NEW YORK

STATUTES

- CONTROLLED SUBSTANCES ACT
  Public Health Law
  Article 2-A. Prescription Drugs
  Article 33. Controlled Substances

- MEDICAL PRACTICE ACT
  Education Law; Title VIII. The Professions; Article 131. Medicine

- PHARMACY PRACTICE ACT (*No provisions found*)
  Education Law; Title VIII. The Professions; Article 137. Pharmacy

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Title 10. Department of Health; Chapter II. Administrative Rules and Regulations; Subchapter K. Controlled Substances; Part 80. Rules and Regulations on Controlled Substances

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Title 8. Education Department; Chapter II. Regulations of the Commissioner; Subchapter B. Regulation of Professions; Part 60. Medicine, Physician Assistant, Specialist Assistant and Acupuncture

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Title 8. Education Department; Chapter II. Regulations of the Commissioner; Subchapter B. Regulation of Professions; Part 63. Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD POLICY STATEMENT
  Board of Professional Medical Conduct. *Pain Management: A Guide for Physicians.* Approved: August, 2007.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- FACILITIES
  Unconsolidated Laws; Public Health; Chapter 214-A. New York City Health and Hospitals Corporation

- HOSPITALS
  Public Health Law; Article 28. Hospitals

- HEALTH INFORMATION
  Public Health Law; Article 29-D. Health Information and Quality Improvement; Title 1. Health Information

- NURSING HOME STANDARDS
  Title 10. Department of Health; Chapter V. Medical Facilities; Subchapter A. Medical Facilities – Minimum Standards; Article 3. Residential Care Facilities

- HOSPICE OPERATION
  Title 10. Department of Health; Chapter V. Medical Facilities; Subchapter C. State Hospital Code; Article 9. Hospice Operation

- OPIOID TREATMENT PROGRAMS
  Title 14. Department of Mental Hygiene; Chapter XXI. Office of Alcoholism and Substance Abuse Services; Part 822. Chemical Dependence Outpatient Services; Subpart 822-5. Opioid Treatment Programs (OTP)

NEW YORK

STATUTES

Controlled Substances Act

(+) *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.

NY CLS Pub Health § 3300-a

§ 3300-a. Legislative purposes

The purposes of this article are:

1. to combat illegal use of and trade in controlled substances; and

2. to allow legitimate use of controlled substances in health care, including palliative care; veterinary care; research and other uses authorized by this article or other law; under appropriate regulation and subject to this article, title eight of the education law, and other applicable law.

NY CLS Pub Health § 3302

§ 3302. Definitions of terms of general use in this article

Except where different meanings are expressly specified in subsequent provisions of this article, the following terms have the following meanings:

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29. "Practitioner" means:
A physician, dentist, podiatrist, veterinarian, scientific investigator, or other person licensed, or otherwise permitted to dispense, administer or conduct research with respect to a controlled substance in the course of a licensed professional practice or research licensed pursuant to this article. Such person shall be deemed a "practitioner" only as to such substances, or conduct relating to such substances, as is permitted by his license, permit or otherwise permitted by law.

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

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NY CLS Pub Health § 3309-a

§ 3309-a. Prescription pain medication awareness program

1. There is hereby established within the department a prescription pain medication awareness program to educate the public and health care practitioners about the risks associated with prescribing and taking controlled substance pain medications.

2. Within the amounts appropriated, the commissioner, in consultation with the commissioner of the office of alcoholism and substance abuse services, shall:

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(b) Establish a work group, no later than June first, two thousand twelve, which shall be composed of experts in the fields of palliative and chronic care pain management and addiction medicine. Members of the work group shall receive no compensation for their services, but shall be allowed actual and necessary expenses in the performance of their duties pursuant to this section. The work group shall:

(i) Report to the commissioner regarding the development of recommendations and model courses for continuing medical education, refresher courses and other training materials for licensed health care professionals on appropriate use of prescription pain medication. Such recommendations, model courses and other training materials shall be submitted to the commissioner, who shall make such information available for the use in medical education, residency programs, fellowship programs, and for use in continuing medication education programs no later than January first, two thousand thirteen. Such recommendations also shall include recommendations on: (A) educational and continuing medical education requirements for practitioners appropriate to address prescription pain medication awareness among health care professionals; (B) continuing education requirements for pharmacists related to prescription pain medication awareness; and (C) continuing education in palliative care as it relates to pain management, for which purpose the work group shall consult the New York state palliative care education and training council;

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (recommendations for continuing education) to ensure that pain management is an essential part of patient palliative care.

2013

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

NEW YORK

STATUTES

Controlled Substances Act

NY CLS Pub Health § 3332

§ 3332. Making of official New York state prescriptions for scheduled substances

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3. No such prescription shall be made for a quantity of controlled substances which would exceed a thirty day supply if the controlled substance were used in accordance with the directions for use specified on the prescription. A practitioner may, however, issue a prescription for up to a three month supply of a controlled substance provided that the controlled substance has been prescribed to treat one of the conditions that have been enumerated by the commissioner pursuant to regulations as warranting the prescribing of greater than a thirty day supply of a controlled substance and that the practitioner specifies the condition on the face of the prescription. No additional prescriptions for a controlled substance may be issued by a practitioner to an ultimate user within thirty days of the date of any prescription previously issued unless and until the ultimate user has exhausted all but a seven day supply of the controlled substance provided by any previously issued prescription. A practitioner may, however, issue a prescription for up to a six month supply of any substance listed in subdivision (h) [fig 1] of Schedule II of section three thousand three hundred six of this article provided that such substance has been prescribed to treat one of the conditions that have been enumerated by the commissioner pursuant to regulations as warranting the prescribing of a six month supply and that the practitioner specifies the condition on the face of the prescription.

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NY CLS Pub Health § 3333

§ 3333. Dispensing upon official New York state prescription or electronic prescription

1. A licensed pharmacist may, in good faith and in the course of his or her professional practice, sell and dispense to an ultimate user controlled substances only upon the delivery of an official New York state prescription ***or the receipt of an electronic prescription*** to such pharmacist, within thirty days of the date such prescription was signed by an authorized practitioner; provided, however, a pharmacist may dispense a part or portion of such prescription in accordance with regulations of the commissioner in consultation with the commissioner of education. No pharmacy or pharmacist may sell or dispense greater than a thirty day supply of a controlled substance to an ultimate user unless and until the ultimate user has exhausted all but a seven day supply of the controlled substance provided pursuant to any previously issued prescription, except that a pharmacy or pharmacist may sell or dispense up to a three month supply of a controlled substance if there appears, on [fig 1] the official New York state prescription ***or electronic prescription*** , a statement that the controlled substance has been prescribed to treat one of the conditions that have been enumerated by the regulations of the commissioner as warranting the prescribing of greater than a thirty day supply of a controlled substance. A pharmacy or pharmacist may sell or dispense up to a six month supply of any substance listed in subdivision (h) of Schedule II of section [fig 2] ***thirty-three*** hundred six of this article if there appears, on [fig 3] the official New York state prescription ***or on an electronic prescription*** , a statement that the substance has been prescribed to treat one of the conditions that have been enumerated by the regulations of the commissioner as warranting the prescribing of a specified greater supply.

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

CATEGORY B:
Issues related to patients

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

(-) *CRITERION 14:*
Undue prescription requirements

COMMENT: Although it is reasonable for physicians to monitor medication compliance, strict enforcement of such a provision could be a burden to the practitioner, pharmacist, or the patient. This provision could necessitate that the practitioner and pharmacist also confirm the supply of the medication remaining for every patient.

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Madison, Wisconsin

NEW YORK

STATUTES

Controlled Substances Act

(+) *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.

NY CLS Pub Health § 3350

§ 3350. Dispensing prohibition

Controlled substances may not be prescribed for, or administered or dispensed to addicts or habitual users of controlled substances, except as provided by this title or title III.

NY CLS Pub Health § 3351

§ 3351. Dispensing for medical use

1. Controlled substances may be prescribed for, or administered or dispensed to an addict or habitual user:
(a) during emergency medical treatment unrelated to abuse of controlled substances;
(b) who is a bona fide patient suffering from an incurable and fatal disease such as cancer or advanced tuberculosis;
(c) who is aged, infirm, or suffering from serious injury or illness and the withdrawal from controlled substances would endanger the life or impede or inhibit the recovery of such person.

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

CATEGORY A:
Restrictions based on patient characteristics

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NEW YORK

STATUTES

Medical Practice Act

NY CLS Educ § 6521

§ 6521. Definition of practice of medicine

The practice of the profession of medicine is defined as diagnosing, treating, operating or prescribing for any human disease, pain, injury, deformity or physical condition.

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

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NEW YORK

REGULATIONS

Controlled Substances Regulations

10 NYCRR § 80.62

§ 80.62 Use of controlled substances in treatment.

(a) Physicians and other authorized practitioners in the course of their professional practice, may dispense, administer or prescribe controlled substances for legitimate medical purposes or treatment, other than treatment for addiction to controlled substances, when the practitioner regulates the dosage and prescribes or administers a quantity of such drugs no greater than that ordinarily recognized by members of his profession as sufficient for proper treatment in a given case.

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10 NYCRR § 80.67

§ 80.67 Schedule II and certain other substances

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(c) Except as provided for in subdivision (d) of this section, no such prescription shall be made for a quantity of substances which would exceed a 30-day supply if the substance were used in accordance with the directions for use, specified on the prescription. No additional prescriptions for a controlled substance may be issued by a practitioner to an ultimate user within 30 days of the date of any prescription previously issued unless and until the ultimate user has exhausted all but a seven days' supply of that controlled substance provided by any previously issued prescription.

(d)(1) A practitioner may issue a prescription for up to a three-month supply of a controlled substance, including chorionic gonadotropin, or up to a six-month supply of an anabolic steroid if used in accordance with the directions for use, provided that the prescription has been issued for the treatment of:

(i) panic disorders, designated as code A;

(ii) attention deficit disorder, designated as code B;

(iii) chronic debilitating neurological conditions characterized as a movement disorder or exhibiting seizure, convulsive or spasm activity, designated as code C;

(iv) relief of pain in patients suffering from conditions or diseases known to be chronic or incurable, designated as code D;

(v) narcolepsy, designated as code E; or

(vi) hormone deficiency states in males, gynecologic conditions that are responsive to treatment with anabolic steroids or chorionic gonadotropin, metastatic breast cancer in women, anemia and angioedema, designated as code F.

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

(-) *CRITERION 14:*
Undue prescription requirements

COMMENT: Strict enforcement of such a provision could be a burden to the practitioner and the patient. This provision could necessitate that the practitioner confirm the supply of the medication remaining for every patient.

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

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT: Although it is reasonable to expect practitioners to avoid contributing to diversion, "ordinarily recognized as sufficient for proper treatment " implies there is a known standard, but the standard is not specified.

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REGULATIONS

Controlled Substances Regulations

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

CATEGORY A:
Restrictions based on patient characteristics

10 NYCRR § 80.76

§ 80.76 Dispensing; prohibition

Controlled substances shall not be prescribed for, administered or dispensed to addicts or habitual users of controlled substances except as provided by the Public Health Law or this Part.

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§ 80.85 Administration of controlled substances to addicts and habitual users

(a) The administration of controlled substances to narcotic addicts or habitual users of controlled substances is prohibited except as provided for in this Part.

(b) Controlled substances may be administered to narcotic addicts or habitual users of controlled substances upon the order of a person authorized by law to practice medicine or osteopathy in this State and who possesses a Federal registration by the Drug Enforcement Administration, United States Department of Justice, authorizing him to use controlled substances in connection with his professional practice as follows:

(1) for bona fide patients suffering from disease known to be incurable, such as cancer, advanced tuberculosis, and other diseases well recognized as coming within this class;

(2) for addicts who are aged and infirm, or severely ill and it is determined that withdrawal of controlled substances would be dangerous to life, provided that:

(i) such determination has been confirmed by adequate consultation;

(ii) complete records of treatment, administration or dispensing of controlled substances including patient's name, date and type and quantity of controlled substance administered or dispensed are kept;

(iii) adequate safeguards have been taken against diversion of the controlled substances from the intended use; and

(iv) the patient is carefully supervised;

(3) to relieve acute withdrawal symptoms, except that:

(i) only the amount of controlled substances essential for relief of such acute symptoms shall be administered; and

(ii) administration shall be in an institutional or other setting reasonably certain to provide a drug-free environment;

(4) for detoxification of an addict participating in an authorized treatment program approved pursuant to article 23 of the Mental Hygiene Law; and

(5) for treatment of addicts participating in an authorized methadone or other controlled substances maintenance program approved pursuant to article 23 of the Mental Hygiene Law.

(c) In properly verified cases of severe illness, infirmity, or physical disability, a licensed physician, registered nurse, licensed practical nurse, or registered pharmacist may deliver medication to the patient.

(+) *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.

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Madison, Wisconsin

NEW YORK

OTHER GOVERNMENTAL POLICY

Medical Board Policy Statement

PAIN MANAGEMENT: A GUIDE FOR PHYSICIANS

INTRODUCTION

The New York State Board for Professional Medical Conduct (Board) recognizes that principles of quality medical practice dictate that the people of the State of New York have access to appropriate and effective pain relief. Inadequate pain control may result from physician[1] lack of knowledge about pain management, inadequate understanding of addiction, or fear of investigation or action by the Board or other federal, state or local regulatory agencies. This publication therefore has been developed to clarify the Board's position on pain control, to encourage better pain management and to dispel physician fears of unwarranted legal consequences.

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 complexity of pain management often requires intradisciplinary consultation.

The Board encourages and expects physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, including pain as a result of terminal illness.

All physicians should become knowledgeable about effective methods of pain evaluation and treatment, as well as statutory requirements for prescribing controlled substances.

CONTROLLED SUBSTANCES

The Board recognizes that controlled substances, including opioid analgesics, are often essential in the treatment of acute and chronic pain (both malignant and nonmalignant). If the treatments are based on accepted medical practices and sound clinical grounds, the Board considers prescribing, administering or dispensing controlled substances for pain to be legitimate. The Board also recognizes that tolerance and physical dependency may be pharmacological effects of sustained use of opioid analgesics and are not synonymous with addiction.

Pursuant to the laws of the State of New York, the Board is bound to protect the public health and safety. Inappropriate prescribing of controlled substances may lead to drug diversion and abuse by individuals who seek drugs for other than legitimate medical use. Therefore, physicians should be aware that the Board will not tolerate the diversion of drugs for illegitimate purposes.

(CONTINUED ON NEXT PAGE)

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies the potential impact of important barriers on the provision of effective pain care.

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

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

(+) *CRITERION 4:*
Encourages pain management

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

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

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NEW YORK

OTHER GOVERNMENTAL POLICY

Medical Board Policy Statement

(CONTINUED)

POINTS OF INFORMATION

- An adequate assessment of the patient and the pain should be performed and documented.
- Pain should be considered a fifth vital sign that is viewed as a fundamental assessment of well-being, and which is regularly monitored.
- Communication is essential. Many patients, for various reasons, are unable to describe adequately their pain. Physicians should initiate conversations to identify pain and qualify/quantify it and its impact on the patient's life.
- Treatment should be based on the diagnosis, type of pain, intensity and duration of pain, prior therapies, and the impact on quality of life.
- Ongoing evaluation of pain, patient compliance, and treatment efficacy should be performed and documented.
- The definition of **addict** under the Controlled Substance Law excludes patients using controlled substances for legitimate medical purposes. The term **addiction** refers to compulsive use of controlled substances for non-legitimate purposes and is associated with loss of control and use despite harm. Many patients are reluctant to seek pain relief because of the fear of addiction. Clarification from their physicians is essential.
- Certain patients with pain, such as those with history of substance abuse or comorbid psychiatric disorder, may require extra attention, monitoring, documentation and consultation.
- The Board evaluates **inappropriate** versus **appropriate** prescribing, not the quantity of drugs prescribed. The Bureau of Narcotic Enforcement has reviewed and concurs with these guidelines.

1 For the purposes of this document, the term physicians shall refer to physicians, medical residents, physician assistants and specialist assistants.

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

CATEGORY B:
Issues related to patients

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

(+) *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 include improvements in patient functioning and quality of life.

