
Mandated consultation

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

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

FLORIDA

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
Title 46. Crimes; Chapter 893. Drug Abuse Prevention and Control
- MEDICAL PRACTICE ACT
Title 32. Regulation of Professions and Occupations; Chapter 458. Medical Practice
- OSTEOPATHIC PRACTICE ACT
Title 32. Regulation of Professions and Occupations; Chapter 459. Osteopathic Medicine
- PHARMACY PRACTICE ACT
Title 32. Regulation of Professions and Occupations; Chapter 465. Pharmacy
- INTRACTABLE PAIN TREATMENT ACT
No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*No provisions found*)
Title 64. Department of Health; 64F Division of Family Health Services; Chapter 64F-12
Regulations for Drugs, Devices and Cosmetics
- MEDICAL BOARD REGULATIONS
Title 64. Department of Health; 64B8 Board of Medicine
- OSTEOPATHIC BOARD REGULATIONS
Title 64. Department of Health; 64B15 Board of Osteopathic Medicine
- PHARMACY BOARD REGULATIONS
Title 64. Department of Health; 64B16 Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- JOINT BOARD POLICY STATEMENT
Florida Boards of Medicine, Nursing, Osteopathic Medicine, and Pharmacy. *Joint Statement on Pain Management: Florida Boards of Medicine, Nursing, Osteopathic Medicine, and Pharmacy*. Adopted: September 19, 2005.

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

- CIVIL RIGHTS
Title 44. Civil Rights; Chapter 765. Health Care Advanced Directives; Part 1. General Provisions
- HOSPICE SERVICES
Title 58. Department of Elder Affairs; Chapter 58A-2. Hospice



Provisions that may <i>ENHANCE</i> pain management								
Criteria	1	2	3	4	5	6	7	8
	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		•	•					
Osteopathic Practice Act		•						
Pharmacy Practice Act ¹								
Intractable Pain Treatment Act ²								
REGULATIONS								
Controlled Substances ¹								
Medical Board		•	•	•	•	•	•	•
Osteopathic Board		•	•	•	•	•	•	•
Pharmacy Board		•		•	•			
OTHER GOVERNMENTAL POLICIES								
Joint Board Policy Statement		•		•				•
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Civil Rights								•
Hospice Services								•

Note: A dot indicates that one or more provisions were identified
¹ No provisions were found in this policy, ² No policy found

Provisions that may <i>IMPEDE</i> pain management								
Criteria	9	10	11	12	13	14	15	16
	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		•						•
Osteopathic Practice Act ¹								
Pharmacy Practice Act								•
Intractable Pain Treatment Act ²								
REGULATIONS								
Controlled Substances ¹								
Medical Board ¹								
Osteopathic Board ¹								
Pharmacy Board				•				
OTHER GOVERNMENTAL POLICIES								
Joint Board Policy Statement ¹								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Civil Rights ¹								
Hospice Services ¹								

Note: A dot indicates that one or more provisions were identified
¹ No provisions were found in this policy, ² No policy found



STATUTES

Controlled Substances Act

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

Fla. Stat. § 893.13

§ 893.13. Prohibited acts; penalties

(1) (a) Except as authorized by this chapter and chapter 499, it is unlawful for any person to sell, manufacture, or deliver, or possess with intent to sell, manufacture, or deliver, a controlled substance...

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(9) The provisions of subsections (1)-(8) are not applicable to the delivery to, or actual or constructive possession for medical or scientific use or purpose only of controlled substances by, persons included in any of the following classes, or the agents or employees of such persons, for use in the usual course of their business or profession or in the performance of their official duties:

(a) Pharmacists.

(b) Practitioners.

(c) Persons who procure controlled substances in good faith and in the course of professional practice only, by or under the supervision of pharmacists or practitioners employed by them, or for the purpose of lawful research, teaching, or testing, and not for resale.

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(+) CRITERION 3:
Opioids are part of professional practice

STATUTES

Medical Practice Act

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

Fla. Stat. § 458.305

458.305 Definitions.

As used in this chapter:

(1) "Board" means the Board of Medicine.

(2) "Department" means the Department of Health.

(3) "Practice of medicine" means the diagnosis, treatment, operation, or prescription for any human disease, pain, injury, deformity, or other physical or mental condition.

(4) "Physician" means a person who is licensed to practice medicine in this state.

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(+) CRITERION 2:
Pain management is part of medical practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



STATUTES

Medical Practice Act

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

Fla. Stat. § 458.326

§ 458.326. Intractable pain; authorized treatment

(1) For the purposes of this section, the term "intractable pain" means pain for which, in the generally accepted course of medical practice, the cause cannot be removed and otherwise treated.

(2) Intractable pain must be diagnosed by a physician licensed under this chapter and qualified by experience to render such diagnosis.

(3) Notwithstanding any other provision of law, a physician may prescribe or administer any controlled substance under Schedules II-V, as provided for in s. 893.03, to a person for the treatment of intractable pain, provided the physician does so in accordance with that level of care, skill, and treatment recognized by a reasonably prudent physician under similar conditions and circumstances.

(4) Nothing in this section shall be construed to condone, authorize, or approve mercy killing or euthanasia, and no treatment authorized by this section may be used for such purpose.

Fla. Stat. § 458.331

458.331 Grounds for disciplinary action; action by the board and department.

(1) The following acts shall constitute grounds for which the disciplinary actions specified in subsection (2) may be taken:

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(q) Prescribing, dispensing, administering, mixing, or otherwise preparing a legend drug, including any controlled substance, other than in the course of the physician's professional practice. For the purposes of this paragraph, it shall be legally presumed that prescribing, dispensing, administering, mixing, or otherwise preparing legend drugs, including all controlled substances, inappropriately or in excessive or inappropriate quantities is not in the best interest of the patient and is not in the course of the physician's professional practice, without regard to his or her intent.

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(-) CRITERION 10:
Implies opioids are not part of professional practice

(+) CRITERION 3:
Opioids are part of professional practice

(-) CRITERION 16:
Provisions that are ambiguous

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT:
"Inappropriate" and "excessive" implies there is a limit, but the limit is not specified. Also, elimination of the critically important intent of the physician in deciding cases appears to add to the uncertainty of how this provision might be interpreted.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



STATUTES

Osteopathic Practice Act

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

Fla. Stat. § 459.003

§ 459.003. Definitions

As used in this chapter:

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(3) "Practice of osteopathic medicine" means the diagnosis, treatment, operation, or prescription for any human disease, pain, injury, deformity, or other physical or mental condition, which practice is based in part upon educational standards and requirements which emphasize the importance of the musculoskeletal structure and manipulative therapy in the maintenance and restoration of health.

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(+) CRITERION 2:
Pain management is part of medical practice

STATUTES

Pharmacy Practice Act

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

Fla. Stat. § 465.016

465.016 Disciplinary actions.

(1) The following acts shall be grounds for disciplinary action set forth in this section:

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(i) Compounding, dispensing, or distributing a legend drug, including any controlled substance, other than in the course of the professional practice of pharmacy. For purposes of this paragraph, it shall be legally presumed that the compounding, dispensing, or distributing of legend drugs in excessive or inappropriate quantities is not in the best interests of the patient and is not in the course of the professional practice of pharmacy.

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(-) CRITERION 16:
Provisions that are ambiguous

CATEGORY A:
Arbitrary standards for legitimate prescribing

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

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



REGULATIONS

Medical Board Regulations

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

64B8-9.013, F.A.C.

64B8-9.013 Standards for the Use of Controlled Substances for Treatment of Pain.

(1) Pain management principles.