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NEW YORK

STATUTES

Facilities

NY CLS Unconsol Ch 214-A, § 3

§ 3. Definitions

As used or referred to in this act, unless a different meaning clearly appears from the text:

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13. "Health and medical services" shall mean items or services provided by or under the supervision of a physician or other person trained or licensed to render health care necessary for the prevention, care, diagnosis or treatment of human disease, pain, injury, deformity or other physical or mental condition including, but not limited to, pre-admission, out-patient, in-patient and post-discharge care, home care, physicians' care, nursing care, medical care provided by interns or residents-in-training and other paramedical care, ambulance service, bed and board, drugs, biologicals, supplies, appliances, equipment, laboratory services and x-ray, radium and radio-active-isotope therapy.

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

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STATUTES

Hospitals

NY CLS Pub Health § 2800

§ 2800. Declaration of policy and statement of purpose

Hospital and related services including health-related service of the highest quality, efficiently provided and properly utilized at a reasonable cost, are of vital concern to the public health. In order to provide for the protection and promotion of the health of the inhabitants of the state, pursuant to section three of the article seventeen of the constitution, the department of health shall have the central, comprehensive responsibility for the development and administration of the state's policy with respect to hospital and related services, and all public and private institutions, whether state, county, municipal, incorporated or not incorporated, serving principally as facilities for the prevention, diagnosis or treatment of human disease, pain, injury, deformity or physical condition or for the rendering of health-related service shall be subject to the provisions of this article.

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Recognizes that pain management is an essential part of hospital care.

NY CLS Pub Health § 2807-n

§ 2807-n. Palliative care education and training

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6. New York state palliative care education and training council.

(a) The New York state palliative care education and training council is established in the department as an expert panel in palliative medicine, education and training. Its members shall be appointed by the commissioner. The commissioner shall seek recommendations for appointments to such council from New York state-based health care professional, consumer, medical institutional and medical educational leaders. Members of the council shall include: nine representatives of medical schools and hospital organizations; two representatives of medical academies; two patient advocates; individual representatives of an organization broadly representative of physicians, internal medicine, family physicians, nursing, hospice, neurology, psychiatry, pediatrics, obstetrics-gynecology, surgery, and the hospital philanthropic community; and the executive director or a member of the governor's taskforce on life and the law and of the New York state council on graduate medical education. Members shall have expertise in palliative care or pain management. Members shall serve a term of three years with renewable terms. Members shall receive no compensation for their services, but shall be allowed actual and necessary expenses in the performance of their duties.

(b) A chairperson and vice-chairperson of the council shall be elected annually by the council. The council shall meet upon the call of the chairperson, and may adopt bylaws consistent with this section.

(c) The commissioner shall designate such employees and provide other resources of the department as are reasonably necessary to provide support services to the council. The council, acting by the chair of the council, may employ additional staff and consultants and incur other expenses to carry out its duties, to be paid from amounts which may be made available to the council for that purpose.

(d) The council may provide technical information and guidance for practitioners on the latest palliative care strategies, therapies and medications.

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (education and training council) to ensure that pain management/palliative care is an essential part of patient care.

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NEW YORK

STATUTES

Health Information

NY CLS Pub Health § 2997-c

§ 2997-c. Palliative care patient information

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2. If a patient is diagnosed with a terminal illness or condition, the patient's attending health care practitioner shall offer to provide the patient with:

(a) information and counseling regarding palliative care and end-of-life options appropriate to the patient, including but not limited to: the range of options appropriate to the patient; the prognosis, risks and benefits of the various options; and the patient's legal rights to comprehensive pain and symptom management at the end of life, *and*

(b) *information regarding other appropriate treatment options should the patient wish to initiate or continue treatment* . The information and counseling may be provided orally or in writing. Where the patient lacks capacity to reasonably understand and make informed choices relating to palliative care, the attending health care practitioner shall provide information and counseling under this section to a person with authority to make health care decisions for the patient. The attending health care practitioner may arrange for information and counseling under this section to be provided by another professionally qualified individual.

3. Where the attending health care practitioner is not willing to provide the patient with information and counseling under this section, he or she shall arrange for another physician or nurse practitioner to do so, or shall refer or transfer the patient to another physician or nurse practitioner willing to do so.

NY CLS Pub Health § 2997-d

§ 2997-d. Hospital, nursing home, home care, special needs assisted living residences and enhanced assisted living residences palliative care support

1. (a) "Palliative care" means health care treatment, including interdisciplinary end-of-life care, and consultation with patients and family members, to prevent or relieve pain and suffering and to enhance the patient's quality of life, including hospice care under article forty of this chapter.

(b) "Appropriate" has the same meaning as paragraph (a) of subdivision one of section twenty-nine hundred ninety-seven-c of this title.

2. General hospitals, nursing homes, organizations licensed or certified pursuant to article thirty-six of this chapter, and organizations licensed as special needs assisted living residences or enhanced assisted living residences pursuant to article forty-six-B of this chapter shall establish policies and procedures to provide patients with advanced life limiting conditions and illnesses who might benefit from palliative care, including associated pain management, services with access to information and counseling regarding such options appropriate to the patient. Policies must include provision for patients who lack capacity to make medical decisions, so that access to such information and counseling shall be provided to the persons who are legally authorized to make medical decisions on behalf of such patients.

3. General hospitals, nursing homes, organizations licensed or certified pursuant to article thirty-six of this chapter, and organizations licensed as special needs assisted living residences or enhanced assisted living residences pursuant to article forty-six-B of this chapter shall facilitate access to appropriate palliative care consultations and services, including associated pain management consultations and services, including but not limited to referrals consistent with patient needs and preferences. The department shall take into account access and proximity of palliative care services, including the availability of hospice and palliative care board certified practitioners and other related workforce staff, geographic factors, and facility size that may impact development of palliative care services.

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

CATEGORY C:
Regulatory or policy issues

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

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (provision of patient information and counseling) for healthcare facilities to ensure that pain management is an essential part of patient care.

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Madison, Wisconsin

NEW YORK

REGULATIONS

Nursing Homes

10 NYCRR § 415.26

§ 415.26 ADMINISTRATIVE 415.26 Organization and administration

A nursing home shall be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.

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(i) The nurse aide training program shall include classroom and clinical training which enhances both skills and knowledge and, when combined, shall be of at least 100 hours' duration. The clinical training shall as a minimum include at least 30 hours of supervised practical experience in a nursing home. The nurse aide training program shall include stated goals, objectives, and measurable performance criteria specific to the curriculum subject material, the resident population and the purpose of the facility, and shall be consistent with the curriculum outlined below. This curriculum shall be taught at a fourth to sixth grade English literacy level. Facilities with special populations shall supplement the curriculum to address the needs of such populations accordingly. The curriculum shall otherwise include, but not be limited to the following:

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(n) nursing care needs of resident with special needs due to medical conditions such as but not limited to:

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(6) pain management;

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (training program) for nursing homes to ensure that pain management is an essential part of patient care.

REGULATIONS

Hospice Operation

10 NYCRR § 794.4

§ 794.4 Hospice inpatient and residence services

(a) Part 702 of this Title and Part 14 of the Sanitary Code shall apply to all hospice inpatient settings and hospice residence settings, as applicable.

(b) The hospice may provide short-term inpatient services for pain control and management of symptoms related to the terminal illness in a free-standing hospice facility, a skilled nursing facility or a general hospital.

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Recognizes that pain management is an essential part of hospice care.

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NEW YORK

REGULATIONS

Opioid Treatment Programs

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for OTP staff to refer patients who have chronic pain for treatment of their pain.

14 NYCRR § 822-5.4

§ 822-5.4 Admission assessment and initial services

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(m) Prospective patients with only a primary medical diagnosis of a chronic pain condition must be referred to specialists qualified to treat chronic pain conditions and are not eligible for treatment in an OTP. Each OTP must comply with the provisions of section 815.9 of this Title if any patient is prescribed medications by an outside prescriber.

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Pain & Policy Studies Group
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NORTH CAROLINA

STATUTES

- CONTROLLED SUBSTANCES ACT
  Chapter 90. Medicine and Allied Occupations;
  Article 5. North Carolina Controlled Substances Act
  Article 5E. North Carolina Controlled Substances Reporting System Act (*No provisions found*)

- MEDICAL PRACTICE ACT
  Chapter 90. Medicine and Allied Occupations; Article 1. Practice of Medicine

- PHARMACY PRACTICE ACT (*No provisions found*)
  Chapter 90. Medicine and Allied Occupations; Article 4A. North Carolina Pharmacy Practice Act

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Title 10A. Department of Health and Human Services; Chapter 26. Mental Health: General; Subchapter
  26E. Manufacturers: Distributors: Dispensers and Researchers of Controlled Substances
  26F. Controlled Substances

- MEDICAL BOARD REGULATIONS
  Title 21. Occupational Licensing Boards; Chapter 32. North Carolina Medical Board

- PHARMACY BOARD REGULATIONS
  Title 21. Occupational Licensing Boards; Chapter 46. Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD POLICY STATEMENT
  North Carolina Medical Board. *Policy for the Use of Controlled Substances for the Treatment of Pain*. Adopted: July 2005.

- MEDICAL BOARD POLICY STATEMENT
  North Carolina Board of Medical Examiners. *End-of-Life Responsibilities and Palliative Care*. Adopted: October 21, 1999; Modified: May 2007, March 2008.

- JOINT BOARD POLICY STATEMENT
  North Carolina Medical, Nursing, and Pharmacy Boards. *Joint Statement on Pain Management in End-of-Life Care*. Adopted: October 1, 1999; Modified: January 2011.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- FOOD, DRUGS AND COSMETICS
  Chapter 106. Agriculture; Article 12. Food, Drugs and Cosmetics

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NORTH CAROLINA

STATUTES

Controlled Substances Act

N.C. Gen. Stat. § 90-87

§ 90-87. Definitions

As used in this Article:

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(13) "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 use of that controlled substance on a continuous basis. Drug dependence is characterized by behavioral and other responses which include a strong compulsion to take the substance on a continuous basis in order to experience its psychic effects, or to avoid the discomfort of its absence.

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(22) "Practitioner" means:

a. A physician, dentist, optometrist, 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 so long as such activity is within the normal course of professional practice or research in this State.

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N.C. Gen. Stat. § 90-109.1

§ 90-109.1. Treatment

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(c) Every practitioner that provides treatment or rehabilitation services to a person dependent upon drugs shall periodically as required by the Secretary of the North Carolina Department of Health and Human Services commencing January 1, 1972, make a statistical report to the Secretary of the North Carolina Department of Health and Human Services in such form and manner as the Secretary shall prescribe for each such person treated or to whom rehabilitation services were provided. The form of the report prescribed shall be furnished by the Secretary of the North Carolina Department of Health and Human Services. Such report shall include the number of persons treated or to whom rehabilitation services were provided; the county of such person's legal residence; the age of such person; the number of such persons treated as inpatients and the number treated as outpatients; the number treated who had received previous treatment or rehabilitation services; and any other data required by the Secretary. If treatment or rehabilitation services are provided to a person by a hospital, public agency, or drug treatment facility, such hospital, public agency, or drug treatment facility shall coordinate with the treating medical practitioner so that statistical reports required in this section shall not duplicate one another. The Secretary shall cause all such reports to be compiled into periodical reports which shall be a public record.

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N.C. Gen. Stat. § 90-113.71

§ 90-113.71. Legislative findings and purpose

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(b) This Article is intended to improve the State's ability to identify controlled substance abusers or misusers and refer them for treatment, and to identify and stop diversion of prescription drugs in an efficient and cost-effective manner that will not impede the appropriate medical utilization of licit controlled substances.

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

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

(-) *CRITERION 14:*
Practitioners are subject to undue prescription requirements

COMMENT: This provision requires reporting. Requires practitioners to submit reports of all patients considered drug dependent, which the Secretary of the North Carolina Department of Health and Human Services will compile into a public record. The state legal definition of drug dependence could include patients with pain who are physically dependent as a result of opioid treatment.

(+) *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.

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STATUTES

Medical Practice Act

N.C. Gen. Stat. § 90-1.1

§ 90-1.1. Definitions

The following definitions apply in this Article:

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(5) The practice of medicine or surgery. -- The practice of medicine or surgery, for purposes of this Article, includes any of the following acts:

a. Advertising, holding out to the public, or representing in any manner that the individual is authorized to practice medicine in this State.

b. Offering or undertaking to prescribe, order, give, or administer any drug or medicine for the use of any other individual.

c. Offering or undertaking to prevent or diagnose, correct, prescribe for, administer to, or treat in any manner or by any means, methods, or devices any disease, illness, pain, wound, fracture, infirmity, defect, or abnormal physical or mental condition of any individual, including the management of pregnancy or parturition.

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

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REGULATIONS

Controlled Substances Regulations

10A N.C.A.C. 26E.0102

.0102 DEFINITIONS

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(10) The term "individual practitioner" means same as defined in *G.S. 90-87* (by reference: A physician, dentist, optometrist, 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 so long as such activity is within the normal course of professional practice or research in this State.)

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

REGULATIONS

Medical Board Regulations

21 N.C.A.C. 32B.1001

.1001 AUTHORITY TO PRESCRIBE

(a) A license to practice medicine issued under this Subchapter allows the physician to prescribe medications, including controlled substances, so long as the physician complies with all state and federal laws and regulations governing the writing and issuance of prescriptions.

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

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REGULATIONS

Pharmacy Board Regulations

21 N.C.A.C. 46.1801

.1801 RIGHT TO REFUSE A PRESCRIPTION

(a) A pharmacist or device and medical equipment dispenser may refuse to fill or refill a prescription order, if, in his professional judgment, it would be harmful to the recipient, is not in the recipient's best interest or if there is a question as to its validity.

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(-) CRITERION 16: Provisions that are ambiguous

CATEGORY A: Arbitrary standards for legitimate prescribing

COMMENT: Although it is reasonable to expect pharmacists to avoid knowingly filling prescriptions that could result in harm, this requirement could become a barrier if the pharmacist determined potential harm based solely on the quantity of the prescription. Also, how does the pharmacist support a determination that a prescription is not in the patient's "best interest"?

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OTHER GOVERNMENTAL POLICY

Medical Board Policy Statement

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

- Appropriate treatment of chronic pain may include both pharmacologic and non-pharmacologic modalities. The Board realizes that controlled substances, including opioid analgesics, may be an essential part of the treatment regimen.
- All prescribing of controlled substances must comply with applicable state and federal law.
- Guidelines for treatment include: (a) complete patient evaluation, (b) establishment of a treatment plan (contract), (c) informed consent, (d) periodic review, and (e) consultation with specialists in various treatment modalities as appropriate.
- Deviation from these guidelines will be considered on an individual basis for appropriateness.

Section I: Preamble

The North Carolina Medical Board recognizes that principles of quality medical practice dictate that the people of the State of North Carolina 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, this policy have been developed to clarify the Board's position on pain control, particularly as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

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

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

(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 practice might be.

(+) *CRITERION 4:*
Encourages pain management

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

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies the potential impact of important barriers on the provision of effective pain care.

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

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OTHER GOVERNMENTAL POLICY

Medical Board Policy Statement

(CONTINUED)

The North Carolina Medical Board is obligated under the laws of the State of North Carolina 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.

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

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

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

Section II: Guidelines

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

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

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

(CONTINUED ON NEXT PAGE)

(+) *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 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 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 goal of pain treatment should include improvements in patient functioning and quality of life.

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OTHER GOVERNMENTAL POLICY

Medical Board Policy Statement

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

(CONTINUED)

Informed Consent and Agreement for Treatment —The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including

- 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.

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,

(CONTINUED ON NEXT PAGE)

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

CATEGORY B:
Issues related to patients

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

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NORTH CAROLINA

OTHER GOVERNMENTAL POLICY

Medical Board Policy Statement

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

(CONTINUED)

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 of North Carolina 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 Policy Statement

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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.

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NORTH CAROLINA

OTHER GOVERNMENTAL POLICY

Medical Board Policy Statement

END-OF-LIFE RESPONSIBILITIES AND PALLIATIVE CARE

Assuring Patients
Death is part of life. When appropriate processes have determined that the use of life prolonging measurers or invasive interventions will only prolong the dying process, it is incumbent on physicians to accept death "not as a failure, but the natural culmination of our lives."*

It is the position of the North Carolina Medical Board that patients and their families should be assured of competent, comprehensive palliative care at the end of their lives. Physicians should be knowledgeable regarding effective and compassionate pain relief, and patients and their families should be assured such relief will be provided.