(a) The Board of Medicine recognizes that principles of quality medical practice dictate that the people of the State of Florida 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 as well as statutory requirements for prescribing controlled substances.

(+) **CRITERION 2:**
Pain management is part of medical practice

(b) 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. Physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agencies for prescribing, dispensing, or administering controlled substances including opioid analgesics, for a legitimate medical purpose and that is supported by appropriate documentation establishing a valid medical need and treatment plan. 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.

(+) **CRITERION 4:**
Encourages pain management

(+) **CRITERION 5:**
Addresses fear of regulatory scrutiny

(c) 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. Physicians are referred to the U.S. Agency for Health Care Policy and Research Clinical Practical Guidelines for a sound approach to the management of acute and cancer-related pain. The medical management of pain including intractable pain should be based on current knowledge and research and includes 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.

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

(d) The Board of Medicine is obligated under the laws of the State of Florida 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.

(+) **CRITERION 3:**
Opioids are part of professional practice

(e) 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.

(+) **CRITERION 8:**
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

(f) 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 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.

COMMENT: Recognizes 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.

[CONTINUED ON NEXT PAGE]

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



REGULATIONS

Medical Board Regulations

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

[CONTINUED]

(+) **CRITERION 6:**
*Prescription amount
alone does not
determine legitimacy*

(g) 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.

(2) Definitions.

(a) Acute Pain. For the purpose of this rule, acute pain is defined as 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.

(b) Addiction. For the purpose of this rule, addiction is defined as 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. For the purpose of this rule, analgesic tolerance is defined as 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.

(d) Chronic Pain. For the purpose of this rule, chronic pain is defined as a pain state which is persistent.

(e) Pain. For the purpose of this rule, pain is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

(f) Physical Dependence. For the purpose of this rule, physical dependence on a controlled substance is defined as 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.

(g) Pseudoaddiction. For the purpose of this rule, pseudoaddiction is defined as a pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

(h) Substance Abuse. For the purpose of this rule, substance abuse is defined as the use of any substances for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

(i) Tolerance. For the purpose of this rule, tolerance is defined as 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.

(3) Guidelines. The Board has adopted the following guidelines when evaluating the use of controlled substances for pain control:

[CONTINUED ON NEXT PAGE]

(+) **CRITERION 8:**
*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.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



REGULATIONS

Medical Board Regulations

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

[CONTINUED]

(a) 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.

(b) 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.

(c) 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, but not limited to:

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

(d) 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.

(e) 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.

[CONTINUED ON NEXT PAGE]

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



REGULATIONS

Medical Board Regulations

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

[CONTINUED]

(f) Medical Records. The physician is required to keep accurate and complete records to include, but not be limited to:

1. the medical history and physical examination;
2. diagnostic, therapeutic, and laboratory results;
3. evaluations and consultations;
4. treatment objectives;
5. discussion of risks and benefits;
6. treatments;
7. medications (including date, type, dosage, and quantity prescribed);
8. instructions and agreements; and
9. periodic reviews.

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

(g) 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: An Informational Outline of the Controlled Substances Act of 1970, published by the U.S. Drug Enforcement Agency, for specific rules governing controlled substances as well as applicable state regulations.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



REGULATIONS

Osteopathic Board Regulations

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

64B15-14.005, F.A.C.

64B15-14.005 Standards for the Use of Controlled Substances for Treatment of Pain.

(1) Pain management principles.

(a) The Board of Osteopathic Medicine recognizes that principles of quality medical practice dictate that the people of the State of Florida 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 osteopathic 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 osteopathic physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

(b) Inadequate pain control may result from an osteopathic physician's 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. Osteopathic physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agencies for prescribing, dispensing, or administering controlled substances including opioid analgesics, for a legitimate medical purpose and that is supported by appropriate documentation establishing a valid medical need and treatment plan. 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.

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(+) CRITERION 2:
Pain management is part
of medical practice

(+) CRITERION 5:
Addresses fear of
regulatory scrutiny

(+) CRITERION 4:
Encourages pain
management

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



REGULATIONS

Osteopathic Board Regulations

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

[CONTINUED]

(c) 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. Osteopathic physicians are referred to the U.S. Agency for Health Care Policy and Research Clinical Practice Guidelines for a sound approach to the management of acute and cancer-related pain. The medical management of pain including intractable pain should be based on current knowledge and research and includes 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. Osteopathic physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.

(d) The Board of Osteopathic Medicine is obligated under the laws of the State of Florida 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. Osteopathic physicians should be diligent in preventing the diversion of drugs for illegitimate purposes.

(e) 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.

(f) Each case of prescribing for pain will be evaluated on an individual basis. The Board will not take disciplinary action against an osteopathic physician for failing to adhere strictly to the provisions of these guidelines, if good cause is shown for such deviation. The osteopathic 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.

(g) The Board will judge the validity of prescribing based on the osteopathic 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.

(2) Definitions.

(a) Acute Pain. For the purpose of this rule, "acute pain" is defined as 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.

(b) Addiction. For the purpose of this rule, "addiction" is defined as 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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(+) **CRITERION 7:**
Physical dependence or analgesic tolerance are not confused with "addiction"

(+) **CRITERION 3:**
Opioids are part of professional practice

(+) **CRITERION 8:**
Other provisions that may enhance pain management

CATEGORY A:
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.

(+) **CRITERION 6:**
Prescription amount alone does not determine legitimacy

(+) **CRITERION 8:**
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.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



REGULATIONS

Osteopathic Board Regulations

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

[CONTINUED]

(c) Analgesic Tolerance. For the purpose of this rule, "analgesic tolerance" is defined as 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.

(d) Chronic Pain. For the purpose of this rule, "chronic pain" is defined as a pain state which is persistent.

(e) Pain. For the purpose of this rule, "pain" is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

(f) Physical Dependence. For the purpose of this rule, "physical dependence" on a controlled substance is defined as 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.

(g) Pseudoaddiction. For the purpose of this rule, "pseudoaddiction" is defined as a pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

(h) Substance Abuse. For the purpose of this rule, "substance abuse" is defined as the use of any substances for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

(i) Tolerance. For the purpose of this rule, "tolerance" is defined as 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.

(3) Guidelines. The Board has adopted the following guidelines when evaluating the use of controlled substances for pain control:

(a) 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.

(b) 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 osteopathic 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.

(c) Informed Consent and Agreement for Treatment. The osteopathic 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 osteopathic 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 osteopathic physician may employ the use of a written agreement between physician and patient outlining patient responsibilities, including, but not limited to:

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



REGULATIONS

Osteopathic Board Regulations

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

[CONTINUED]

1. Urine/serum medication levels screening when requested;
2. Number and frequency of all prescription refills; and
3. Reasons for which drug therapy may be discontinued (i.e., violation of agreement).

(d) Periodic Review. At reasonable intervals based on the individual circumstances of the patient, the osteopathic 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 osteopathic 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 osteopathic physician should reevaluate the appropriateness of continued treatment. The osteopathic physician should monitor patient compliance in medication usage and related treatment plans.

(e) Consultation. The osteopathic 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.

(f) Medical Records. The osteopathic physician is required to keep accurate and complete records to include, but not be limited to:

1. The medical history and physical examination;
2. Diagnostic, therapeutic, and laboratory results;
3. Evaluations and consultations;
4. Treatment objectives;
5. Discussion of risks and benefits;
6. Treatments;
7. Medications (including date, type, dosage, and quantity prescribed);
8. Instructions and agreements; and
9. Periodic reviews.

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

(g) Compliance with Controlled Substances Laws and Regulations. To prescribe, dispense, or administer controlled substances, the osteopathic physician must be licensed in the state and comply with applicable federal and state regulations. Osteopathic physicians are referred to the Physicians Manual: An Informational Outline of the Controlled Substances Act of 1970, published by the U.S. Drug Enforcement Agency, for specific rules governing controlled substances as well as applicable state regulations.

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REGULATIONS

Pharmacy Board Regulations

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

64B16-27.210, F.A.C.

64B16-27.210 General Terms and Conditions to Be Followed by a Pharmacist When Ordering and Dispensing Approved Medicinal Drug Products.

Pharmacists may order the medicinal drug products set forth in each rule subject to the following terms and limitations:

- (1) Injectable products shall not be ordered by the pharmacist.
- (2) No oral medicinal drugs shall be ordered by a pharmacist for a pregnant patient or nursing mother.
- (3) In any case of dispensing hereunder, the amount or quantity of drug dispensed shall not exceed a 34-day supply or standard course of treatment unless subject to the specific limitations in this rule. Patients shall be advised that they should seek the advice of an appropriate health care provider if their present condition, symptom, or complaint does not improve upon the completion of the drug regimen.
- (4) The directions for use of all prescribed medicinal drugs shall not exceed the manufacturer's recommended dosage.

(-) CRITERION 12:
Medical decisions are restricted

CATEGORY D:
Undue prescription limitations

COMMENT: Under Federal law, physicians are not restricted to the recommended dosage listed in the manufacturer's literature.

(-) CRITERION 12:
Medical decisions are restricted

CATEGORY C:
Restrictions regarding quantity prescribed or dispensed

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



REGULATIONS

Pharmacy Board Regulations

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

64B16-27.831, F.A.C.

64B16-27.831 Standards of Practice for the Dispensing of Controlled Substances for Treatment of Pain.

(1) The Board of Pharmacy recognizes that principles of quality pharmacy practice dictate that the people of the State of Florida 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 pharmacies to view effective pain management as a part of quality pharmacy 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 pharmacists should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing and dispensing controlled substances.

(+) CRITERION 2:
Pain management is part of medical practice

(2) Inadequate pain control may result from pharmacists' 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. Pharmacists should not fear disciplinary action from the Board or other state regulatory or enforcement agencies for dispensing controlled substances for a legitimate medical purpose. 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 pharmacist uncertainty and to encourage better pain management.

(+) CRITERION 5:
Addresses fear of regulatory scrutiny

(+) CRITERION 4:
Encourages pain management

(3) The Board of Pharmacy is obligated under the laws of the State of Florida to protect the public health and safety. The Board recognizes that inappropriate dispensing of controlled substances 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.

(4) An order purporting to be a prescription issued not in the usual course of professional treatment nor in legitimate and authorized research is not a prescription and the pharmacist knowingly filling such a purported prescription shall be subject to penalties for violations of the law. The following criteria should cause a pharmacist to question whether a prescription was issued for a legitimate medical purpose: (1) Frequent loss of controlled substance medications, (2) Only controlled substance medications are prescribed for a patient, (3) One person presents controlled substance prescriptions with different patient names, (4) Same or similar controlled substance medication is prescribed by two or more prescribers at same time, (5) Patient always pays cash and always insists on brand name product. If any of these criteria is met, the pharmacist should insist that the person to whom medication is dispensed provide picture identification and the pharmacist should photocopy such picture identification for the pharmacist's records. If a photocopier is not available, the pharmacist should document on the back of the prescription complete descriptive information from the picture identification. If the person to whom medication is dispensed has no picture identification, the pharmacist should confirm the person's identity and document on the back of the prescription complete information on which the confirmation is based. The pharmacist should also verify the prescription with the prescriber. A pharmacist who believes a prescription for a controlled substance medication to be valid, but who has not been able to verify it with the prescriber, may determine that he or she is unable to supply the full quantity and may dispense a partial supply, not to exceed a 72 hour supply. After verification by the prescriber, the pharmacist may dispense the balance of the prescription within a 72 hour time period following the initial partial filling, unless otherwise prohibited by law.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



REGULATIONS

Pharmacy Board Regulations

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

[CONTINUED]

(5) Every pharmacy permit holder shall maintain a computerized record of controlled substance prescriptions dispensed. A hard copy printout summary of such record, covering the previous 60 day period, shall be made available within 72 hours following a request for it by any law enforcement personnel entitled to request such summary under authority of *Section 465.017(2), F.S.* Such summary shall include information from which it is possible to determine the volume and identity of controlled substance medications being dispensed under the prescription of a specific prescriber, and the volume and identity of controlled substance medications being dispensed to a specific patient.

(6) Any pharmacist who believes that a prescriber of controlled substances is involved in the diversion of controlled substances shall report such prescriber to the Department of Health.

(7) Any pharmacist that dispenses a controlled substance subject to the requirements of this rule when dispensed by mail shall be exempt from the requirements to obtain suitable identification.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



OTHER GOVERNMENTAL POLICY

Joint Board Policy Statement

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

The Florida Boards of Medicine, Nursing, Osteopathic Medicine, and Pharmacy recognize that principles of quality medical practice dictate that the people of the state of Florida 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; including non-treatment, under-treatment, over-treatment, and the continued use of ineffective treatments.

It is, therefore, incumbent upon Minnesota physicians, nurses and pharmacists to work cooperatively and effectively to address the dimensions of pain and to provide maximum pain relief with minimal side effects. Towards that end, and in the interest of public protection, the Minnesota Boards of Medical Practice, Nursing and Pharmacy issue the following joint statement.

To effectively assist patients in the management of pain, health care professionals should, within their scope of practice:

- Consistently and thoroughly assess all patients for pain. If pain is reported, the pain should be evaluated with a complete history and physical with laboratory and diagnostic testing, if indicated;
- Work collaboratively in a multi-disciplinary approach to develop and implement an individualized, written treatment plan utilizing pharmacologic and non-pharmacologic interventions with specific objectives for the patient;
- Regularly evaluate the effectiveness of the treatment plan, using a consistent, developmentally appropriate, standardized pain scale, and make adjustments as needed;
- Document all aspects of pain assessment and care in a timely, clear, consistent, complete and accurate manner;
- Anticipate and effectively manage side effects of pain medications;
- Provide adequate and culturally appropriate information to patients and family members or caregivers to support patients in making informed decisions and participate in the management of their pain;
- Be aware of the risks of diversion and abuse of controlled substances and take appropriate steps to minimize these risks;
- Recognize individuals with chemical dependency may experience pain requiring medications, including opioids, and may require specialized management;
- Consult with, and refer patients to, other providers when appropriate;
- Develop organization-appropriate and evidence-based policies and protocols for pain management;
- Become and remain knowledgeable regarding effective pain management; and
- Comply with all state and federal laws and regulations regarding prescribing, dispensing, and administering legend drugs, including controlled substances.

The Florida Boards of Medicine, Nursing, Osteopathic Medicine, and Pharmacy also recognize that concerns of drug diversion hinders quality medical practice and access to appropriate effective pain relief for the citizens of the state of Florida.

Towards that end and in the interest of public protection, the Florida Boards of Medicine, Osteopathic Medicine, Nursing and Pharmacy issue the following joint statement.

To effectively assist health care practitioners in the management of patient pain care and in order to effectively address prescription drug diversion the state of Florida must:

Develop a statewide electronic controlled substance prescription monitoring system that could be used by practitioners to assist them in treating patient pain as well as drug abuse.