Palliative Care
Palliative care is an approach that improves the quality of life of patients and their families facing the problems associated with life-threatening illness, through the prevention and relief of suffering by means of early identification an impeccable assessment and treatment of pain and other physical, psychosocial and spiritual problems. Palliative care:

- provides relief from pain and other distressing symptoms;
- affirms life and regards dying as a normal process;
- intends neither to hasten nor postpone death;
- integrates the psychological and spiritual aspects of patient care;
- offers a support system to help patients live as actively as possible until death;
- offers a support system to help the family cope during the patient's illness and in their own bereavement;
- uses a team approach to address the needs of patients and their families;
- including bereavement counseling, if indicated;
- will enhance quality of life, and may also positively influence the course of illness;
- [may be] applicable early in the course of illness, in conjunction with other therapies that are intended to prolong life, such as chemotherapy or radiation therapy, and includes those investigations needed to better understand and manage distressing clinical complications.**

Opioid Use
The Board will assume opioid use in such patients is appropriate if the responsible physician is familiar with and abides by acceptable medical guidelines regarding such use, is knowledgeable about effective and compassionate pain relief, and maintains an appropriate medical record that details a pain management plan. (See the Board's position statement on the Policy for the Use of Controlled Substances for the Treatment of Pain for an outline of what the Board expects of physicians in the management of pain.) Because the Board is aware of the inherent risks associated with effective pain relief in such situations, it will not interpret their occurrence as subject to discipline by the Board.

*Steven A. Schroeder, MD, President, Robert Wood Johnson Foundation.

** Taken from the world Health Organization definition of Palliative Care (2002): (http:www.who.int/cancer/palliative/definition/en)

(+) *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 goal of pain treatment should 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: Recognizes the need for a multidisciplinary approach to pain management.

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

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NORTH CAROLINA

OTHER GOVERNMENTAL POLICY

Joint Board Policy Statement

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies the potential impact of important barriers on the provision of effective pain care.

JOINT STATEMENT ON PAIN MANAGEMENT
IN END-OF-LIFE CARE

Through dialogue with members of the healthcare community and consumers, a number of perceived regulatory barriers to adequate pain management in end-of-life care have been expressed to the Boards of Medicine, Nursing, and Pharmacy. The following statement attempts to address these misperceptions by outlining practice expectations for licensees and other health care professionals authorized to prescribe medications, as well as nurses and pharmacists involved in this aspect of end-of-life care. The statement is based on:

- the legal scope of practice for each of these licensed health professionals;
- professional collaboration and communication among health professionals providing palliative care; and
- a standard of care that assures on-going pain assessment, a therapeutic plan for pain management interventions; and evidence of adequate symptom management for the dying patient.

(+) *CRITERION 4:*
Encourages pain management

It is the position of all three Boards that patients and their families should be assured of competent, comprehensive palliative care at the end of their lives. Licensees, nurses and pharmacists should be knowledgeable regarding effective and compassionate pain relief, and patients and their families should be assured such relief will be provided.

Because of the overwhelming concern of patients about pain relief, the licensee needs to give special attention to the effective assessment of pain. It is particularly important that the licensee frankly but sensitively discuss with the patient and the family their concerns and choices at the end of life. As part of this discussion, the licensee should make clear that, in some end of life care situations, there are inherent risks associated with effective pain relief. *The Medical Board will assume opioid use in such patients is appropriate if the responsible licensee is familiar with and abides by acceptable medical guidelines regarding such use, is knowledgeable about effective and compassionate pain relief, and maintains an appropriate medical record that details a pain management plan.* Because the Board is aware of the inherent risks associated with effective pain relief in such situations, it will not interpret their occurrence as subject to discipline by the Board.

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

With regard to pharmacy practice, North Carolina has no quantity restrictions on dispensing controlled substances including those in Schedule II. This is significant when utilizing the federal rule that allows the partial filling of Schedule II prescriptions for up to 60 days. In these situations it would minimize expenses and unnecessary waste of drugs if the prescriber would note on the prescription that the patient is terminally ill and specify the largest anticipated quantity that could be needed for the next two months. The pharmacist could then dispense smaller quantities of the prescription to meet the patient's needs up to the total quantity authorized. Government-approved labeling for dosage level and frequency can be useful as guidance for patient care. Health professionals may, on occasion, determine that higher levels are justified in specific cases. However, these occasions would be exceptions to general practice and would need to be properly documented to establish informed consent of the patient and family.

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OTHER GOVERNMENTAL POLICY

Joint Policy Statement

(CONTINUED)

Federal and state rules also allow the fax transmittal of an original prescription for Schedule II drugs for hospice patients. If the prescriber notes the hospice status of the patient on the faxed document, it serves as the original. Pharmacy rules also allow the emergency refilling of prescriptions in Schedules III, IV, and V. While this does not apply to Schedule II drugs, it can be useful in situations where the patient is using drugs such as Vicodin for pain or Xanax for anxiety.

The nurse is often the health professional most involved in on-going pain assessment, implementing the prescribed pain management plan, evaluating the patient's response to such interventions and adjusting medication levels based on patient status. In order to achieve adequate pain management, the prescription must provide dosage ranges and frequency parameters within which the nurse may adjust (titrate) medication in order to achieve adequate pain control. Consistent with the licensee's scope of practice, the RN or LPN is accountable for implementing the pain management plan utilizing his/her knowledge base and documented assessment of the patient's needs. *The nurse has the authority to adjust medication levels within the dosage and frequency ranges stipulated by the prescriber and according to the agency's established protocols.* However, the nurse does not have the authority to change the medical pain management plan. When adequate pain management is not achieved under the currently prescribed treatment plan, the nurse is responsible for reporting such findings to the prescriber and documenting this communication. Only the licensee or other health professional with authority to prescribe may change the medical pain management plan.

Communication and collaboration between members of the healthcare team, and the patient and family are essential in achieving adequate pain management in end-of-life care. Within this interdisciplinary framework for end of life care, effective pain management should include:

- thorough documentation of all aspects of the patient's assessment and care;
- a working diagnosis and therapeutic treatment plan including pharmacologic and non-pharmacologic interventions;
- regular and documented evaluation of response to the interventions and, as appropriate, revisions to the treatment plan;
- evidence of communication among care providers;
- education of the patient and family; and
- a clear understanding by the patient, the family and health care team of the treatment goals.

It is important to remind health professionals that licensing boards hold each licensee accountable for providing safe, effective care. Exercising this standard of care requires the application of knowledge, skills, as well as ethical principles focused on optimum patient care while taking all appropriate measures to relieve suffering. The health care team should give primary importance to the expressed desires of the patient tempered by the judgment and legal responsibilities of each licensed health professional as to what is in the patient's best interest.

(+) *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 C:
Regulatory or policy issues

COMMENT: Informs healthcare professionals about acceptable practices under Federal and state policies.

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NORTH CAROLINA

STATUTES

Food, Drugs and Cosmetics

N.C. Gen. Stat. § 106-121

§ 106-121. Definitions and general considerations

For the purpose of this Article:

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(14b) The term "practitioner" means a physician, dentist, veterinarian, or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a drug so long as such activity is within the normal course of professional practice or research.

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

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NORTH DAKOTA

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 19. Foods, Drugs, Oils, and Compounds; Chapter 19-03.1. Uniform Controlled Substances Act

- PAIN TREATMENT ACT (*Part of Uniform Controlled Substances Act*)
  Title 19. Foods, Drugs, Oils, and Compounds; Chapter 19-03.3. Controlled Substances for Care and Treatment

- MEDICAL PRACTICE ACT (*No provisions found*)
  Title 43. Occupations and Professions; Chapter 43-17. Physicians and Surgeons

- PHARMACY PRACTICE ACT
  Title 43. Occupations and Professions; Chapter 43-15. Pharmacists

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (Part of Pharmacy Board Regulations) *(No provisions found)*
  Title 61. State Board of Pharmacy; Article 13. Controlled Substances

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Title 50. State Board of Medical Examiners

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Title 61. State Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

No policies found

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- HOMICIDE
  Title 12.1. Criminal Code; Chapter 12.1-16. Homicide

- FOOD, DRUGS AND COSMETICS
  Title 19. Foods, Drugs, Oils, and Compounds; Chapter 19-02.1. Food, Drug, and Cosmetics

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NORTH DAKOTA

STATUTES

Controlled Substances Act

N.D. Cent. Code, § 19-03.1-01

19-03.1-01. Definitions.

As used in this chapter and in chapters 19-03.2 and 19-03.4, unless the context otherwise requires:

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25. "Practitioner" means:

a. A physician, dentist, veterinarian, pharmacist, scientific investigator, or other person licensed, registered, or otherwise permitted by the jurisdiction in which the individual is practicing to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research.

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

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NORTH DAKOTA

STATUTES

Pain Treatment Act

N.D. Cent. Code, § 19-03.3-01 – § 19-03.3-06

19-03.3-01. Definitions.

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

1. "Board" means the state board of medical examiners.

2. "Pain" means acute pain and chronic pain. Acute pain is the normal, predicted physiological response to a noxious chemical or thermal or mechanical stimulus and typically is associated with invasive procedures, trauma, or disease, and is generally time-limited. Chronic pain is a state that 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.

3. "Physician" means a physician licensed by the board.

19-03.3-02. Prescription or administration of drugs by physician.

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

Notwithstanding any other provision of law, a physician may prescribe or administer controlled substances to a patient in the course of the physician's treatment of the patient for pain. A physician shall keep records of purchases and disposals of controlled substances prescribed or administered under this section. The records must include the date of purchase, the date of sale or administration by the physician, the name and address of the patient, and the reason for the prescribing or the administering of the substances to the patient.

19-03.3-03. Restriction by hospital or health care facility of prescribed drug use prohibited.

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Attempts to provide a secure environment for physicians prescribing in their healthcare facility.

No hospital or health care facility may forbid or restrict the use of controlled substances when prescribed or administered by a physician having staff privileges at that hospital or health care facility for a patient diagnosed and treated by a physician for pain.

19-03.3-04. Disciplinary action for prescribing or administering drug treatment prohibited.

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

The board may not discipline a physician for prescribing or administering controlled substances in the course of treatment of a patient for pain under this chapter.

19-03.3-05. Application.

This chapter does not apply to a person being treated by a physician for chemical dependency because of the person's use of controlled substances not related to treatment for pain. This chapter does not authorize a physician to prescribe or administer any drug legally classified as a controlled substance or as an addictive or dangerous drug for other than medically accepted therapeutic purposes. A person to whom controlled substances are prescribed or administered for pain is not exempt from section 39-08-01 or 39-20-04.1.

19-03.3-06. Cancellation, revocation, or suspension of physician's license.

This chapter does not limit the authority of the board to cancel, revoke, or suspend the license of any physician who:

1. Prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in the manner the drug or treatment is administered or prescribed.

2. Fails to keep complete and accurate records of purchases and disposals of controlled substances listed in chapter 19-03.1.

3. Writes false or fictitious prescriptions for controlled substances scheduled in chapter 19-03.1.

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STATUTES

Pharmacy Practice Act

N.D. Cent. Code, § 43-15-01

43-15-01. Definitions.

In this chapter, unless the context or subject matter otherwise requires:

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25. "Practitioner" means an individual licensed, registered, or otherwise authorized by the jurisdiction in which the individual is practicing to prescribe drugs in the course of professional practice.

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

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STATUTES

Homicide

N.D. Cent. Code, § 12.1-16-06

12.1-16-06. Construction.

Sections 12.1-16-04 through 12.1-16-06 do not preclude the use of medications or procedures necessary to relieve a person's pain or discomfort if the use of the medications or procedures is not intentionally or knowingly prescribed or administered to cause the death of that person. In addition, sections 12.1-16-04 through 12.1-16-06 do not preclude the withholding or withdrawal of life-prolonging treatment pursuant to state or federal law.

(+) 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.

STATUTES

Food, Drug and Cosmetic Act

N.D. Cent. Code, § 19-02.1-01

19-02.1-01. Definitions.

For the purpose of this chapter:

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20. "Practitioner" means an individual licensed, registered, or otherwise authorized by the jurisdiction in which the individual is practicing to prescribe drugs in the course of professional practice which are subject to this chapter.

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

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STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 37. Health, Safety, Morals; Chapter 3719. Controlled Substances

- MEDICAL PRACTICE ACT
  Title 47. Occupations, Professions; Chapter 4731. Physicians, Limited Practitioners

- INTRACTABLE PAIN TREATMENT ACT (*Part of Medical Practice Act*)
  Title 47. Occupations, Professions; Chapter 4731. Physicians, Limited Practitioners; §4731.052

- PHARMACY PRACTICE ACT
  Title 47. Occupations, Professions; Chapter 4729. Pharmacists, Dangerous Drugs

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*Part of Pharmacy Board Regulations*) (*No provisions found*)
  4729. State Board of Pharmacy; 4729-9. Dangerous Drugs

- MEDICAL BOARD REGULATIONS
  4731. State Medical Board

- PHARMACY BOARD REGULATIONS
  4729. State Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

No policies found

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- ASSISTED SUICIDE
  Title 21. Courts – Probate – Juvenile; Chapter 2133. Modified Uniform Rights of the Terminally Ill Act and the DNR Identification and Do-Not-Resuscitate Order Law

- ASSISTED SUICIDE
  Title 37. Health, Safety, Morals; Chapter 3795. Assisted Suicide

- HOSPICE CARE
  3701. Department of Health, Administration and Director;
  Chapter 3701-19. Hospice Care Programs

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STATUTES

Controlled Substances Act

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

ORC Ann. 3719.06

§ 3719.06. Authority of licensed health professional; contents of prescription

(A) (1) A licensed health professional authorized to prescribe drugs, if acting in the course of professional practice, in accordance with the laws regulating the professional's practice, and in accordance with rules adopted by the state board of pharmacy, may, except as provided in division (A)(2) of this section, do the following:

(a) Prescribe schedule II, III, IV, and V controlled substances;

(b) Administer or personally furnish to patients schedule II, III, IV, and V controlled substances;

(c) Cause schedule II, III, IV, and V controlled substances to be administered under the prescriber's direction and supervision.

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STATUTES

Medical Practice Act

ORC Ann. 4731.283

§ 4731.283. Continuing education concerning intractable pain

The state medical board shall approve one or more continuing medical education courses of study included within the programs certified by the Ohio state medical association and the Ohio osteopathic association pursuant to *section 4731.281 of the Revised Code* that assist doctors of medicine and doctors of osteopathic medicine in diagnosing and treating chronic pain, as defined in *section 4731.052 of the Revised Code*.

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

CATEGORY C:
Regulatory or policy issues

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

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STATUTES

Intractable Pain Treatment Act

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

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (rules) for the Board to ensure that pain management is an essential part of patient care.

ORC Ann. 4731.052

§ 4731.052. Management of intractable pain with dangerous drugs

(A) As used in this section:

(1) "Chronic pain" means pain that has persisted after reasonable medical efforts have been made to relieve the pain or cure its cause and that has continued, either continuously or episodically, for longer than three continuous months. "Chronic pain" does not include pain associated with a terminal condition or with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition.

(2) "Controlled substance" has the same meaning as in *section 3719.01 of the Revised Code*.

(3) "Physician" means an individual authorized under this chapter to practice medicine and surgery or osteopathic medicine and surgery.

(B) The state medical board shall adopt rules in accordance with Chapter 119. of the Revised Code that establish standards and procedures to be followed by physicians in the diagnosis and treatment of chronic pain, including standards for a physician's consultation with one or more other physicians who specialize in the treatment of the area, system, or organ of the body perceived as the source of pain and managing chronic pain by prescribing, personally furnishing, or administering controlled substances or products containing tramadol.

(C) When a physician diagnoses a patient as having chronic pain, the physician may, subject to division (D) of this section, treat the pain by managing it with controlled substances and products containing tramadol. The physician's diagnosis and treatment decisions shall be made according to accepted and prevailing standards for medical care. For the purpose of assisting with the diagnosis of chronic pain, the physician shall obtain and review all available medical records or detailed written summaries of the patient's treatment for chronic pain or the condition causing the chronic pain. It is recommended that the physician also consider having the patient evaluated by one or more other physicians who specialize in the treatment of the area, system, or organ of the body perceived as the source of the pain.

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STATUTES

Intractable Pain Treatment Act

(CONTINUED)

(D) For each patient a physician diagnoses as having chronic pain, the physician shall maintain a written record of all of the following:

(1) Medical history and physical examination of the patient;

(2) The diagnosis of chronic pain, including signs, symptoms, and causes;

(3) The plan of treatment proposed, the patient's response to treatment, and any modification to the plan of treatment, including all of the following:

(a) Documentation that other medically reasonable treatments for relief of the patient's chronic pain have been offered or attempted without adequate or reasonable success;

(b) Periodic assessment and documentation of the patient's functional status, including the ability to engage in work or other purposeful activities, the pain intensity and its interference with activities of daily living, quality of family life and social activities, and physical activity of the patient;

(c) Periodic assessment and documentation of the patient's progress toward treatment objectives, including the intended role of controlled substances or products containing tramadol within the overall plan of treatment;

(d) Periodic assessment and documentation for indicators of possible addiction, drug abuse, or drug diversion;

(e) Notation of any adverse drug effects.