(+) **CRITERION 4:**
Pain management is encouraged

(+) **CRITERION 2:**
Pain management is part of medical practice

(+) **CRITERION 8:**
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes a practitioner's responsibility to provide patients information about pain management and palliative care when considering treatment options.

(+) **CRITERION 8:**
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Identifies concerns of drug diversion as an important barrier to access to appropriate pain relief.

(+) **CRITERION 8:**
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.

(+) **CRITERION 8:**
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.

(+) **CRITERION 8:**
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Recognizes that a patient's prior history or current status of drug abuse does not contraindicate appropriate pain management.

(+) **CRITERION 8:**
Other provisions that may enhance pain management

CATEGORY C:
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.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



STATUTES

Civil Rights

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

(+) **CRITERION 8:**
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (standards and guidelines and continuing education) to provide practitioners information/education about pain management and palliative care.

Fla. Stat. § 765.102

§ 765.102. Legislative findings and intent

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(4) The Legislature recognizes the need for all health care professionals to rapidly increase their understanding of end-of-life and palliative care. Therefore, the Legislature encourages the professional regulatory boards to adopt appropriate standards and guidelines regarding end-of-life care and pain management and encourages educational institutions established to train health care professionals and allied health professionals to implement curricula to train such professionals to provide end-of-life care, including pain management and palliative care.

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REGULATIONS

Hospice Services

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

(+) **CRITERION 8:**
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

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

58A-2.014, F.A.C.

58A-2.014 Medical Direction.

(1) The hospice shall employ a medical director who shall be a hospice physician licensed in the State of Florida pursuant to Chapter 458 or 459, F.S., who has admission privileges at one or more hospitals commonly serving patients in that hospice's service area as defined in Rule 59C-1.0355, F.A.C. Duties shall be enumerated in a job description, including job qualifications, which shall be kept in an administrative file.

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(b) Duties of the medical director shall include:

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9. Establishing written protocols for symptom control, i.e., pain, nausea, vomiting, or other symptoms.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

GEORGIA

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
Title 16. Crimes and Offenses; Chapter 13. Controlled Substances
- MEDICAL PRACTICE ACT (*No provisions found*)
Title 43 Professions and Businesses; Chapter 34. Physicians, Acupuncture, Physician's Assistants, Cancer and Glaucoma Treatment, Respiratory Care, Clinical Perfusionists, and Orthotics and Prosthetics Practice; Article 2. Physicians
- PHARMACY PRACTICE ACT (*No provisions found*)
Title 26. Food, Drugs, and Cosmetics; Chapter 4. Pharmacists and Pharmacies
- INTRACTABLE PAIN TREATMENT ACT
No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*Part of Pharmacy Board Regulations*) (*No provisions found*)
Title 480. Georgia State Board of Pharmacy; Chapter 480-34. Controlled Substances
- MEDICAL BOARD REGULATIONS (*No provisions found*)
Title 360. Composite State Board of Medical Examiners
- PHARMACY BOARD REGULATIONS (*No provisions found*)
Title 480. Georgia State Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
Georgia Composite State Board of Medical Examiners. *Management of Prescribing with an Emphasis on Addictive or Dependency-Producing Drugs*. Adopted: 1991.

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

- HOSPICE SERVICES
Title 290. Department of Human Resources Office of Regulatory Services; Chapter 290-9-43 Rules and Regulations for Hospices



Provisions that may <i>ENHANCE</i> pain management								
Criteria	1	2	3	4	5	6	7	8
	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								
Controlled Substances ¹								
Medical Board ¹								
Pharmacy Board ¹								
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline						•		
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Hospice Services								•

Note: A dot indicates that one or more provisions were identified
¹ No provisions were found in this policy, ² No policy found

Provisions that may <i>IMPEDE</i> pain management								
Criteria	9	10	11	12	13	14	15	16
	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 ¹								
Pharmacy Board ¹								
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline	•		•	•				
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Hospice Services ¹								

Note: A dot indicates that one or more provisions were identified
¹ No provisions were found in this policy, ² No policy found



STATUTES

Controlled Substances Act

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

O.C.G.A. § 16-13-21

§ 16-13-21. Definitions

As used in this article, the term:

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(8) "Dependent," "dependency," "physical dependency," "psychological dependency," or "psychic dependency" means and includes the state of dependence by an individual toward or upon a substance, arising from the use of that substance, being characterized by behavioral and other responses which include the loss of self-control with respect to that substance, or a strong compulsion to use that substance on a continuous basis in order to experience some psychic effect resulting from the use of that substance by that individual, or to avoid any discomfort occurring when the individual does not use that substance.

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(23) "Practitioner" means:

(A) A physician, dentist, pharmacist, podiatrist, veterinarian, scientific investigator, or other person licensed, registered, or otherwise authorized under the laws of this state 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;

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(+) CRITERION 3:
Opioids are part of professional practice

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

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



OTHER GOVERNMENTAL POLICY

Medical Board Guideline

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

To All Doctors Licensed to Practice Medicine in Georgia:

MANAGEMENT OF PRESCRIBING WITH AN EMPHASIS ON ADDICTIVE OR DEPENDENCY-PRODUCING DRUGS

"The Composite State Board of Medical Examiners has adopted the following guidelines when evaluating the use of controlled substances for pain control. These guidelines are presented for information only for licensed practitioners. These guidelines are not absolutes and the Board reserves the right to exercise its authority in evaluating each case on its merit."

The Georgia Board of Medical Examiners is charged by law to protect the citizens of the State from harmful physician management. A significant number of physicians who are asked to appear before the Board are required to do so because of their lack of information about the management and responsibilities involved in prescribing controlled substances. Frequently, the inadvertent offender is a physician with a warm heart and a desire to relieve pain and misery, who is always pressed for time and finds himself prescribing controlled drugs on demand over prolonged periods without adequate documentation. These are often for chronic ailments such as headache, arthritis, old injuries, chronic orthopedic problems, backache and anxiety. (Terminal cancer pain management is not a consideration here.) The purpose of the Board of Medical Examiners in presenting the following information is to help licensed physicians in Georgia consider and reevaluate their prescribing practice of controlled substances. Practicing physicians who become new Board members have often mentioned the abrupt education they received in their own prescribing patterns. Moreover, there have been many requests to the Board from physicians for detailed information on prescribing in certain specific situations.

It's not what you prescribe, but how well you manage the patient's care and document that care in legible form, that's important.

The prescribing matters that come before the Board are almost always related to the prescription of controlled substances. We feel that a majority of instances where physicians have been disciplined by the Board for prescribing practices could have been avoided completely if they followed the steps that are being outlined here.

To prevent any misunderstanding, it's necessary to state what the Board does not have.

It does not have a list of "bad" or "disallowed" drugs. All formulary drugs are good if prescribed and administered when properly indicated. Conversely, all drugs are ineffective, dangerous, or even lethal when used inappropriately.

It does not have some magic formula for determining the dosage and duration of administration for any drug. These are aspects of prescribing that must be determined within the confines of the individual clinical case, and continued under proper monitoring. What's good for one patient may be insufficient or fatal for another.

What the Board does have is the expectation that physicians will create a record that shows:

- Proper indication for the use of drug or other therapy
- Monitoring of the patient where necessary
- The patient's response to therapy on follow-up visits
- All rationale for continuing or modifying the therapy

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(+) **CRITERION 6:**
*Prescription amount
alone does not
determine legitimacy*

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



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]

STEP ONE

First and foremost, before you prescribe anything, start with a diagnosis which is supported by history and physical findings, and by the results of any appropriate tests. Too many times a doctor is asked why he or she prescribed a particular drug, and the response is, "Because the patient has arthritis." Then the doctor is asked, "How did you determine that?", and the answer is "Because that's what the patient complained of." Nothing in the record or in the doctor's recollection supports the diagnosis except the patient's assertion. Do a workup sufficient to support a diagnosis, including all necessary tests.

STEP TWO

Create a treatment plan which includes the use of appropriate non-addictive modalities, and make referrals to appropriate specialists, such as neurologists, orthopedists, psychiatrists, etc. The results of the referral should be included in the patient's chart.

STEP THREE

Before beginning a regimen of controlled drugs, make a determination through trial or through a documented history that non-addictive modalities aren't appropriate or they don't work. A finding of intolerance or allergy to Non Steroidal Anti Inflammatory Drugs is one thing, but the assertion of the patient that, "Gosh, doc, nothing seems to work like that Percodan stuff!" is quite another. Too many of the doctors the Board has seen have started a treatment program with powerful controlled substances without ever considering other forms of treatment.

(-) **CRITERION 9:**
Opioids are a last resort

STEP FOUR

Make sure you are not dealing with a drug-seeking patient. If you know the patient, review the prescription records in the patient's chart and discuss the patient's chemical history before prescribing a controlled drug. If the patient is new or otherwise unknown to you, at a minimum obtain an oral drug history, and discuss chemical use and family chemical history with the patient.

STEP FIVE

It's a good idea to obtain the informed consent of the patient before using a drug that has the potential to cause dependency problems. Take the time to explain the relative risks and benefits of the drug and record in the chart the fact that this was done. When embarking on what appears to be the long term use of a potentially addictive substance, it may be wise to hold a family conference and explain the relative risks of dependency or addiction and what that may mean to the patient and to the patient's family.

Refusal of the patient to permit a family conference may be significant information.

STEP SIX

Maintain regular monitoring of the patient, including frequent physical monitoring. If the regimen is for prolonged drug use, it is very important to monitor the patient for the road condition which necessitates the drug, and for the side effects of the drug itself. This is true no matter what type of controlled substance is used or what schedule it belongs to. Also, remember that with certain conditions, drug holidays are appropriate. This allows you to check to see whether the original symptoms recur when the drug is not given - indicating a continuing legitimate need for the drug or whether withdrawal symptoms occur - indicating drug dependence.

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

(-) **CRITERION 12:**
Medical decisions are restricted

CATEGORY D:
Undue prescription limitations

COMMENT: "Drug holidays" are no longer recognized as appropriate medical practice.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



OTHER GOVERNMENTAL POLICY

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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STEP SEVEN

Make sure YOU are in control of the supply of the drug. To do this, at a minimum you must keep detailed records of the type, dose, and amount of the drug prescribed. You must also monitor, record and personally control all refills. Do not authorize your office personnel to refill prescriptions without consulting you. One good way to accomplish this is to require the patient to return to obtain refill authorization, at least part of the time. Records of cumulative dosage and average daily dosage are especially valuable. A thumbnail sketch of three cases will illustrate our point here. In the first case, a physician prescribed Tussionex to a patient for approximately five years for a cumulative dosage of nineteen and one half gallons. In the second case, a physician prescribed Tylenol 3's to a patient for slightly more than a year at the average rate of 30 per day! The third case is very similar, except it was Tylenol 4's at the rate of 20 per day. Some quick observations:

-No physician who was aware of that kind of prescribing would have continued with it.

-Few, if any patients could have been consuming that much Tylenol with codeine. In all likelihood, they were selling it.

Another important part of controlling the supply of drugs is to check on whether the patient is obtaining drugs from other physicians. Checking with pharmacies and pharmacy chains may tell whether a patient is obtaining extra drugs or is doctor shopping. It is a felony in Georgia for a patient to fail to disclose to his physician that he has received controlled substances of a similar therapeutic use from another practitioner at the same time. If you are aware of this occurring, contact your local police, the State Drugs and Narcotics Agency or the Board of Medical Examiners.

STEP EIGHT

Maintaining regular contact with the patient's family is a valuable source of information on the patient's response to the therapy regimen, and may be much more accurate and objective than feedback from the patient alone.

The family is a much better source of information on behavioral changes, especially dysfunctional behavior, than is the patient. Dysfunctional changes may be observable when the patient is taking the drug, or when the drug is withdrawn. These changes, at either time, may be symptoms of the dependency or addiction.

The family is also a good source of information on whether the patient is obtaining drugs from other sources, or is self-medicating with other drugs or alcohol.

STEP NINE

To reiterate, one of the most frequent problems faced by a physician when he or she comes before the Board or other outside review bodies is inadequate records. It's entirely possible that the doctor did everything correctly in managing a case, but without records which reflect all the steps that went into the process, the job of demonstrating it to any outside reviewer becomes many times more difficult. Luckily, this is a problem which is solvable.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



REGULATIONS

Hospice Services

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

Ga. Comp. R. & Regs. r. 290-9-43-.09

290-9-43-.09 Quality Management.

(1) The hospice shall appoint a multidisciplinary quality management committee that reflects the hospice's scope of services. The committee shall develop and implement a comprehensive and ongoing quality management, utilization, and peer review program that evaluates the quality and appropriateness of patient care provided, including the appropriateness of the level of service received by patients, and submits required patient incident reports to the Department.

(2) The quality management, utilization, and peer review program shall establish and use written criteria as the basis to evaluate the provision of patient care. The written criteria shall be based on accepted standards of care and shall include, at a minimum, systematic reviews of:

- (a) Appropriateness of admissions, continued stay, and discharge;
- (b) Appropriateness of professional services and level of care provided;
- (c) Effectiveness of pain control and symptom relief;

(+) **CRITERION 8:**
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

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

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

HAWAII

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
Division 1. Government; Title 19. Health; Chapter 329. Uniform Controlled Substances Act
- MEDICAL PRACTICE ACT
Title 25. Professions and Occupations; Chapter 453. Medicine and Surgery
- OSTEOPATHIC PRACTICE ACT
Title 25. Professions and Occupations; Chapter 460. Osteopathy
- PHARMACY PRACTICE ACT (*No provisions found*)
Title 25. Professions and Occupations; Chapter 461. Pharmacists and Pharmacy
- PAIN PATIENT'S BILL OF RIGHTS
Division 1. Government; Title 19. Health; Chapter 327H Pain Patient's Bill of Rights
- INTRACTABLE PAIN TREATMENT ACT
No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
Title 23. Department of Public Safety; Subtitle 3. Law Enforcement; Chapter 200. Regulation of Controlled Substances
- MEDICAL BOARD REGULATIONS (*No provisions found*)
Title 16. Department of Commerce and Consumer Affairs; Chapter 85. Medical Examiners
- OSTEOPATHIC BOARD REGULATIONS (*No provisions found*)
Title 16. Department of Commerce and Consumer Affairs; Chapter 93. Osteopaths
- PHARMACY BOARD REGULATIONS (*No provisions found*)
Title 16. Department of Commerce and Consumer Affairs; Chapter 95. Pharmacists and Pharmacies

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
Hawaii Board of Medical Examiners. *Hawaii Board of Medical Examiners Pain Management Guidelines*. Adopted: January, 2006.