(4) The dates on which controlled substances or products containing tramadol were prescribed, furnished, or administered, the name and address of the patient to or for whom the controlled substances or products containing tramadol were prescribed, furnished, or administered, and the amounts and dosage forms for the controlled substances or products containing tramadol prescribed, furnished, or administered;

(5) A copy of any record or report made by another physician that was used or consulted for the purpose of diagnosing the patient's chronic pain or treating the patient for chronic pain.

(E) A physician shall not prescribe, personally furnish, or administer to a patient a controlled substance or product containing tramadol without taking into account the potential for abuse of the controlled substance or product, the possibility the controlled substance or product may lead to dependence, the possibility the patient will obtain the controlled substance or product for a nontherapeutic use or distribute it to other persons, and the potential existence of an illicit market for the controlled substance or product. In addition, the physician shall address with the patient the risks associated with protracted treatment with controlled substances or products containing tramadol, including informing the patient of the potential for dependence, tolerance, and addiction and the clinical or monitoring tools the physician may use if signs of addiction, drug abuse, or drug diversion are present.

(F) A physician who treats chronic pain by managing it with controlled substances or products containing tramadol is not subject to disciplinary action by the board under *section 4731.22 of the Revised Code* solely because the physician treated the chronic pain with controlled substances or products containing tramadol.

(+) *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 include improvements in patient functioning and quality of life.

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

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STATUTES

Pharmacy Practice Act

ORC Ann. 4729.01

§ 4729.01. Definitions

As used in this chapter:

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(I) "Licensed health professional authorized to prescribe drugs" or "prescriber" means an individual who is authorized by law to prescribe drugs or dangerous drugs or drug therapy related devices in the course of the individual's professional practice, including only the following:

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

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REGULATIONS

Medical Board Regulations

OAC Ann. 4731-21-01 – 4731-21-06

4731-21-01. Definitions.

As used in *Chapter 4731-21 of the Administrative Code*:

(A) "Addiction" means a compulsive disorder in which an individual becomes preoccupied with obtaining and using a substance, despite adverse social, psychological and/or physical consequences, the continued use of which results in a decreased quality of life. Physical dependence alone is not evidence of addiction.

(B) "Believes" or "has reason to believe" does not require absolute certainty or complete unquestioning acceptance; but only an opinion based on reasonable information that a patient is suffering from addiction or drug abuse or engaging in diversion of drugs.

(C) "Board" means the state medical board of Ohio.

(D) "Diversion" means the conveyance of a prescription drug to a person other than the person for whom the drug was prescribed or dispensed by a practitioner.

(E) "Drug abuse" means a maladaptive or inappropriate use or overuse of a medication.

(F) "Emergency" means an unforeseen combination of circumstances or the resulting state that calls for immediate action.

(G) "Intractable pain" means a state of pain that is determined, after reasonable medical efforts have been made to relieve the pain or cure its cause, to have a cause for which no treatment or cure is possible or for which none has been found. "Intractable pain" does not include pain experienced by a patient with a terminal condition. "Intractable pain" does not include the treatment of pain associated with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition.

(H) "Pain" means an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.

(I) "Physical dependence" means a physiologic state of adaptation to a specific drug or medication characterized by the development of a withdrawal syndrome following abrupt cessation of a drug or on administration of an antagonist.

(J) "Practitioner" means any of the following:

(1) An individual holding a certificate to practice medicine and surgery or osteopathic medicine and surgery under Chapter 4731. of the Revised Code;

(2) An individual holding a certificate to practice podiatric medicine and surgery under Chapter 4731. of the Revised Code and practicing within his or her scope of practice as defined in *section 4731.51 of the Revised Code*; or

(3) An individual holding both of the following:

(a) A certificate to practice as a physician assistant under Chapter 4730. of the Revised Code and practicing within his or her scope of practice in compliance with that chapter; and

(b) A certificate to prescribe under Chapter 4730. of the Revised Code and exercising physician delegated prescriptive authority in compliance with that chapter.

(K) "Prescription drug" means a drug which under state or federal law may be administered or dispensed only by or upon the order of a practitioner and includes the term "dangerous drug" as defined by *section 4729.02 of the Revised Code*.

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(-) CRITERION 16:
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: Although similar language is used in Federal regulation, in the context of this statute this definition suggests that physicians would qualify for the immunity and, thus, relief from concerns about regulatory scrutiny provided by this statute only if they prescribe opioids after other treatments have been tried and failed, regardless of other clinical considerations.

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REGULATIONS

Medical Board Regulations

[CONTINUED]

(L) "Protracted basis" means for a period in excess of twelve continuous weeks.

(M) "Terminal condition" means an irreversible, incurable, and untreatable condition caused by disease, illness, or injury, which will likely result in death. A terminal condition is one in which there can be no recovery, although there may be periods of remission.

A terminal condition shall be determined to a reasonable degree of medical certainty in accordance with reasonable medical standards by a patient's attending medical doctor or doctor of osteopathic medicine and one other individual holding a certificate under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery who has examined the patient.

(N) "Tolerance" means decreasing response to the same dosage of a prescription drug over time as a result of physiologic adaptation to that drug.

(O) "Utilizing prescription drugs" means prescribing, administering, dispensing, supplying, selling or giving a prescription drug.

4731-21-02. Utilizing prescription drugs for the treatment of intractable pain.

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

(A) When utilizing any prescription drug for the treatment of intractable pain on a protracted basis or when managing intractable pain with prescription drugs in amounts or combinations that may not be appropriate when treating other medical conditions, a practitioner shall comply with accepted and prevailing standards of care which shall include, but not be limited to, the following:

(1) An initial evaluation of the patient shall be conducted and documented in the patient's record that includes a relevant history, including complete medical, pain, alcohol and substance abuse histories; an assessment of the impact of pain on the patient's physical and psychological functions; a review of previous diagnostic studies and previously utilized therapies; an assessment of coexisting illnesses, diseases or conditions; and an appropriate physical examination;

(2) A medical diagnosis shall be established and documented in the patient's medical record that indicates not only the presence of intractable pain but also the signs, symptoms, and causes and, if determinable, the nature of the underlying disease and pain mechanism;

(3) An individualized treatment plan shall be formulated and documented in the patient's medical record. The treatment plan shall specify the medical justification of the treatment of intractable pain by utilizing prescription drugs on a protracted basis or in amounts or combinations that may not be appropriate when treating other medical conditions, the intended role of prescription drug therapy within the overall plan, and, when applicable, documentation that other medically reasonable treatments for relief of the patient's intractable pain have been offered or attempted without adequate or reasonable success. The prescription drug therapy shall be tailored to the individual medical needs of each patient. The practitioner shall document the patient's response to treatment and, as necessary, modify the treatment plan;

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REGULATIONS

Medical Board Regulations

[CONTINUED]

(4) (a) The practitioner's diagnosis of intractable pain shall be made after having the patient evaluated by one or more other practitioners who specialize in the treatment of the anatomic area, system, or organ of the body perceived as the source of the pain. For purposes of this rule, a practitioner "specializes" if the practitioner limits the whole or part of his or her practice, and is qualified by advanced training or experience to so limit his or her practice, to the particular anatomic area, system, or organ of the body perceived as the source of the pain. The evaluation shall include review of all available medical records of prior treatment of the intractable pain or the condition underlying the intractable pain; a thorough history and physical examination; and testing as required by accepted and prevailing standards of care. The practitioner shall maintain a copy of any report made by any practitioner to whom referral for evaluation was made under this paragraph. A practitioner shall not provide an evaluation under this paragraph if that practitioner would be prohibited by *sections 4731.65* to *4731.69 of the Revised Code* or any other rule adopted by the board from providing a designated health service upon referral by the treating practitioner; and

(b) The practitioner shall not be required to obtain such an evaluation, if the practitioner obtains a copy of medical records or a detailed written summary thereof showing that the patient has been evaluated and treated within a reasonable period of time by one or more other practitioners who specialize in the treatment of the anatomic area, system, or organ of the body perceived as the source of the pain and the treating practitioner is satisfied that he or she can rely on that evaluation for purposes of meeting the further requirements of this chapter of the Administrative Code. The practitioner shall obtain and review all available medical records or detailed written summaries thereof of prior treatment of the intractable pain or the condition underlying the intractable pain. The practitioner shall maintain a copy of any record or report of any practitioner on which the practitioner relied for purposes of meeting the requirements under this paragraph; and

(5) The practitioner shall ensure and document in the patient's record that the patient or other individual who has the authority to provide consent to treatment on behalf of that patient gives consent to treatment after being informed of the benefits and risks of receiving prescription drug therapy on a protracted basis or in amounts or combinations that may not be appropriate when treating other medical conditions, and after being informed of available treatment alternatives.

(B) Upon completion and satisfaction of the conditions prescribed in paragraph (A) of this rule, and upon a practitioner's judgment that the continued utilization of prescription drugs is medically warranted for the treatment of intractable pain, a practitioner may utilize prescription drugs on a protracted basis or in amounts or combinations that may not be appropriate when treating other medical conditions, provided that the practitioner continues to adhere to accepted and prevailing standards of care which shall include, but not be limited to, the following:

[CONTINUED ON NEXT PAGE]

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

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(+) ***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 include improvements in patient functioning and quality of life.

[CONTINUED]

(1) Patients shall be seen by the practitioner at appropriate periodic intervals to assess the efficacy of treatment, assure that prescription drug therapy remains indicated, evaluate the patient's progress toward treatment objectives and note any adverse drug effects. During each visit, attention shall be given to changes in the patient's ability to function or to the patient's quality of life as a result of prescription drug usage, as well as indications of possible addiction, drug abuse or diversion. Compliance with this paragraph of the rule shall be documented in the patient's medical record;

(2) Some patients with intractable pain may be at risk of developing increasing prescription drug consumption without improvement in functional status. Subjective reports by the patient should be supported by objective data. Objective measures in the patient's condition are determined by an ongoing assessment of the patient's functional status, including the ability to engage in work or other gainful activities, the pain intensity and its interference with activities of daily living, quality of family life and social activities, and physical activity of the patient. Compliance with this paragraph of the rule shall be documented in the patient's medical record;

(3) Based on evidence or behavioral indications of addiction or drug abuse, the practitioner may obtain a drug screen on the patient. It is within the practitioner's discretion to decide the nature of the screen and which type of drug(s) to be screened. If the practitioner obtains a drug screen for the reasons described in this paragraph, the practitioner shall document the results of the drug screen in the patient's medical record. If the patient refuses to consent to a drug screen ordered by the practitioner, the practitioner shall make a referral as provided in paragraph (C) of this rule;

(4) The practitioner shall document in the patient's medical record the medical necessity for utilizing more than one controlled substance in the management of a patient's intractable pain; and

(5) The practitioner shall document in the patient's medical record the name and address of the patient to or for whom the prescription drugs were prescribed, dispensed, or administered, the dates on which prescription drugs were prescribed, dispensed, or administered, and the amounts and dosage forms of the prescription drugs prescribed, dispensed, or administered, including refills.

(C) If the practitioner believes or has reason to believe that the patient is suffering from addiction or drug abuse, the practitioner shall immediately consult with an addiction medicine specialist or other substance abuse professional to obtain formal assessment of addiction or drug abuse.

(1) For purposes of this rule:

(a) Addiction medicine specialist means a physician who is qualified by advanced formal training in addiction medicine or other substance abuse specialty, and includes a medical doctor or doctor of osteopathic medicine who is certified by a specialty examining board to so limit the whole or part of his or her practice.

(b) Substance abuse professional includes a psychologist licensed pursuant to Chapter 4732. of the Revised Code and certified as a clinical health psychologist, an independent chemical dependency counselor, or a chemical dependency counselor III.

(2) The practitioner shall do all of the following:

(a) Document the recommendations of the consultation in the patient's record;

(b) Continue to actively monitor the patient for signs and symptoms of addiction, drug abuse or diversion; and

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Medical Board Regulations

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(c) Maintain a copy of any written report made by the addiction medicine specialist or substance abuse professional to whom referral for evaluation was made under this paragraph.

(3) Prescription drug therapy may be continued consistent with the recommendations of the consultation. If the consulting addiction medicine specialist or other substance abuse professional believes the patient to be suffering from addiction or drug abuse, prompt referral shall be made to one of the following:

(a) An addiction medicine specialist or substance abuse professional; or

(b) An addiction medicine or substance abuse treatment facility.

4731-21-03 Continuing Medical Education.

The board encourages those practitioners who encounter patients with intractable pain in the usual course of their practices to complete continuing medical education related to the treatment of intractable pain, including coursework related to pharmacology, alternative methods of pain management and treatment, and addiction medicine.

4731-21-04 Tolerance, Physical Dependence and Addiction.

(A) Physical dependence and tolerance by themselves do not indicate addiction.

(B) Physical dependence and tolerance are normal physiological consequences of extended opioid therapy, and do not, in the absence of other indicators of drug abuse or addiction, require reduction or cessation of opioid therapy.

4731-21-05 Violations.

A violation of any provision of any rule in this chapter of the Administrative Code, as determined by the board, shall constitute "failure to use reasonable care discrimination in the administration of drugs," as that clause is used in division (B)(2) of *section 4731.22 of the Revised Code*; "selling, prescribing, giving away, or administering drugs for other than legal and legitimate therapeutic purposes," as that clause is used in division (B)(3) of *section 4731.22 of the Revised Code*, if done knowingly or recklessly, as those words are defined in *section 2901.22 of the Revised Code*; and "a departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in division (B)(6) of *section 4731.22 of the Revised Code*.

4731-21-06 Exceptions.

(A) A practitioner who treats pain by utilizing prescription drugs is not subject to disciplinary action pursuant to this chapter of the Administrative Code under the following circumstances:

(1) The treatment of pain for a patient with a terminal condition:

(2) The treatment of pain associated with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition;

(3) Treatment utilizing only drugs that do not exert their effects at the central nervous system level; and

(4) Treatment utilizing only drugs that are not controlled substances and are classified as antidepressants.

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

CATEGORY C:
Regulatory or policy issues

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

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

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

CATEGORY B:
Issues related to patients

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

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Exempts practitioners who treat pain in patients who do not meet the definition of "intractable pain" from these statutory requirements.

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(B) A practitioner who treats intractable pain by utilizing prescription drugs is not subject to disciplinary action by the board under *section 4731.22 of the Revised Code* solely because the practitioner treated the intractable pain with prescription drugs. The practitioner is subject to disciplinary action only if the prescription drugs are not utilized in accordance with *section 4731.052 of the Revised Code* and the rules adopted under this chapter of the Administrative Code.

(C) A Medical doctor or doctor of osteopathic medicine who provides comfort care as described in division (E)(1) of *section 2133.12 of the Revised Code* to a patient with a terminal condition is not subject to disciplinary action by the board under *section 4731.22 of the Revised Code* if the treatment of pain for a patient with a terminal condition is provided pursuant to the requirements of *section 2133.11 of the Revised Code*.

OAC Ann. 4731-29-01

4731-29-01. Standards and procedures for the operation of a pain management clinic.

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(B) In the operation of a pain management clinic, the following requirements shall be met:

(1) The pain management clinic shall be owned and operated by one or more physicians. Each physician owner of a pain management clinic shall complete at least twenty hours of category I continuing medical education in pain medicine every two years, to include one or more courses addressing the potential for addiction. The courses completed in compliance with this rule shall be accepted toward meeting the category I requirement for certificate of registration renewal for the physician.

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(C) Each physician who provides care at a pain management clinic shall complete at least twenty hours of category I continuing medical education in pain medicine every two years, to include one or more courses addressing the potential for addiction. The courses completed in compliance with this rule shall be accepted toward meeting the category I requirement for certificate of registration renewal for the physician.

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

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

CATEGORY C:
Regulatory or policy issues

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

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University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

OHIO

REGULATIONS

Pharmacy Board Regulations

OAC Ann. 4729-5-01

4729-5-01 Definitions.

As used in Chapter 4729. of the Revised Code:

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(M) "Prescriber" means any person authorized by the Revised Code to prescribe dangerous drugs as part of their professional practice.