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

No policies found



Provisions that may <i>ENHANCE</i> pain management								
Criteria	1	2	3	4	5	6	7	8
	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								•
Osteopathic Practice Act								•
Pharmacy Practice Act ¹								
Pain Patient's Bill of Rights		•		•				•
Intractable Pain Treatment Act ²								
REGULATIONS								
Controlled Substances			•					
Medical Board ¹								
Osteopathic Board ¹								
Pharmacy Board ¹								
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline		•	•	•		•	•	•
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES²								

Note: A dot indicates that one or more provisions were identified
¹ No provisions were found in this policy, ² No policy found

Provisions that may <i>IMPEDE</i> pain management								
Criteria	9	10	11	12	13	14	15	16
	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								
Pain Patient's Bill of Rights								•
Intractable Pain Treatment Act ²								
REGULATIONS								
Controlled Substances					•			
Medical Board ¹								
Osteopathic Board ¹								
Pharmacy Board ¹								
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline ¹								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES²								

Note: A dot indicates that one or more provisions were identified
¹ No provisions were found in this policy, ² No policy found



STATUTES

Controlled Substances Act

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

HRS § 329-1

§ 329-1. Definitions.

As used in this chapter:

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"Practitioner" means:

(1) A physician, dentist, veterinarian, scientific investigator, or other person licensed and registered under section 329-32 to distribute, dispense, or conduct research with respect to a controlled substance in the course of professional practice or research in this State.

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HRS § 329-40

§ 329-40. Methadone treatment programs

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The term "narcotic-dependent person" as used in this section means an individual who physiologically needs heroin or a morphine-like drug to prevent the onset of signs of withdrawal.

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(+) **CRITERION 3:**
Opioids are part of professional practice

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

STATUTES

Medical Practice Act

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

HRS § 453-1.5

453-1.5. Pain management guidelines.

The board of medical examiners may establish guidelines for physicians with respect to patients' pain management. The guidelines shall apply to all patients with severe acute pain or severe chronic pain, regardless of the patient's prior or current chemical dependency or addiction, and may include standards and procedures for chemically dependent individuals.

(+) **CRITERION 8:**
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

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

(+) **CRITERION 8:**
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Recognizes that a patient's prior history or current status of drug abuse does not contraindicate appropriate pain management.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



STATUTES

Osteopathic Practice Act

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

(+) **CRITERION 8:**
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

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

HRS § 460-1.35
[460-1.35.] Pain management guidelines.

The board of medical examiners may establish guidelines for osteopathic physicians with respect to patients' pain management. The guidelines shall apply to all patients with severe acute pain or severe chronic pain, regardless of the patient's prior or current chemical dependency or addiction, and may include standards and procedures for chemically dependent individuals.

(+) **CRITERION 8:**
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Recognizes that a patient's prior history or current status of drug abuse does not contraindicate appropriate pain management.

STATUTES

Pain Patient's Bill of Rights

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

(+) **CRITERION 2:**
Pain management is part of medical practice

(+) **CRITERION 4:**
Encourages pain management

(+) **CRITERION 8:**
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.

HRS prec § 327H-1 – § 327H-2

[§ 327H-1.] Pain patient's bill of rights; findings.

The legislature finds that:

(1) Inadequate treatment of severe acute pain and severe chronic pain originating from cancer or noncancerous conditions is a significant health problem;

(2) For some patients, pain management is the single most important treatment a physician can provide;

(3) A patient who suffers from severe acute pain or severe chronic pain should have access to proper treatment of pain;

(4) Due to the complexity of their problems, many patients who suffer from severe acute pain or severe chronic pain may require referral to a physician with expertise in the treatment of severe acute pain and severe chronic pain. In some cases, severe acute pain and severe chronic pain is best treated by a team of clinicians to address the associated physical, psychological, social, and vocational issues;

(5) In the hands of knowledgeable, ethical, and experienced pain management practitioners, opiates administered for severe acute pain or severe chronic pain can be safe; and

(6) Opiates may be part of an overall treatment plan for a patient in severe acute pain or severe chronic pain who has not obtained relief from any other means of treatment.

[CONTINUED ON NEXT PAGE]

(+) **CRITERION 8:**
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.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



STATUTES

Pain Patient's Bill of Rights

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

[CONTINUED]

[§ 327H-2.] Bill of rights.

The pain patient's bill of rights includes the following:

(1) A patient who suffers from severe acute pain or severe chronic pain has the option to request or reject the use of any or all modalities to relieve the pain:

(2) A patient who suffers from severe acute pain or severe chronic pain has the option to choose from appropriate pharmacologic treatment options to relieve severe acute pain or severe chronic pain, including opiate medications, without first having to submit to an invasive medical procedure.

For purposes of this paragraph, "invasive medical procedure" means surgery, destruction of a nerve or other body tissue by manipulation, or the implantation of a drug delivery system or device;

(3) A patient's physician may refuse to prescribe opiate medication for a patient who requests a treatment for severe acute pain or severe chronic pain. However, that physician may inform the patient of physicians who are qualified to treat severe acute pain and severe chronic pain employing methods that include the use of opiates;

(4) A physician who uses opiate therapy to relieve severe acute pain or severe chronic pain may prescribe a dosage deemed medically necessary to relieve the pain;

(5) A patient may voluntarily request that the patient's physician provide an identifying notice of the prescription for purposes of emergency treatment or law enforcement identification; and

(6) Nothing in this section shall be construed to:

(A) Expand the authorized scope of practice of any licensed physician;

(B) Limit any reporting or disciplinary provisions applicable to licensed physicians and surgeons who violate prescribing practices; and

(C) Prohibit the discipline or prosecution of a licensed physician for:

(i) Failing to maintain complete, accurate, and current records that document the physical examination and medical history of a patient, the basis for the clinical diagnosis of a patient, and the treatment plan for a patient;

(ii) Writing false or fictitious prescriptions for controlled substances scheduled in the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. 801 et seq. or in chapter 329;

(iii) Prescribing, administering, or dispensing pharmaceuticals in violation of the provisions of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. 801 et seq. or of chapter 329;

(iv) Diverting medications prescribed for a patient to the licensed physician's own personal use; and

(v) Causing, or assisting in causing, the suicide, euthanasia, or mercy killing of any individual: provided that it is not "causing, or assisting in causing, the suicide, euthanasia, or mercy killing of any individual" to prescribe, dispense, or administer medical treatment for the purpose of treating severe acute pain or severe chronic pain, even if the medical treatment may increase the risk of death, so long as the medical treatment is not also furnished for the purpose of causing, or the purpose of assisting in causing, death for any reason.

(+) **CRITERION 8:**
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

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

(-) **CRITERION 16:**
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: Allowing a physician to refuse to prescribe opioid medications would appear to conflict with the criteria that recognize that opioids are necessary for public health and are a part of medical practice. Furthermore, how does this qualify as a "Pain Patient's Bill of Rights" if a physician may refuse to provide opioid analgesics to a patient in severe pain? Without commenting on the concept of patients' bills of rights, this language would fall short of providing any rights and thus may establish a false expectation for adequate pain management

(+) **CRITERION 8:**
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 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.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



REGULATIONS

Controlled Substances Regulations

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

WCHR 23-200

23-200. REGULATION OF CONTROLLED SUBSTANCES

§ 23-200-2 Definitions. The following definitions shall apply in the interpretation and enforcement of this chapter:

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"Practitioner" means:

(1) A physician, dentist, veterinarian, scientific investigator, or other person licensed and registered under *section 329-32, Hawaii Revised Statutes*, to distribute, dispense, prescribe or conduct research with respect to a controlled substance in the course of professional practice or research in this State but does not include midlevel practitioners.

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§ 23-200-15 Prescriptions.