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

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STATUTES

Assisted Suicide

ORC Ann. 2133.11

§ 2133.11. Immunity from civil or criminal liability or professional disciplinary action

(A) Subject to division (D) of this section, an attending physician, consulting physician, health care facility, and health care personnel acting under the direction of an attending physician are not subject to criminal prosecution, are not liable in damages in a tort or other civil action, and are not subject to professional disciplinary action for any of the following:

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(6) Prescribing, dispensing, administering, or causing to be administered any particular medical procedure, treatment, intervention, or other measure to a qualified patient or other patient, including, but not limited to, prescribing, personally furnishing, administering, or causing to be administered by judicious titration or in another manner any form of medication, for the purpose of diminishing the qualified patient's or other patient's pain or discomfort and not for the purpose of postponing or causing the qualified patient's or other patient's death, even though the medical procedure, treatment, intervention, or other measure may appear to hasten or increase the risk of the patient's death, if the attending physician so prescribing, dispensing, administering, or causing to be administered or the health care personnel acting under the direction of the attending physician so dispensing, administering, or causing to be administered are carrying out in good faith the responsibility to provide comfort care described in division (E)(1) of *section 2133.12 of the Revised Code*.

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:* Clarifies for physicians the 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, and the practitioners who provide it.

STATUTES

Assisted Suicide

ORC Ann. 3795.03

§ 3795.03 Exceptions to provisions

Nothing in section 3795.01 or 3795.02 of the Revised Code shall do any of the following:

(A) Prohibit or preclude a physician, certified nurse practitioner, certified nurse-midwife, or clinical nurse specialist who carries out the responsibility to provide comfort care to a patient in good faith and while acting within the scope of the physician's or nurse's authority from prescribing, dispensing, administering, or causing to be administered any particular medical procedure, treatment, intervention, or other measure to the patient, including, but not limited to, prescribing, personally furnishing, administering, or causing to be administered by judicious titration or in another manner any form of medication, for the purpose of diminishing the patients' pain or discomfort and not for the purpose of postponing or causing the patient's death, even though the medical procedure, treatment, intervention, or other measure may appear to hasten or increase the risk of the patient's death;

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:* Clarifies for physicians the 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, and the practitioners who provide it.

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REGULATIONS

Hospice Care

OAC Ann. 3701-19-10

3701-19-10 Medical director.

The medical director of a hospice care program shall have overall responsibility for the medical component of the program.

Interpretive guideline: The medical director shall be a physician who is either a paid or contractual staff member or volunteer whose duties shall include:

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(C) Consulting with attending physicians, when appropriate, regarding pain and symptom management;

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OAC Ann. 3701-19-24

3701-19-24. Short-term inpatient care.

(A) Each hospice care program shall provide or arrange for the provision of short-term inpatient care to patients who require it for pain control, symptom management, or respite care. The program may operate its own inpatient facility or may contract with one or more other persons or public agencies that operate inpatient facilities for provision of inpatient care. The inpatient facility or facilities that the program uses to provide inpatient care shall be licensed, certified, or accredited in accordance with applicable Ohio law and, in addition, shall meet the requirements of rules *3701-19-25* and *3701-19-26 of the Administrative Code*.

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OAC Ann. 3701-19-25

3701-19-25. Twenty-four hour nursing services in inpatient facilities.

(A) A hospice care program shall ensure that nursing services are available twenty-four hours per day and seven days a week in each inpatient facility used to provide inpatient care to its patients.

(1) Each inpatient facility used by a hospice care program to provide inpatient care to its patients for pain control and symptom management shall provide nursing services twenty-four hours a day. These services shall be sufficient to meet the total nursing needs of the hospice patients residing in the facility. Each shift shall be staffed by a registered nurse who provides direct patient care.

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

CATEGORY C:
Regulatory or policy issues

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

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

CATEGORY C:
Regulatory or policy issues

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

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

CATEGORY C:
Regulatory or policy issues

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

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OKLAHOMA

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 63. Public Health and Safety; Chapter 2. Uniform Controlled Dangerous Substances Act

- MEDICAL PRACTICE ACT
  Title 59. Professions and Occupations; Chapter 11. Medicine

- OSTEOPATHIC PRACTICE ACT (*No provisions found*)
  Title 59. Professions and Occupations; Chapter 14. Osteopathic Medicine Act

- PHARMACY PRACTICE ACT
  Title 59. Professions and Occupations; Chapter 8. Pharmacy

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Title 475. Oklahoma State Bureau of Narcotics and Dangerous Drugs Control

- MEDICAL BOARD REGULATIONS
  Title 435. State Board of Medical Licensure and Supervision

- OSTEOPATHIC BOARD REGULATIONS
  Title 510. State Board of Osteopathic Examiners

- PHARMACY BOARD REGULATIONS
  Title 535. Oklahoma State Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD POLICY STATEMENT
  Oklahoma State Board of Medical Licensure and Supervision. *Use of Controlled Substances for the Treatment of Pain*. Adopted: March 10, 2005.

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RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- NURSING HOME CARE ACT
  Title 63. Public Health and Safety; Chapter 1. Public Health Code;
  Article 19. Nursing Home Care Act

- ASSISTED SUICIDE PREVENTION ACT
  Title 63. Public Health and Safety; Chapter 61B. Assisted Suicide Prevention Act

- HOSPICE
  Title 310. Oklahoma State Department of Health; Chapter 661. Hospice

- HOSPITAL STANDARDS
  Title 310. Oklahoma State Department of Health; Chapter 667. Hospital Standards;
  Subchapter 3. Patient Rights

- NURSING AND SPECIALIZED FACILITIES
  Title 310. Oklahoma State Department of Health; Chapter 675. Nursing and Specialized Facilities

- OPIOID TREATMENT PROGRAMS
  Title 450. Department of Mental Health and Substance Abuse Services; Chapter 70. Standards and Criteria for Opioid Substitution Treatment Programs;
  Subchapter 3. Facility Record System

OKLAHOMA

STATUTES

Controlled Substances Act

63 Okl. St. § 2-101

§ 2-101. Definitions

As used in the Uniform Controlled Dangerous Substances Act, Section 2-101 et seq. of this title:

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

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63 Okl. St. § 2-551

§ 2-551. Appropriate pain management--high dosages of controlled dangerous drugs

A. Schedule II, III, IV and V controlled dangerous drugs have useful and legitimate medical and scientific purposes and are necessary to maintain the health and general welfare of the people of this state.

B. The State of Oklahoma recognizes that principles of quality medical practice dictate that the people of the State of Oklahoma 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 State of Oklahoma encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic. It is especially important for patients who experience pain as a result of terminal illness.

C. If, in the judgment of the medical doctor or the doctor of osteopathic medicine, appropriate pain management warrants a high dosage of controlled dangerous drugs and the benefit of the relief expected outweighs the risk of the high dosage, the medical doctor or doctor of osteopathic medicine may administer such a dosage, even if its use may increase the risk of death, so long as it is not also furnished for the purpose of causing, or the purpose of assisting in causing, death for any reason and so long as it falls within policies, guidelines and rules of the Oklahoma State Board of Medical Licensure and Supervision or the Oklahoma State Board of Osteopathic Examiners.

D. The Oklahoma State Board of Medical Licensure and Supervision and the Oklahoma State Board of Osteopathic Examiners shall issue policies, guidelines or rules that ensure that physicians who are engaged in the appropriate treatment of pain are not subject to disciplinary action, and the Boards shall consider policies and guidelines developed by national organizations with expertise in pain medicine or in a medical discipline for this purpose.

(+) *CRITERION 1:*
Controlled substances are necessary for public health

(+) *CRITERION 4:*
Encourages pain management

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

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

CATEGORY C:
Regulatory or policy issues

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

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

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

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

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians the 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, and the practitioners who provide it.

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STATUTES

Medical Practice Act

59 Okl. St. § 492

§ 492. Designation of physicians—Employment by hospitals—Practice of medicine defined—Services rendered by trained assistants—Persons practicing nonallopathic healing

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C. The definition of the practice of medicine and surgery shall include, but is not limited to:

1. Advertising, holding out to the public, or representing in any manner that one is authorized to practice medicine and surgery in this state;

2. Any offer or attempt to prescribe, order, give, or administer any drug or medicine and surgery for the use of any other person, except as otherwise authorized by law;

3. a. Any offer or attempt, except as otherwise authorized by law, to prevent, diagnose, correct, or treat in any manner or by any means, methods, devises, or instrumentalities except for manual manipulation any disease, illness, pain, wound, fracture, infirmity, defect, or abnormal physical or mental condition of any person, including the management of pregnancy and parturition, except as otherwise authorized by law.

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

59 Okl. St. § 509

509. Unprofessional Conduct - Definition

"The words 'Unprofessional Conduct' as used in Sections 481 through 514 of this title are hereby declared to include, but shall not be limited to, the following:

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16. Prescribing, dispensing or administering of controlled substances or narcotic drugs in excess of the amount considered good medical practice, or prescribing, dispensing or administering controlled substances or narcotic drugs without medical need in accordance with published standards;

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

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT: Although it is reasonable to expect physicians to avoid contributing to diversion, "in excess" implies there is a known standard, but the standard is not specified.

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STATUTES

Pharmacy Practice Act

59 Okl. St. § 367.2

§ 367.2. Definitions

As used in the Utilization of Unused Prescription Medications Act:

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3. "Health care professional" means any of the following persons licensed and authorized to prescribe and dispense drugs or to provide medical, dental, or other health-related diagnoses, care or treatment within the scope of their professional license:

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

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REGULATIONS

Controlled Substances Regulations

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

O.A.C. § 475:30-1-3.

475:30-1-3. Purpose of issuance of prescriptions

(a) A prescription for a controlled dangerous substance to be effective must be issued for a legitimate medical purpose by a registered or otherwise authorized individual practitioner acting in the usual course of his/her professional practice. The responsibility for the proper prescribing and dispensing of controlled dangerous substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription, as the filling of a prescription is not incumbent on the pharmacy. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of Title 63 Okl.St.Ann. § § 2-309 and 2-312, and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled dangerous substances.

REGULATIONS

Medical Board Regulations

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:* Clarifies for physicians the 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, and the practitioners who provide it.

OAC 435:10-7-4

435:10-7-4 Unprofessional Conduct

"The Board has the authority to revoke or take other disciplinary action against a licensee or certificate holder for unprofessional conduct. Pursuant to 59 O.S., 1991, Section 509, "Unprofessional Conduct" shall be considered to include :

(1) Indiscriminate or excessive prescribing, dispensing, or administering of Controlled or Narcotic Drugs.

(2) Prescribing, dispensing or administering of Controlled substances or Narcotic drugs in excess of the amount considered good medical practice or prescribing, dispensing or administering controlled substances or narcotic drugs without medical need in accordance with published standard.

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(47) 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 alleviating pain or discomfort in accordance with Oklahoma Administrative Code 435:10-7-11, even if such use may increase the risk of death, so long as it is not also furnished for the purpose of causing, or the purpose of assisting in causing, death for any reason.

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

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT: Although it is reasonable to expect physicians to avoid contributing to diversion, "excessive" implies there is a known standard, but the standard is not specified.

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REGULATIONS

Medical Board Regulations

O.A.C. § 435:10-7-11

435:10-7-11 Use of controlled substances for the management of chronic pain

The Board has recognized that principles of quality medical practice dictate that the people of the State of Oklahoma have access to appropriate and effective pain relief and has adopted the following criteria when evaluating the physician's treatment of pain, including the use of controlled substances:(1) 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) 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) 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:

(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 (e.g. violation of agreement)

(4) 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) 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.

[CONTINUED ON NEXT PAGE]

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

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

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

CATEGORY B:
Issues related to patients

COMMENT:
Acknowledges 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 A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

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REGULATIONS

Medical Board Regulations

[CONTINUED]

(6) Records should remain current and be maintained in an accessible manner, readily available for review. The physician should keep accurate and complete records to include:

(A) the medical history and physical examination (including vital signs),

(B) diagnostic, therapeutic and laboratory results,

(C) evaluations, consultations and follow-up evaluations,

(D) treatment objectives,

(E) discussion of risks and benefits,

(F) informed consent,

(G) treatments,

(H) medications (including date, type, dosage and quantity prescribed),

(I) instructions and agreements and

(J) periodic reviews.

(7) To prescribe, dispense or administer controlled substances, the physician must be licensed in Oklahoma 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.

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

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Madison, Wisconsin

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REGULATIONS

Osteopathic Board Regulations

O.A.C. § 510:5-7-1.

510:5-7-1. Unprofessional conduct relating to prescribing or dispensing dangerous drugs

The Board has the right to refuse to issue, renew or reinstate a license and may revoke a license or impose other appropriate sanctions for unprofessional conduct. In addition to those acts of unprofessional conduct listed in Title 59 O.S., Section 637 the following acts shall be included without limiting, in any way the Board's ability to interpret other acts as unprofessional conduct:
(1) Indiscriminate or excessive prescribing, dispensing or administering controlled dangerous drugs.

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O.A.C. § 510:5-9-2.
510:5-9-2. Guidelines and requirements

This rule requires that diagnosis be documented, it requires that certain records be maintained, and it requires that the physician must discuss the risks and benefits with the patient or the patient's guardian.(1) To treat a patient's intractable pain, as long as the benefit of the expected relief outweighs the risk, even if the use of the drug increases the risk of death, so long as it is not furnished for the purpose of causing, or the purpose of assisting in causing death, the physician may prescribe or administer Schedule II, III, IV or V controlled dangerous substances or other pain relieving drugs in higher than normal dosages when, in that physician's judgment, the higher dosages are necessary to produce the desired therapeutic effect.

(2) The determination of intractable pain must include a complete medical history and physical examination which includes an assessment of the patient's pain, physical and psychological function, substance abuse history, underlying or co-existing diseases or conditions and the presence of a recognized medical indication for the use of an analgesic.

(3) The treatment plan must state objectives by which treatment success can be evaluated, such as pain relief and or improved physical and psychological function, and must indicate what further diagnostic evaluations or other treatments are planned. The drug therapy must be tailored to the individual needs of each patient.

(4) The course of treatment and any new information about the etiology of the intractable pain must be reviewed periodically, at least annually, with consideration given to referral for a current second opinion. The continuation or modification of treatment will depend on the results of this review and the evaluation of the patient's progress toward the treatment objectives. If the patient has not improved, the physician must assess the appropriateness of continuing the current therapy and the trial of other modalities.

(5) The management of intractable pain in patients with a history of substance abuse requires extra care, monitoring, documentation and consultation with addiction medicine specialists, and may include the use of agreements between the physician and patient specifying rules for medication use and consequences for its misuse.

(6) The physician must discuss the risks and benefits of the use of controlled substances with the patient or the patient's guardian and obtain informed consent prior to proceeding if it substantially increases the risk of death.

(7) Accurate and complete records documenting these requirements must be kept.

(8) To prescribe controlled substances, the physician must be licensed in Oklahoma, have a valid controlled substances registration and comply with federal and state regulations for issuing controlled substances prescriptions.

[CONTINUED ON NEXT PAGE]

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:* Clarifies for physicians the 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, and the practitioners who provide it.

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

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

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

CATEGORY B:
Mandated consultation

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

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

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT: Although it is reasonable to expect osteopathic physicians to avoid contributing to diversion, "excessive" implies there is a known standard, but the standard is not specified.

(+) *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 include improvements in patient functioning and quality of life.

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

CATEGORY B:
Issues related to patients

COMMENT*:* Acknowledges 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*:* Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

OKLAHOMA

REGULATIONS

Osteopathic Board Regulations

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that it is appropriate medical practice for physicians to prescribe for indications not listed in product package inserts, and is consistent with federal law.

[CONTINUED]

(9) Expert clinical testimony may be used to prove a violation of this rule. As used herein, a "clinical expert" is a physician who, by reason of specialized education or substantial relevant experience in pain management, has knowledge regarding current standards, practices and guidelines.

(10) Nothing in this rule shall limit a physician's authority to prescribe or administer prescription drug products beyond the customary indications as noted in the manufacturer's package insert for use in treating intractable pain, provided the drug is recognized for treatment of intractable pain in standard reference compendia or medical literature.

REGULATIONS

Pharmacy Board Regulations

O.A.C. § 535:10-3-1.2.

535:10-3-1.2. Violations of professional conduct

Violations of the rules of professional conduct, which may also be called unprofessional conduct, include, but are not limited to, the following:

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(10) Not attempting to address the possible addiction or dependency of a patient to a drug dispensed by the pharmacist, if there is reason to believe that the patient may be dependent or addicted.

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

CATEGORY C:
Conflicting or inconsistent policies or provisions

COMMENT:
Implementing this policy could be complicated by Oklahoma's definition of "drug dependence" in statute, which confuses physical dependence with drug dependence, and can lead to patients with pain being misidentified as a "drug dependent person."

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

OKLAHOMA

OTHER GOVERNMENTAL POLICY

Medical Board Policy Statement

Number 138

SUBJECT: Use of Controlled Substances for the Treatment of Pain

POLICY:

The Oklahoma State Board of Medical Licensure and Supervision (Board) recognizes that principles of quality medical practice dictate that the people of the State of Oklahoma 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. 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, 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 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 Oklahoma 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.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 2:*
Pain management is part of healthcare 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 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: Identifies the potential impact of important barriers on the provision of effective pain care.

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

2013

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Madison, Wisconsin

OKLAHOMA

OTHER GOVERNMENTAL POLICY

Medical Board Policy Statement

(CONTINUED)

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

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

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

(+) *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 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 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 goal of pain treatment should include improvements in patient functioning and quality of life.

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OKLAHOMA

STATUTES

Nursing Home Care Act

63 Okl. St. § 1-1918B

§ 1-1918B. Intent of Legislature regarding nursing home residents' pain--Nursing homes to assess residents' pain--Rules and regulations regarding pain management

A. It is the intent of the Legislature that pain experienced by nursing home residents be assessed and treated promptly, effectively, and for as long as pain persists.

B. On and after July 1, 2005, every nursing facility licensed pursuant to the Nursing Home Care Act shall, as a condition of licensure, include pain as an item to be assessed at the same time as vital signs are taken. The nursing 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.

C. The State Board of Health shall promulgate rules, pursuant to recommendations issued by the State Advisory Council on Pain Management, for assessing and documenting pain.

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (promulgating rules) for nursing homes to ensure that pain management is an essential part of patient care.

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Recognizes that pain management is an essential part of nursing home care.

STATUTES

Assisted Suicide Prevention Act

63 Okl. St. § 3141.4

§ 3141.4. Acts not constituting violations

A. A licensed health care professional who administers, prescribes, or dispenses medications or procedures for the purpose of alleviating pain or discomfort, even if their use may increase the risk of death, shall not be deemed to have violated Section 3 of this act or Section 813 or 814 of Title 21 of the Oklahoma Statutes so long as such medications or procedures are not also furnished for the purpose of causing, or the purpose of assisting in causing, death for any reason.

B. A licensed health care professional who withholds or withdraws a medically administered, life-sustaining procedure does not violate Section 3 of this act or Sections 813 or 814 of Title 21 of the Oklahoma Statutes.

C. This section shall not be construed to affect the duty of care or the legal requirements concerning acts or omissions under subsections A or B of this section.

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians the 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, and the practitioners who provide it.

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Madison, Wisconsin

OKLAHOMA

REGULATIONS

Hospice

O.A.C. § 310:661-5-2.1

310:661-5-2.1 Interdisciplinary group, care planning, and coordination of services

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(d) Content of the plan of care. The hospice shall develop an individualized written plan of care for each patient. The plan of care shall reflect patient and family goals and interventions based on the problems identified in the initial, comprehensive, and updated comprehensive assessments. The plan of care shall include all services necessary for the palliation and management of the terminal illness and related conditions, including at least the following:

(1) Interventions to manage pain and symptoms;

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O.A.C. § 310:661-5-4.1

310:661-5-4.1 Additional rights of the patient

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(d) Rights of the patient. The patient has a right to the following:

(1) Receive effective pain management and symptom control from the hospice for conditions related to the terminal illness;

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O.A.C. § 310:661-5-9

310:661-5-9 Short-term inpatient care

(a) Inpatient care shall be available for pain control, symptom management, and respite purposes.

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

CATEGORY C:
Regulatory or policy issues

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

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

CATEGORY C:
Regulatory or policy issues

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

REGULATIONS

Hospital Standards

O.A.C. § 310:667-3-3

310:667-3-3 Medical therapies

The policies and procedures concerning medical therapies shall include:

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(4) Policies for patients who are diagnosed as terminal and the therapies which are aimed at optimizing comfort and alleviating pain.

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

CATEGORY C:
Regulatory or policy issues

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

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OKLAHOMA

REGULATIONS

Nursing and Specialized Facilities

O.A.C. § 310:675-7-9.1. et seq

310:675-7-9.1 Written administrative policies and procedures

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(k) The facility shall adopt a nursing policy and procedure manual, which shall detail all nursing procedures performed within the facility. All procedures shall be in accordance with accepted nursing practice standards, and shall include, but not be limited to, the following:

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(13) Pain assessment and treatment.

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310:675-9-1.1 Nursing and personal care services

(a) The facility shall ensure that resident rights are respected in the provision of care.

(b) Basic nursing and personal care shall be provided for residents as needed.

(1) Nursing care shall include, but not be limited to:

(A) Encouraging residents to be active and out of bed for reasonable time periods.

(B) Measuring resident temperature, blood pressure, pulse and respirations at least once every thirty days and more frequently if warranted by the resident's condition, with the results recorded in the clinical record.

(i) Measuring resident weight at least once every thirty days and more frequently if warranted by the resident's condition, with the results recorded in the clinical record.

(ii) Measuring resident pain whenever vital signs are taken and more frequently if warranted by the resident's condition, with the results recorded in the clinical record.

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310:675-9-5.1 Assessment and care plans

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(c) Efforts shall be made to include the resident and resident's representative in development and implementation of the care planning process.

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(2) Resident pain assessment

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[CONTINUED ON NEXT PAGE]

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (policies and procedures) for nursing and specialized facilities to ensure that pain management is an essential part of patient care.

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

CATEGORY C:
Regulatory or policy issues

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

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

CATEGORY C:
Regulatory or policy issues

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

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Madison, Wisconsin

OKLAHOMA

REGULATIONS

Nursing and Specialized Facilities

[CONTINUED]

O.A.C. § 310:675-13-5

310:675-13-5 Nursing service

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(i) Inservice. The facility shall provide all direct care staff with two hours of inservice training specific to their job assignment per month. This training shall include, at least, the following:

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(8) Each registered nurse shall be provided training in pain assessment and pain management at the time of orientation and at least once every six months thereafter.

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (inservice training) for nursing and specialized facilities to ensure that pain management is an essential part of patient care.

REGULATIONS

Opioid Treatment Programs

O.A.C. § 450:70-3-5

450:70-3-5 Intake assessment and record content

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(u) The OSTP shall have written policy and procedure requiring treatment by a multi-disciplinary team of medical practitioners; including specialists in addiction medicine and pain management, for physically dependent or addicted patients with a chronic pain disorder. The OSTP shall coordinate with the physician treating the patient for pain.

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(+) *CRITERION 8:*
OTHER PROVISIONS THAT MAY ENHANCE PAIN MANAGEMENT

CATEGORY C:
REGULATORY OR POLICY ISSUES

COMMENT: Establishes a responsibility for OTP staff to refer methadone-maintained patients who have chronic pain for treatment of their pain

(+) *CRITERION 8:*
OTHER PROVISIONS THAT MAY ENHANCE PAIN MANAGEMENT

CATEGORY B:
Issues related to patients

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

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OREGON

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 37. Alcoholic Liquors, Controlled Substances, Drugs. Chapter 475. Controlled Substances, Illegal Drug Cleanup, Paraphernalia, Precursors. Uniform Controlled Substances Act

- MEDICAL PRACTICE ACT
  Title 52. Occupations and Professions. Chapter 677. Regulation of Medicine, Podiatry and Acupuncture

- PAIN TREATMENT ACT (*Part of Medical Practice Act*)
  Title 52. Occupations and Professions. Chapter 677. Regulation of Medicine, Podiatry and Acupuncture; Physicians and Surgeons; Podiatric Physicians and Surgeons; Administration of Controlled Substances for Intractable Pain

- PHARMACY PRACTICE ACT
  Title 52. Occupations and Professions. Chapter 689. Pharmacists, Drug Outlets, Drug Sales

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*Part of Pharmacy Board Regulations*) (*No provisions found*)
  Chapter 855. Board of Pharmacy; Division 80. Schedule of Controlled Substances

- MEDICAL BOARD REGULATIONS
  Chapter 847. Oregon Medical Board

- PHARMACY BOARD REGULATIONS
  Chapter 855. Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD POLICY STATEMENT
  Oregon Medical Board. *Statement of Philosophy: Pain Management*. Adopted: April 16, 1999; Amended: July 9, 2004; Amended: April 8, 2011; Amended: January 2013.

- PHARMACY BOARD POLICY STATEMENT
  Oregon Board of Pharmacy. *Treatment and Management of Pain*. Adopted: June, 2006.

- JOINT BOARD POLICY STATEMENT
  Oregon Pain Management Commission. *Joint Statement on Pain Management*. Adopted: September 15, 2006.

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RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- PAIN MANAGEMENT COMMISSION
  Title 34. Human Services, Juvenile Code, Corrections; Chapter 413. Oregon Health Authority

- PROFESSIONAL PRACTICE
  Title 52. Occupations and Professions.
  Chapter 670. Occupations and Professions Generally
  Chapter 676. Health Professions Generally

- PAIN MANAGEMENT COMMISSION
  Chapter 409. Oregon Health Authority, Office for Oregon Health Policy and Research.
  Division 50. Pain Management

- PERSONAL CARE SERVICES
  Chapter 411. Department of Human Services, Seniors and People with Disabilities Division.
  Division 34. Personal Care Services

OREGON

STATUTES

Controlled Substances Act

ORS § 475.005

475.005. Definitions for ORS 475.005 to 475.285 and 475.940 to 475.999.

As used in *ORS 475.005* to *475.285* and *475.940* to *475.999*, unless the context requires otherwise:

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(18) "Practitioner" means physician, dentist, veterinarian, scientific investigator, certified nurse practitioner, physician assistant or other person licensed, registered or otherwise permitted by law to dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in this state but does not include a pharmacist or a pharmacy.

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

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OREGON

STATUTES

Medical Practice Act

ORS § 677.085

677.085. What constitutes practice of medicine.

A person is practicing medicine if the person does one or more of the following:

(1) Advertise, hold out to the public or represent in any manner that the person is authorized to practice medicine in this state.

(2) For compensation directly or indirectly received or to be received, offer or undertake to prescribe, give or administer any drug or medicine for the use of any other person.

(3) Offer or undertake to perform any surgical operation upon any person.

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

(4) Offer or undertake to diagnose, cure or treat in any manner, or by any means, methods, devices or instrumentalities, any disease, illness, pain, wound, fracture, infirmity, deformity, defect or abnormal physical or mental condition of any person.

(5) Except as provided in ORS 677.060, append the letters "M.D." or "D.O." to the name of the person, or use the words "Doctor," "Physician," "Surgeon," or any abbreviation or combination thereof, or any letters or words of similar import in connection with the name of the person, or any trade name in which the person is interested, in the conduct of any occupation or profession pertaining to the diagnosis or treatment of human diseases or conditions mentioned in this section.

ORS § 677.228

677.228. Automatic lapse of license for failure to pay registration fee or report change of location; reinstatement.

(1) A person's license to practice under this chapter automatically lapses if the licensee fails to:

(a) Pay the registration fee as required by rule of the Board of Medical Examiners for the State of Oregon.

(b) Notify the board of a change of location not later than the 30th day after such change.

(c) Complete prior to payment of the registration fee described in paragraph (a) of this subsection, or provide documentation of previous completion of, if required by rule of the board:

(A) A pain management education program approved by the board and developed in conjunction with the Pain Management Commission established under ORS 409.500; or

(B) An equivalent pain management education program, as determined by the board.

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

CATEGORY C:
Regulatory or policy issues

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

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OREGON

STATUTES

Pain Treatment Act

ORS § 677.470-677.480

677.470. Definitions for ORS 677.470 to 677.480.

As used in ORS 677.470 to 677.480:

(1) "Controlled substance" has the meaning given that term under ORS 475.005.

(2) "Health care professional" means a person licensed by a health professional regulatory board who is practicing within the scope of practice of that licensure and who is authorized to prescribe or administer controlled substances.

(3) "Health professional regulatory board" has the meaning given that term in ORS 676.440.

677.474. Administration of controlled substances for pain allowed; exceptions.

(1) Notwithstanding any other provision of this chapter and notwithstanding ORS 678.010 to 678.410 and ORS chapters 679 and 689, a health care professional may prescribe or administer controlled substances to a person in the course of treating that person for a diagnosed condition causing pain.

(2) A health care professional shall not be subject to disciplinary action by a health professional regulatory board for prescribing or administering controlled substances in the course of treatment of a person for pain with the goal of controlling the patient's pain for the duration of the pain.

(3) Subsections (1) and (2) of this section do not apply to:

(a) A health care professional's treatment of a person for chemical dependency resulting from the use of controlled substances;

(b) The prescription or administration of controlled substances to a person the health care professional knows to be using the controlled substances for nontherapeutic purposes;

(c) The prescription or administration of controlled substances for the purpose of terminating the life of a person having pain, except as allowed under ORS 127.800 to 127.897; or

(d) The prescription or administration of a substance that is not a controlled substance approved by the United States Food and Drug Administration for pain relief.

(4) Subsection (2) of this section does not exempt the governing body of any hospital or other medical facility from the requirements of ORS 441.055.

677.480. Discipline.

ORS 677.474 does not prohibit a health professional regulatory board from placing on probation or denying, revoking, limiting or suspending the license of any health care professional who does any of the following:

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

(2) Fails to keep a complete and accurate record of controlled substance purchases, dispensing and disposal as required by the Comprehensive Drug Abuse Prevention and Control Act of 1970 (P.L. 91-513), other federal law or ORS 475.005 to 475.285 and 475.840 to 475.980.

(3) Prescribes controlled substances without a legitimate medical purpose.

(4) Prescribes, administers or dispenses controlled substances in a manner detrimental to the best interest of the public.

(5) Prescribes, administers or dispenses a controlled substance in a manner prohibited under ORS 475.005 to 475.285 or 475.840 to 475.980.(6) Falsifies prescription information, including, but not limited to, the identity of the recipient.

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

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

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

2013

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OREGON

STATUTES

Pharmacy Practice Act

ORS § 689.005

689.005. Definitions.

As used in this chapter:

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(29) "Practitioner" means a person licensed and operating within the scope of such license to prescribe, dispense, conduct research with respect to or administer drugs in the course of professional practice or research:

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ORS § 689.285

689.285. Continuing pharmacy education; rules; fees.

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(3) In accordance with applicable provisions of ORS chapter 183, the board shall make reasonable rules:

(a) Prescribing the procedure and criteria for approval of continuing pharmacy education programs, including the number of hours of courses of study necessary to constitute a continuing pharmacy education unit and the number of continuing pharmacy education units required annually for renewal of a pharmacist license.

(b) Prescribing the scope of the examinations given by the board including grading procedures.

(c) Prescribing the content of the form to be submitted to the board certifying completion of an approved continuing pharmacy education program.

(d) Necessary to carry out the provisions of this chapter.

(e) Prescribing the completion of:
(A) A pain management education program approved by the board and developed in conjunction with the Pain Management Commission established under ORS 409.500; or
(B) An equivalent pain management education program, as determined by the board.

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

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

CATEGORY C:
Regulatory or policy issues

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

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REGULATIONS

Medical Board Regulations

(+) *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.

Or. Admin. R. 847-010-0100

847-008-0075 Mandatory Pain Management Education

(1) All licensees of the Oregon Board of Medical Examiners, except the licensees listed in section (2) of this rule, will complete mandatory continuing medical education (CME) in the subjects of pain management and/or the treatment of terminally ill and dying patients as follows:

(a) A one-hour pain management course specific to Oregon provided by the Pain Management Commission of the Department of Human Services; and

(b) A minimum of six continuing medical education credit hours in the subjects of pain management and/or the treatment of terminally ill and dying patients. Any combination of CME coursework focusing on pain management and/or treatment of terminally ill and dying patients may be used to fulfill this requirement.

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Or. Admin. R. 847-015-0030

847-015-0030 Written Notice Disclosing the Material Risks Associated with Prescribed or Administered Controlled Substances for the Treatment of "Intractable Pain"

(1) Definitions

(a) "Controlled substance" has the meaning given that term under *ORS 475.005*.