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(2) No prescription for a schedule II controlled substance shall be filled later than the third day following the day of issuance;

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(+) **CRITERION 3:**
Opioids are part of professional practice



(-) **CRITERION 13:**
Length of prescription validity is restricted



Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



OTHER GOVERNMENTAL POLICY

Medical Board Guideline

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

Pursuant to section 453-1.5, Hawaii Revised Statutes, the Board of Medical Examiners ("Board") has established guidelines for physicians with respect to the care and treatment of patients with severe acute pain or severe chronic pain. These pain management guidelines are considerations that the Board will take into account in the proper treatment of pain.

**HAWAII BOARD OF MEDICAL EXAMINERS
PAIN MANAGEMENT GUIDELINES**

Section I: Introduction

The Board of Medical Examiners ("Board") recognizes that principles of quality medical practice dictate that the people of the State of Hawaii have access to appropriate and effective pain relief. The Board affirms that controlled substances may be necessary to relieve pain, and the medical use of opioid analgesics is recognized to be part of legitimate medical practice.

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. The Board believes that all physicians who treat patients directly should have sufficient knowledge about pain and its management to provide comfort for those in pain, or utilize consultations when possible to obtain necessary information to make treatment decisions for their patients. Accordingly, this policy has been developed to clarify the Board's position on pain management, particularly as related to the use of controlled substances.

The Board is obligated under the laws of the State of Hawaii to protect the public health and safety. The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes poses 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. The Board considers acceptable the ordering, prescribing, dispensing or administration of controlled substances, including opioid analgesics, for a legitimate medical purpose to be acceptable particularly in the case of terminal illness. The Board considers the use of controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. 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.

The Board will consider the inappropriate treatment of pain to be a departure from standards of practice and therefore investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate to the diagnosis.

Section II: Evaluation of Physician Practice

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 a case-by-case basis. Deviation from this policy may be appropriate when contemporaneous medical records document reasonable cause for deviation.

In determining whether the physician has acted appropriately, the Board will consider the clinical outcome, whether drugs used are appropriate for the type of pain, and whether there is improvement in patient functioning and/or quality of life as factors.

[CONTINUED ON NEXT PAGE]

(+) **CRITERION 4:**
Encourages pain management

(+) **CRITERION 2:**
Pain management is part of medical practice

(+) **CRITERION 6:**
Prescription amount alone does not determine legitimacy

(+) **CRITERION 3:**
Opioids are part of professional practice

(+) **CRITERION 8:**
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.

(+) **CRITERION 8:**
Other provisions that may enhance pain management

CATEGORY A:
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.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



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]

Section III: Practice Guidelines for Chronic Pain Management

Evaluation of the Patient – A medical history and physical examination should be performed 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 or other compulsive behaviors.

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. The treatment plan should be adjusted and documented according to the individual needs of each patient.

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. The patient's pain medication should be managed by 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 have written treatment agreements outlining the patient's responsibilities during treatment and should obtain informed consent before prescriptions are provided.

The treatment agreements may specify many of the following items:

- Urine or blood samples will be provided by patients upon request for urine/serum drugs of abuse screening and/or determining medication levels by their physicians;
- The number and frequency of all prescription refills may be limited at their physicians' discretion;
- Therapy with controlled substances may be discontinued by physicians under certain situations (e.g. significant violation of treatment agreements by patients);
- Physician/patient relationships may be discontinued under certain situations (e.g. violation of treatment agreements by patients);
- Medication refills will be provided under specified rules, within mutually agreed upon time-frames (e.g. early refills may not be allowed, lost medications may not be replaced, refills may only occur during regular business hours, etc.);
- All therapies may be provided on a time-limited basis to determine potential effectiveness, and may be discontinued if judged ineffective or unacceptably toxic;
- Referral of patients to substance abuse treatment programs will occur when use of controlled substances is determined to be due to underlying addiction and not pain.

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.

Use of consultation with pain management specialists, addiction medicine specialists, and other medical specialties is encouraged. Physicians should be willing to refer their patients as necessary for additional evaluations and therapies to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse, abuse or diversion.

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Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

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]

Medical Records – The physician should keep accurate, current and complete medical records. Elements considered for completeness may include, but are not limited to the following:

1. An initial medical history and physical examination;
3. Diagnostic imaging, therapeutic and laboratory results;
4. Ongoing evaluations and consultations;
5. Establishment of treatment objectives;
6. Discussion and documentation of risks, benefits and alternatives;
7. Results of treatment(s) provided (changes in pain intensity and character, interference with activities of daily living), and management of side effects;
8. Intended use of medications (information about date, name of medication, dosage, quantity prescribed with instructions);
9. Treatment instructions and agreements provided; and
10. Evidence of ongoing periodic review process with treatment modification if necessary.

Compliance With Controlled Substances Laws and Rules – To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state laws and rules.

Section IV: Definitions (as taken from the Federation of State Medical Boards)

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

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

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

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.

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.

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.

Tolerance - Tolerance is a physiological 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.

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.

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

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

IDAHO

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
General Laws; Title 37. Food, Drugs, and Oil; Chapter 27. Uniform Controlled Substances
- MEDICAL PRACTICE ACT (*No provisions found*)
General Laws; Title 54. Professions, Vocations and Businesses; Chapter 18. Physicians and Surgeons; Medical Practice Act
- PHARMACY PRACTICE ACT
General Laws; Title 54. Professions, Vocations and Businesses; Chapter 17. Pharmacists
- INTRACTABLE PAIN TREATMENT ACT
No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
No policy found
- MEDICAL BOARD REGULATIONS (*No provisions found*)
IDAPA 22: Board of Medicine
- PHARMACY BOARD REGULATIONS
IDAPA 27: Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
Idaho State Board of Medicine. *Policy for the Use of Controlled Substances for the Treatment of Pain*. Adopted: August 26, 2005.

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

No policies found



Provisions that may <i>ENHANCE</i> pain management								
Criteria	1	2	3	4	5	6	7	8
	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								
Controlled Substances ¹								
Medical Board ¹								
Pharmacy Board			•					
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline		•	•	•	•	•	•	•
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES²								

Note: A dot indicates that one or more provisions were identified
¹ No provisions were found in this policy, ² No policy found

Provisions that may <i>IMPEDE</i> pain management								
Criteria	9	10	11	12	13	14	15	16
	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 ¹								
Pharmacy Board			•					
OTHER GOVERNMENTAL POLICIES								
Medical Board Guideline ¹								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES²								

Note: A dot indicates that one or more provisions were identified
¹ No provisions were found in this policy, ² No policy found



STATUTES

Controlled Substances Act

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

Idaho Code § 37-2701

§ 37-2701. Definitions

As used in this act:

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(z) "Practitioner" means:

(1) A physician, dentist, veterinarian, scientific investigator, 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 his professional practice or research in this state;

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(+) CRITERION 3:
Opioids are part of professional practice

STATUTES

Pharmacy Practice Act

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

Idaho Code § 54-1705

§ 54-1705. Definitions

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(24) "Practitioner" shall mean a physician, dentist, veterinarian, scientific investigator or other person (other than a pharmacist) licensed in this state and permitted by such license to dispense, conduct research with respect to or administer drugs in the course of professional practice or research in this state.

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(+) CRITERION 3:
Opioids are part of professional practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



REGULATIONS

Pharmacy Board Regulations

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

ID BReg 432.

Definitions: A -- G.

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09. Drug Dependent Person. The term "Drug Dependent Person" means a person who is using a controlled substance (as defined in Section 37-2720, Idaho Code) and who is in a state of psychic or physical dependence, or both, arising from the use of that substance on a continuous basis.

10. Drug Dependence. Drug dependence is defined as 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 caused by its absence.

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IDAPA 27.01.01.433

433. DEFINITIONS - (H -- Z).

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02. Individual Practitioner. The term "individual practitioner" means a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted, by the state in which he practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.