(b) "Intractable pain" means a chronic pain state in which the cause of the pain cannot be removed or otherwise treated and for which, in the generally accepted course of medical practice, no relief or cure of the cause of the pain has been found after reasonable efforts, including, but not limited to, evaluation by the attending physician.

(2) Controlled substances may be prescribed for long term treatment of intractable pain. The attending physician records must contain the attending physician's examination, diagnosis and any other supporting diagnostic evaluations and other therapeutic trials, including records from previous providers. If there is a consulting physician, written documentation of his/her corroborating findings, diagnosis and recommendations shall be included in the record.

(3) Before initiating treatment of intractable pain with controlled substances or, when it is apparent that pain which is already being treated with controlled substances has now become intractable, the attending physician shall discuss with the patient the procedures, alternatives and risks associated with the prescribing or administering controlled substances for long term management of pain. Following the discussion the patient will be given an opportunity to request further explanations. When the patient is satisfied with the explanation of the issues related to the prescribing of these drugs over long periods of time, the attending physician shall provide to the person and the person shall sign a written document outlining the issues discussed associated with the prescribed or administered controlled substances.

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(+) *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 when considering treatment options.

Pain & Policy Studies Group
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Madison, Wisconsin

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REGULATIONS

Medical Board Regulations

(CONTINUED)

Or. Admin. R. 847-015-0030

(4) The material risk notice should include but not be limited to:

(a) The diagnosis;

(b) The controlled substance and/or group of controlled substances to be used;

(c) Anticipated therapeutic results;

(A) Pain relief;

(B) Functional goals;

(d) Alternatives to controlled substance therapy;

(e) Potential additional therapies to be used in conjunction with controlled substances; and

(f) Potential side effects (if applicable):

(A) Cardiovascular;

(B) Central Nervous System;

(C) Gastrointestinal;

(D) Endocrine;

(E) Respiratory;

(F) Dermatologic;

(G) Urinary;

(H) Pregnancy, and

(I) Other.

(g) Allergy Potential;

(h) Interaction/Potentiation of other medications;

(i) Potential for dose escalation/tolerance;

(j) Withdrawal precautions;

(k) Potential for dependence and addiction;

(l) Potential for impairment of judgment and/or motor skills;

(m) Satisfaction with or desire for more explanation; and

(n) Patient signature (dated).

(5) The material risk consent form will be maintained as a permanent component of the patient record as shall documentation of long term follow-up to demonstrate the continued need for this form of therapy. A dispensing record of the amount and dose of the prescribed or administered controlled substances shall be maintained as part of the patient record.

(+) *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 include improvements in patient functioning and quality of life.

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

OREGON

REGULATIONS

Pharmacy Board Regulations

Or. Admin. R. 855-021-0016

855-021-0016 Continuing Education in Pain Management

(1) A pharmacist licensed under these rules must complete seven hours of continuing education in pain management as detailed in the following sub-sections. This is a one-time requirement:

(a) A one-hour pain management course, specific to Oregon, provided by the Pain Management Commission of the Oregon Department of Human Services; and

(b) A minimum of six hours of continuing education in pain management. This requirement may be fulfilled by any combination of continuing education coursework focusing on pain management including but not limited to the treatment of terminally ill and dying patients, and those with chronic, non-malignant pain.

(2) A licensee must complete the required continuing education within 24 months of their first license renewal after January 2, 2006.

(3) A licensee must retain for three years, documentation showing they have met the requirement of this rule, and must provide this documentation if requested by the Board.

(4) The pain management continuing education required under this rule shall count towards the 1.5 continuing pharmacy education units required under *OAR 855-021-0005*, in the license cycle in which the pain management continuing education is completed. Any portion of this continuing education may count towards the requirement in *OAR 855-021-0010(1)(a)* for 11 hours continuing education in therapeutics.

(+) *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.

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

OREGON

OTHER GOVERNMENTAL POLICY

Medical Board Policy Statement

STATEMENT OF PHILOSOPHY: PAIN MANAGEMENT

Pain Management

The OMB urges the skillful use of effective pain control for all patients. It is important for providers to be well-informed on relevant pain management techniques and hone their skills for the optimal treatment of their patients, taking into account the etiology of the pain. Types of pain include, but are not limited to, acute post-operative or traumatic pain, chronic non-cancer pain, chronic pain caused by malignancies and pain associated with terminal illness. Providers are encouraged to treat pain within the scope of their practice and refer patients to the appropriate specialists when indicated.

Acute Pain
Effective treatment of acute pain promotes recovery and return to normal function. The potential for addiction is low when short courses of opioids are used to treat acute pain and discontinued as the patient recovers. Inadequately managed acute pain may result in chronic pain. Patients who are not recovering as expected must be carefully assessed. Skillful pain management techniques including oral, parenteral and, when available, regional pain management techniques, can achieve maximum patient comfort and may reduce the need for opioids.

Chronic Pain
Patients with chronic pain require complex care and treatment decisions for multi-faceted problems. Providers have a responsibility to diagnose and manage chronic pain while maximizing the benefits and minimizing the potential adverse effects of treatment. Opioids are not always required or effective for the treatment of chronic pain, and they should be discontinued if the patient's pain control or function does not improve with their use.

Pain management treatment must be evidence-based and individualized to the patient. Oregon statute protects providers from disciplinary action by the Board when prescribing or administering controlled substances as part of a treatment plan for pain with the goal of controlling the patient's pain for the duration of the pain. However, prescribing controlled substances without a legitimate medical purpose is prohibited.

Patient safety should be a key factor in determining a treatment plan for pain management. When the provider prescribes opioids as part of the treatment plan, the provider must consider drug safety, efficacy and treatment goals for the patient. Safe opioid prescribing requires knowledge of the pharmacology of various opioid classes, and of potential drug interactions. Opioids are most likely to be successful in reducing pain and restoring function when they are combined with other pain management approaches such as physical therapy and psychological techniques.

When prescribing opioids for chronic pain, Oregon law requires practitioners to provide careful assessment and documentation of the medical condition causing pain as well as co-morbid medical and mental health conditions. Goals for treatment should be established with the patient before prescribing opioids. The provider's assessment, diagnosis and discussion must be documented in the patient record. The diagnosis, drugs used, goals, alternatives, and side effects must be included in a signed document demonstrating consent and understanding of the treatment plan and its risks. A sample document may be found here. In addition to the signed informed consent document, a written patient-provider agreement is recommended for patients requiring opioids for chronic pain. In all cases of pain management, practitioners should maintain records to track prescriptions and coordinate care with other treating practitioners.

[CONTINUED ON NEXT PAGE]

(+) *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 goal of pain treatment should 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*:* Recognizes the need for a multidisciplinary approach to pain management.

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

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

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Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

OREGON

OTHER GOVERNMENTAL POLICY

Medical Board Policy Statement

[CONTINUED]

The OMB recommends enrollment and participation in the Oregon Prescription Drug Monitoring Program (PDMP), a division of the Oregon Health Authority, to help guide treatment plans. The PDMP is a database that allows prescribers of controlled substances to access a patient's name, the controlled substance prescribed, the dosage, and the name and contact information of the prescriber.

Terminal Illness

The OMB believes that physicians should make every effort to relieve the pain and suffering of their terminally ill patients. Patients nearing the end of their lives should receive sufficient opioid dosages to produce comfort. The physician should acknowledge that the natural dying process usually involves declining blood pressures, decreasing respirations and altered levels of consciousness. Opioids should not be withheld on the basis of physiologic parameters when patients continue to experience pain.

Some physicians express concerns that the use of opioids in these patients may hasten death through pneumonia or respiratory depression. For these reasons, at times physicians may have limited the use of opioids in dying patients out of fear that they may be investigated for inappropriate prescribing or allegations of euthanasia.

The OMB is concerned that such fear on the part of physicians may result in inadequate pain control and unnecessary suffering in terminally ill patients. The OMB encourages physicians to employ skillful and compassionate pain control for patients near the end of life and believes that relief from suffering remains the physician's primary obligation to these patients.

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians the 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, and the practitioners who provide it.

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Madison, Wisconsin

OREGON

OTHER GOVERNMENTAL POLICY

Pharmacy Board Policy Statement

Treatment and Management of Pain

Healthcare leaders and patient advocates have come together in legislatively mandated pain commission to work toward providing well managed and adequate pain control to the citizens of Oregon. Involvement with The Oregon Pain Commission has prompted the Board of Pharmacy to take a leadership role in promoting the effective management of pain for the state's citizens. The mission of the Oregon Board of Pharmacy is to promote, preserve and protect the public health, safety and welfare by regulating the practice of pharmacy and the distribution of drugs within and into the state. As a part of that endeavor, the Board strives to ensure that all Oregonians have access to appropriate pain relief. Appropriate and effective pain therapies, including the use of controlled substance medications, can greatly improve a patient's quality of life and reduce unnecessary morbidity and cost associated with inadequate treatment of pain.

Inadequate pain control, in some cases, may result from a lack of knowledge or understanding of proper pain management by health care professionals and patients. Under-treatment of pain can also be the result of fear or misunderstanding of the position of regulatory boards or law enforcement agencies regarding the use of controlled substances in the treatment and management of pain. This statement is intended to clarify the Board of Pharmacy's position regarding pain management in the practice of pharmacy.

The Oregon Board of Pharmacy recognizes that the use of controlled substances, including opioid analgesics, is often essential for the treatment and management of both acute and chronic pain of any origin. A pharmacist involved in the care of a patient undergoing treatment for pain should not fear disciplinary action from the board for dispensing controlled substances, including opioid analgesics, for a legitimate medical purpose as defined in the state of Oregon. Pharmacists' involvement with pain management in the usual course of their professional practice should be based upon accepted scientific knowledge and sound clinical judgment.

The Board of Pharmacy also recognizes that controlled substances, by their nature, carry with them a risk of abuse or misuse. All health care professionals must remain alert to the fact that these drugs are subject to abuse and that some people will seek them for inappropriate uses. Care must be taken to balance this risk with the desired outcome of effective pain control for all who are in need.

Dispensing of controlled substances for the treatment of pain must be based upon a valid prescription issued within currently accepted standards. All pharmacists are encouraged to increase their knowledge of current medical standards for the treatment of pain and develop effective strategies for delivering pharmaceutical care to patients suffering with pain. Pharmacists should actively participate on the health care team by providing expertise to the patient, physician, nurse and hospice provider or other care giver. As a member of the health care team, pharmacists can contribute to positive therapeutic outcomes for patients suffering from pain and can reduce the potential for drug abuse. Detailed documentation of the patient's medical condition and clinical response to treatment provides the strongest foundation for providing optimal patient care.

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies the potential impact of important barriers on the provision of effective pain care.

(+) *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 the need for a multidisciplinary approach to pain management.

(+) *CRITERION 4:*
Encourages pain management

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

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

(+) *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.

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OREGON

OTHER GOVERNMENTAL POLICY

Joint Board Policy Statement

Oregon Pain Management Commission Joint Statement on Pain Management

This statement is intended to join Oregon Healthcare Boards, professionals and interested parties in a commitment to improve the pain management services of all Oregon citizens. Towards this end, the undersigned groups issue the following joint statement:

Inadequate pain relief is a serious public health problem in the United States. Estimates of Americans suffering from chronic pain range from 20%-30% of the population. The physical, psychological, emotional and behavioral effects of under treated pain are serious and wide-ranging. Pain continues to be undertreated. This causes unnecessary suffering and reduced function and quality of life in people with pain as well as increased healthcare utilization and lost workforce productivity.

Several reasons have been identified as barriers to effective pain treatment including: lack of knowledge of healthcare standards and guidelines, lack of reimbursement for multidisciplinary pain care, fear of sanctions by regulatory boards or law enforcement agencies, lack of familiarity of regulatory agencies and misunderstanding of addiction, tolerance and physical dependence.

To effectively assist patients with the effective management of pain, all Oregon healthcare professionals should, within their scope of practice:

- Routinely assess all patients for pain. All pain should be evaluated with a complete history and physical with laboratory and diagnostic tests when indicated
- Work with a multidisciplinary team to develop and implement a comprehensive treatment plan utilizing appropriate pharmacological and non-pharmacological interventions for treatment of pain and suffering
- Regularly re-evaluate the effectiveness of the treatment plan and adjust as needed
- Document the complete assessment and plan of care in a clear, consistent and accurate manner
- Treat side effects
- Be mindful of the risks of addiction and diversion of controlled substances and minimize risks using an opioid treatment plan. Recognize that people with chemical dependency also deserve to have pain effectively treated and that opioids may be a part of treatment
- Refer and consult with specialists as necessary
- Comply with all state and federal laws and encourage changes to promote improved pain management

A licensed practitioner involved in the care of a person in pain should not fear disciplinary action from their respective licensing board for prescribing or dispensing controlled substances, including opioid analgesics, for a legitimate medical purpose as defined by the State of Oregon, based on accepted scientific knowledge and sound clinical judgment.

All Oregon practitioners are encouraged to increase their knowledge of current guidelines and standards for the treatment of pain, develop effective strategies for delivering effective care to patients suffering from pain and actively participate in the healthcare team providing expertise to the patient. By working in a team, optimal care can be provided while striving to reduce the potential for drug abuse. Detailed and complete documentation of the patient's assessment and treatment response provides the foundation for optimal patient care.

The Pain Management Commission's Joint Statement on Pain Management is supported by the following licensing boards and professional organizations:

Board of Chiropractic Examiners; Board of Psychologist Examiners; Board of Medical Examiners; Board of Nursing; Physical Therapist Licensing Board; Occupational Therapy Licensing Board; Board of Naturopathic Examiners; Board of Dentistry; Board of Pharmacy and Board of Medical Examiners-Acupuncture Program.

Others endorsing the statement are the Oregon Acupuncture Association; Oregon Psychological Association; Oregon State Pharmacy Association; Pain Society of Oregon; Oregon Hospice Association; Leukemia and Lymphoma Society; Oregon Academy of Family Physicians; Oregon Medical Directors Association; Oregon Geriatrics Society; Oregon Society of Physician Assistants; Oregon Health Care Association; and the Oregon Alliance of Senior and Health Services.

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

CATEGORY B:
Issues related to patients

COMMENT: Acknowledges 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: Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Identifies the potential impact of important barriers on the provision of effective pain care.

(+) *CRITERION 4:*
Encourages pain management

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

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OREGON

STATUTES

Pain Management Commission

ORS § 409.570

409.570. Rules.

In accordance with applicable provisions of ORS chapter 183, the Pain Management Commission may adopt rules necessary to implement *ORS 413.570* to *413.599*.

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (Pain Management Commission) to improve pain management.

ORS § 413.570-413.590

413.570. Pain Management Commission; duties; staffing.

(1) The Pain Management Commission is established within the Oregon Health Authority. The commission shall:

(a) Develop pain management recommendations;

(b) Develop ways to improve pain management services through research, policy analysis and model projects; and

(c) Represent the concerns of patients in Oregon on issues of pain management to the Governor and the Legislative Assembly.

(2) The pain management coordinator of the authority shall serve as staff to the commission.

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (rules) for the Pain Management Commission to ensure that pain management is an essential part of patient care.

413.572. Additional duties of commission.

(1) The Pain Management Commission shall:

(a) Develop a pain management education program curriculum and update it biennially.

(b) Provide health professional regulatory boards and other health boards, committees or task forces with the curriculum.

(c) Work with health professional regulatory boards and other health boards, committees or task forces to develop approved pain management education programs as required.

(d) Review the pain management curricula of educational institutions in this state that provide post-secondary education or training for persons required by ORS 13.590 to complete a pain management education program. The commission shall make recommendations about legislation needed to ensure that adequate information about pain management is included in the curricula reviewed and shall report its findings to the Legislative Assembly in the manner required by ORS 192.245 by January 1 of each odd-numbered year.

(b) As used in this subsection, "educational institution" has the meaning given that term in ORS 348.105.

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (education program curriculum) to provide practitioners information/education about pain management, as well as to review the curricula that is created.

413.590. Pain management education required of certain licensed health care professionals; duties of Oregon Medical Board; rules.

(1) A physician assistant licensed under ORS chapter 677, a nurse licensed under ORS chapter 678, a psychologist licensed under ORS 675.010 to 675.150, a chiropractic physician licensed under ORS chapter 684, a naturopath licensed under ORS chapter 685, an acupuncturist licensed under ORS 677.759, a pharmacist licensed under ORS chapter 689, a dentist licensed under ORS chapter 679, an occupational therapist licensed under ORS 675.210 to 675.340 and a physical therapist licensed under ORS 688.010 to 688.201 must complete one pain management education program described under ORS 413.572.