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

(+) CRITERION 3:
Opioids are part of professional practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



OTHER GOVERNMENTAL POLICY

Medical Board Guideline

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

Idaho State Board of Medicine
Policy for the Use of Controlled Substances for the Treatment of Pain

Section I: Preamble

The Idaho State Board of Medicine recognizes that principles of quality medical practice dictate that the people of the State of Idaho 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, under treatment, over treatment, 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 has 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 Idaho State Board of Medicine is obligated under the laws of the State of Idaho to protect the public health and safety. The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes poses 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.

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.

[CONTINUED ON NEXT PAGE]

(+) CRITERION 8:
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.

(+) CRITERION 2:
Pain management is part of medical practice

(+) CRITERION 4:
Encourages pain management

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

(+) CRITERION 5:
Addresses fear of regulatory scrutiny

(+) CRITERION 3:
Opioids are part of professional practice

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



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]

(+) **CRITERION 6:**
Prescription amount alone does not determine legitimacy

(+) **CRITERION 8:**
Other provisions that may enhance pain management

CATEGORY A:
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.

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.

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

- urine/serum medication levels screening when requested;
- 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.

[CONTINUED ON NEXT PAGE]

(+) **CRITERION 8:**
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.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



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]

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,
2. diagnostic, therapeutic and laboratory results,
3. evaluations and consultations,
4. treatment objectives,
5. discussion of risks and benefits,
6. informed consent,
7. treatments,
8. 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.

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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]

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.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.

ILLINOIS

Citations for Policies Evaluated

STATUTES

- CONTROLLED SUBSTANCES ACT
Chapter 720. Criminal Offenses; Crimes Against the Public; Illinois Controlled Substances Act
- MEDICAL PRACTICE ACT (*No provisions found*)
Chapter 225. Professions and Occupations; Health; Medical Practice Act of 1987
- PHARMACY PRACTICE ACT (*No provisions found*)
Chapter 225. Professions and Occupations; Health; Pharmacy Practice Act of 1987
- INTRACTABLE PAIN TREATMENT ACT
No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
Title 77. Public Health; Chapter XV. Department of Professional Regulation; Part 3100. Illinois Controlled Substances Act
- MEDICAL BOARD REGULATIONS (*No provisions found*)
Title 68. Professions and Occupations; Chapter VII. Department of Financial and Professional Regulation; Subchapter b. Professions and Occupations; Part 1285. Medical Practice Act of 1987
- PHARMACY BOARD REGULATIONS (*No provisions found*)
Title 68. Professions and Occupations; Chapter VII. Department of Financial and Professional Regulation; Subchapter b. Professions and Occupations; Part 1330. Pharmacy Practice Act of 1987

OTHER GOVERNMENTAL POLICIES

No policies found

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

- HOSPICE SERVICES
Title 77. Public Health; Chapter I. Department of Public Health; Subchapter b. Hospitals and Ambulatory Care Facilities; Part 280. Hospice Programs; Subpart B. Hospice Services

Note: Illinois Controlled Substances Regulations continue to reference the triplicate prescription program that was repealed in 2000; although not considered a barrier to practice, efforts should be made to remove from state law all references to this vestigial policy.



Provisions that may <i>ENHANCE</i> pain management								
Criteria	1	2	3	4	5	6	7	8
	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								
Controlled Substances			•					
Medical Board ¹								
Pharmacy Board ¹								
OTHER GOVERNMENTAL POLICIES²								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Hospice Services								•

Note: A dot indicates that one or more provisions were identified
¹ No provisions were found in this policy, ² No policy found

Provisions that may <i>IMPEDE</i> pain management								
Criteria	9	10	11	12	13	14	15	16
	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								
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REGULATIONS								
Controlled Substances ¹								
Medical Board ¹								
Pharmacy Board ¹								
OTHER GOVERNMENTAL POLICIES²								
RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES								
Hospice Services ¹								

Note: A dot indicates that one or more provisions were identified
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STATUTES

Controlled Substances Act

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

720 ILCS 570/102

§ 720 ILCS 570/102. Definitions

Sec. 102. Definitions. As used in this Act, unless the context otherwise requires:

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(kk) "Practitioner" means a physician licensed to practice medicine in all its branches, dentist, podiatrist, veterinarian, scientific investigator, pharmacist, physician assistant, advanced practice nurse, licensed practical nurse, registered nurse, hospital, laboratory, or pharmacy, or other person licensed, registered, or otherwise lawfully permitted by the United States or this State to distribute, dispense, conduct research with respect to, administer or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

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720 ILCS 570/312

§ 720 ILCS 570/312. Requirements for dispensing controlled substances

Sec. 312. Requirements for dispensing controlled substances. (a) A practitioner, in good faith, may dispense a Schedule II controlled substance, which is a narcotic drug listed in Section 206 of this Act [720 ILCS 570/206]; or which contains any quantity of amphetamine or methamphetamine, their salts, optical isomers or salts of optical isomers; phenmetrazine and its salts; pentazocine; or which is hereafter determined to be a "designated product," as defined in Section 102 of this Act [720 ILCS 570/102] and Schedule III, IV, or V controlled substances to any person upon a written prescription of any prescriber, dated and signed by the person prescribing on the day when issued and bearing the name and address of the patient for whom, or the owner of the animal for which the controlled substance is dispensed, and the full name, address and registry number under the laws of the United States relating to controlled substances of the prescriber, if he is required by those laws to be registered. If the prescription is for an animal it shall state the species of animal for which it is ordered. The practitioner filling the prescription shall write the date of filling and his own signature on the face of the written prescription. The written prescription shall be retained on file by the practitioner who filled it or pharmacy in which the prescription was filled for a period of 2 years, so as to be readily accessible for inspection or removal by any officer or employee engaged in the enforcement of this Act. Whenever the practitioner's or pharmacy's copy of any prescription is removed by an officer or employee engaged in the enforcement of this Act, for the purpose of investigation or as evidence, such officer or employee shall give to the practitioner or pharmacy a receipt in lieu thereof. A prescription form for a Schedule II controlled substance shall not be filled more than 7 days after the date of issuance. A written prescription for Schedule III, IV or V controlled substances shall not be filled or refilled more than 6 months after the date thereof or refilled more than 5 times unless renewed, in writing, by the prescriber.

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(+) **CRITERION 3:**
Opioids are part of professional practice

(-) **CRITERION 13:**
Length of prescription validity is restricted

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.



REGULATIONS

Controlled Substances Regulations

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

77 Ill. Adm. Code 3100.400

§ 3100.400 Requirement of Prescription.

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b) An individual practitioner may administer or dispense directly a controlled substance listed in Schedule II in the course of his professional practice subject to the Act and this Part.

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(+) **CRITERION 3:**
Opioids are part of professional practice

REGULATIONS

Hospice Services

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

77 Ill. Adm. Code 280.2070

§ 280.2070 Medical Director and Physician Services

a) Each full hospice program shall have a medical director who shall be a physician licensed to practice medicine in all of its branches. (Section 8(d) of the Act) In his/her absence the medical director shall designate another physician to serve as hospice physician designee.

b) The medical director shall have overall responsibility for medical direction of the care and treatment of patients and their families rendered by the hospice care team, and shall consult and cooperate with the patient's attending physician. (Section 8(d) of the Act)

c) Duties of the medical director shall include but not be limited to:

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9) Establishing written guidelines for symptom control, i.e., pain, nausea, vomiting, or other symptoms.

(+) **CRITERION 8:**
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

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

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.