(2) The Oregon Medical Board, in consultation with the Pain Management Commission, shall identify by rule physicians licensed under ORS chapter 677 who, on an ongoing basis, treat patients in chronic or terminal pain and who must complete one pain management education program established under ORS 413.572. The board may identify by rule circumstances under which the requirement under this section may be waived.

(+) *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.

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OREGON

STATUTES

Professional 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.

ORS § 676.440

676.440. Duty of health professional regulatory boards to encourage multidisciplinary pain management services.

(1) Health professional regulatory boards shall encourage the development of state-of-the-art multidisciplinary pain management services and the availability of these services to the public.

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(+) *CRITERION 4:*
Encourages pain management

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REGULATIONS

Pain Management Commission

Or. Admin. R. 409-050-0100

409-050-0100 Purpose

The Pain Management Commission was established within the Department of Human Services for the purpose of developing pain management <u>educational programs, recommendations and curriculum</u>; representing patient concerns to the Governor and Legislative Assembly; and creating ways to improve pain management in Oregon through research, policy analysis, and model projects. In addition, the Pain Management Commission is charged with developing a specific pain management educational program for required completion by health care professionals under specified Licensing Boards.

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

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

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

REGULATIONS

Personal Care Services

Or. Admin. R. 411-034-0070

411-034-0070 State Plan Personal Care Service Assessment, Authorization, and Monitoring

(1) CASE MANAGER RESPONSIBILITIES.
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(2) LONG TERM CARE (LTC) COMMUNITY NURSING SERVICES. A LTC community nurse is a licensed, registered nurse (RN) who has been approved under a contract or provider agreement with the Department, Division, or Designee to provide nursing assessment for indicators identified in subsection (a) of this section and may provide on-going nursing services as identified in subsection (b) of this section to certain individuals served by the Department, Division, or Designee. Individuals receiving LTC community nursing services are primarily older adults and adults with disabilities.

(a) A case manager may refer a LTC community nurse where available, for nursing assessment and monitoring when it appears an individual needs assistance to manage health support needs and may need delegated nursing tasks, nurse assessment and consultation, teaching, or services requiring RN monitoring. Indicators of the need for LTC community nurse assessment and monitoring include:

(A) Complex health problem or multiple diagnoses resulting in the need for assistance with health care coordination;

(B) Medical instability, as demonstrated by frequent emergency care, physician visits, or hospitalizations;

(C) Behavioral symptoms or changes in behavior or cognition;

(D) Nutrition, weight, or dehydration issues;

(E) Skin breakdown or risk for skin breakdown;

(F) <u>Pain issues</u>;

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

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

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

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PENNSYLVANIA

STATUTES

- CONTROLLED SUBSTANCES ACT
  Pennsylvania Statutes; Title 35. Health and Safety
  Chapter 6. The Controlled Substance, Drug, Device and Cosmetic Act
  Chapter 6B. Drugs, Poisons and Dangerous Substances

- MEDICAL PRACTICE ACT (*No provisions found*)
  Pennsylvania Statutes; Title 63. Professions and Occupations (State Licensed);
  Chapter 12. Medical Practice Act of 1985

- OSTEOPATHIC PRACTICE ACT (*No provisions found*)
  Pennsylvania Statutes; Title 63. Professions and Occupations (State Licensed);
  Chapter 9. Osteopaths

- PHARMACY PRACTICE ACT (*No provisions found*)
  Pennsylvania Statutes; Title 63. Professions and Occupations (State Licensed);
  Chapter 11. Pharmacy Act

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Title 28. Health and Safety; Part III. Prevention of Diseases;
  Chapter 25. Controlled Substances, Drugs, Devices, and Cosmetics

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Title 49. Professional and Vocational Standards; Part 1. Department of State;
  Subpart A. Professional and Occupational Affairs;
  Chapter 16. State Board of Medicine – General Provisions
  Chapter 17. State Board of Medicine – Medical Doctors

- OSTEOPATHIC BOARD REGULATIONS (*No provisions found*)
  Title 49. Professional and Vocational Standards; Part 1. Department of State;
  Subpart A. Professional and Occupational Affairs; Chapter 25. State Board of Osteopathic Medicine

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Title 49. Professional and Vocational Standards; Part 1. Department of State;
  Subpart A. Professional and Occupational Affairs; Chapter 27. State Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
  Pennsylvania State Board of Medicine. *Guidelines for the Use of Controlled Substances in the Treatment of Pain. Pennsylvania State Board of Medicine Bulletin.* Winter, pp. 4-5, 1998-1999. Adopted: October 20, 1998.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

No policies found

Pain & Policy Studies Group
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Madison, Wisconsin

PENNSYLVANIA

STATUTES

Controlled Substances Act

35 P.S. § 780-102

§ 780-102. Definitions

(a) The definitions contained and used in the "Pennsylvania Drug and Alcohol Abuse Control Act" shall also apply for purposes of this act.

(b) As used in this act:

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"DRUG DEPENDENT PERSON" means a person who is using a drug, controlled substance or alcohol, and who is in a state of psychic or physical dependence, or both, arising from administration of that drug, controlled substance or alcohol on a continuing basis. Such dependence is characterized by behavioral and other responses which include a strong compulsion to take the drug, controlled substance or alcohol on a continuous basis in order to experience its psychic effects, or to avoid the discomfort of its absence. This definition shall include those persons commonly known as "drug addicts."

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"PRACTITIONER" means: (i) a physician, osteopath, dentist, veterinarian, pharmacist, podiatrist, nurse, scientific investigator, or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance, other drug or device in the course of professional practice or research in the Commonwealth of Pennsylvania; (ii) a pharmacy, hospital, clinic or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance, other drug or device in the course of professional practice or research in the Commonwealth of Pennsylvania.

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

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

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PENNSYLVANIA

REGULATIONS

Controlled Substances Regulations

28 Pa. Code § 25.131

§ 25.131. Every dispensing practitioner

Every pharmacy shall, at the end of each month, on forms issued for this purpose by the Office of the Attorney General of the Commonwealth, provide the Office of the Attorney General of the Commonwealth with the name of each person to whom a drug or preparation, which is classified by the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C.A. § 3801 and the act as a controlled substance in Schedule II, was sold, dispensed, distributed or given away, except when used in anesthetic procedures, together with such other information as may be required, under the act.

(-) *CRITERION 14: Undue prescription requirements*

COMMENT: This provision requires reporting. Submission to the Attorney General of the names of all pain patients who receive Schedule II pain medications suggests that there is something about these drugs or these patients that requires scrutiny by law enforcement, which may reinforce concerns about regulatory scrutiny.

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PENNSYLVANIA

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

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

Section I: Preamble

The Pennsylvania State Board of Medicine recognizes that principles of quality medical practice dictate that the citizens of the Commonwealth 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 legal requirements for prescribing controlled substances.

Inadequate pain control may result from physicians' lack of knowledge about pain management or an inadequate understanding of addiction. Fears of investigation or sanction by federal, state and local regulatory agencies may also result in an inappropriate or inadequate treatment of chronic pain patients. Accordingly, these guidelines have been developed to clarify the board's position on pain control, specifically as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management. The board has found that these guidelines are consistent with the board's regulations pertaining to prescribing, administering and dispensing controlled substances located at 49 Pa. Code §16.92.

The board recognizes that controlled substances, including opioid analgesics, are essential in the treatment of acute pain due to trauma, surgery and chronic pain due to cancer and other progressive diseases. 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 should be based upon current knowledge and research and includes the use of both pharmaceutical and non-pharmaceutical modalities. Pain should be assessed and treated promptly and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.

The State Board of Medicine is obligated under the law 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 and non-medical uses.

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 and in compliance of applicable state or federal law.

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 treat the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, physiological, 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.

[CONTINUED ON NEXT PAGE]

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

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

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

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

(+) *CRITERION 4:*
Encourages pain management

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

(+) *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 include improvements in patient functioning and quality of life.

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PENNSYLVANIA

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

[CONTINUED]

Section II: Guidelines
The board has found that the following guidelines indicate acceptable standards of practice when evaluating the use of controlled substances for pain control:

1. Evaluation of the Patient

A complete medical history and physical examination must be conducted and documented in the medical report. The medical record should document the nature and intensity of the pain, evaluate 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.

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, significant other(s) or guardian. 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).

4. Periodic Review

At reasonable intervals based upon the individual circumstance of the patient, the physician should review the course of opioid treatment and any new information about the etiology of the pain. Continuation or modification of opioid 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, such as ability to work, need of health care resources, activities of daily living and quality of social life. If reasonable treatment goals are not being achieved despite medication adjustments, the physician should monitor patient compliance in medication usage and related treatment plans.

5. Consultation

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

[CONTINUED ON NEXT PAGE]

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

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

CATEGORY B:
Issues related to patients

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

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University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

PENNSYLVANIA

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

[CONTINUED]

6. 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.

7. Compliance with Controlled Substances Laws and Regulations

To prescribe controlled substances, the physician must be licensed in the state, have a valid controlled substances registration and comply with federal and state regulations for issuing controlled substances prescriptions. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and the regulations of the board for specific rules governing issuance of controlled substances prescriptions as well as applicable state regulations.

Pain & Policy Studies Group
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Madison, Wisconsin

RHODE ISLAND

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 21. Food and Drugs; Chapter 28. Uniform Controlled Substances Act

- MEDICAL PRACTICE ACT
  Title 5. Businesses and Professions; Chapter 37. Board of Medical Licensure and Discipline

- INTRACTABLE PAIN TREATMENT ACT (*Part of Medical Practice Act*)
  Title 5. Businesses and Professions; Chapter 37.4. Intractable Pain Treatment

- PAIN ASSESSMENT ACT (*Part of Medical Practice Act*)
  Title 5. Businesses and Professions; Chapter 37.6. Pain Assessment Act

- PHARMACY PRACTICE ACT (*No provisions found*)
  Title 5. Businesses and Professions; Chapter 19.1. Pharmacies

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Agency 14. Department of Health; Sub-Agency 060. Food and Drug Control

- MEDICAL BOARD REGULATIONS
  Agency 14. Department of Health; Sub-Agency 140. Office of Health Professionals Regulation; Chapter 031. Licensure and Discipline of Physicians

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Agency 14. Department of Health; Sub-Agency 130. Pharmacy Board

OTHER GOVERNMENTAL POLICIES

No policy found

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- ASSISTED SUICIDE
  Title 11. Criminal Offenses; Chapter 60. Assisted Suicide

- DRUG ABUSE CONTROL
  Title 21. Food and Drugs; Chapter 28.2. Drug Abuse Control

- LICENSING OF HEALTH CARE FACILITIES
  Title 23. Health and Safety; Chapter 17. Licensing of Health Care Facilities

- RIGHTS OF NURSING HOME PATIENTS
  Title 23. Health and Safety; Chapter 17.5. Rights of Nursing Home Patients

- RIGHTS OF NURSING HOME PATIENTS
  Title 23. Health and Safety;
  Chapter 89. The Rhode Island Palliative Care and Quality of Life Act

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- PROFESSIONAL PRACTICE
  Agency 14. Department of Health; Sub-Agency 000. General

- LICENSING HOSPICE CARE
  Agency14. Department of Health; Sub-Agency 090. Health Facilities, Licensure, Construction; Chapter 017. Licensing Hospice Care

- LICENSING REHABILITATION HOSPITAL CENTERS
  Agency14. Department of Health; Sub-Agency 090. Health Facilities, Licensure, Construction; Chapter 018. Licensing Rehabilitation Hospital Centers

- LICENSING OF NURSING FACILITIES
  Agency14. Department of Health; Sub-Agency 090. Health Facilities, Licensure, Construction; Chapter 023. Licensing of Nursing Facilities

Note: Rhode Island's Uniform Controlled Substances Act continues to reference the duplicate prescription program that was repealed in 1997; although not considered a barrier to practice, efforts should be made to remove from state law all references to this vestigial policy.

RHODE ISLAND

STATUTES

Controlled Substances Act

R.I. Gen. Laws § 21-28-1.02

§ 21-28-1.02. Definitions

Unless the context otherwise requires, the words and phrases as defined in this section are used in this chapter in the sense given them in the following definitions:

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(37) "Practitioner" means:

(i) A physician, osteopath, dentist, chiropodist, veterinarian, scientific investigator, or other person licensed, registered or 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

R.I. Gen. Laws § 5-37-1

§ 5-37-1. Definitions

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(15) "Practice of medicine" shall include the practice of allopathic and osteopathic medicine. Any person shall be regarded as practicing medicine within the meaning of this chapter who holds himself or herself out as being able to diagnose, treat, operate, or prescribe for any person ill or alleged to be ill with disease, pain, injury, deformity or abnormal physical or mental condition, or who shall either profess to heal, offer or undertake, by any means or method to diagnose, treat, operate, or prescribe for any person for disease, pain, injury, deformity or physical or mental condition. In addition, one who attaches the title, M.D., physician, surgeon, D.O., osteopathic physician and surgeon, or any other similar word or words or abbreviation to his or her name indicating that he or she is engaged in the treatment or diagnosis of the diseases, injuries or conditions of persons shall be held to be engaged in the practice of medicine.

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

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RHODE ISLAND

STATUTES

Intractable Pain Treatment Act

R.I. Gen. Laws § 5-37.4-1 – § 5-37.4-3

§ 5-37.4-1. Title

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

§ 5-37.4-2. Definitions

For purposes of this chapter:

(1) "Director" means the director of the department of health of the state of Rhode Island.

(2) "Intractable pain" means a pain state that persists beyond the usual course of an acute disease or healing of an injury or results from a chronic disease or condition that causes continuous or intermittent pain over a period of months or years.

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

(3) "Practitioner" means health care professionals licensed to distribute, dispense, or administer controlled substances in the course of professional practice as defined in § 21-28-1.02(36).

(4) "Therapeutic purpose" means the use of controlled substances for the treatment of pain in appropriate doses as indicated by the patient's medical record. Any other use is nontherapeutic.

§ 5-37.4-3. Controlled substances

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

(a) A practitioner may prescribe, administer, or dispense controlled substances not prohibited by law for a therapeutic purpose to a person diagnosed and treated by a practitioner for a condition resulting in intractable pain, if this diagnosis and treatment has been documented in the practitioner's medical records. No practitioner shall be subject to disciplinary action by the board solely for prescribing, administering, or dispensing controlled substances when prescribed, administered, or dispensed for a therapeutic purpose for a person diagnosed and treated by a practitioner for a condition resulting in intractable pain, if this diagnosis and treatment has been documented in the practitioner's medical records.

(b) The provisions of subsection (a) of this section do not apply to those persons being treated by a practitioner for chemical dependency because of their use of controlled substances not related to the therapeutic purposes of treatment of intractable pain.

(c) The provisions of subsection (a) of this section provide no authority to a practitioner to prescribe, administer, or dispense controlled substances to a person the practitioner knows or should know to be using the prescribed, administered, or dispensed controlled substance non-therapeutically.

(d) Drug dependency or the possibility of drug dependency in and of itself is not a reason to withhold or prohibit prescribing, administering, or dispensing controlled substances for the therapeutic purpose of treatment of a person for intractable pain, nor shall dependency relating solely to this prescribing, administering, or dispensing subject a practitioner to disciplinary action by the director.

(e) Nothing in this section shall deny the right of the director to deny, revoke, or suspend the license of any practitioner or discipline any practitioner who:

(1) Prescribes, administers, or dispenses a controlled substance that is nontherapeutic in nature or nontherapeutic in the manner in which it is prescribed, administered, or dispensed, or fails to keep complete and accurate on-going records of the diagnosis and treatment plan;

[CONTINUED ON NEXT PAGE]

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

CATEGORY B:
Issues related to patients

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

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STATUTES

Intractable Pain Treatment Act

[CONTINUED]

(2) Fails to keep complete and accurate records of controlled substances received, prescribed, dispensed and administered, and disposal of drugs as required by law or of controlled substances scheduled in the Comprehensive Drug Abuse Prevention and Control Act of 1970, *21 U.S.C. § 801*, et seq. A practitioner shall keep records of controlled substances received, prescribed, dispensed and administered, and disposal of these drugs shall include the date of receipt of the drugs, the sale or disposal of the drugs by the practitioner, the name and address of the person receiving the drugs, and the reason for the disposal or the dispensing of the drugs to the person;

(3) Writes false or fictitious prescriptions for controlled substances as prohibited by law, or for controlled substances scheduled in the Comprehensive Drug Abuse Prevention and Control Act of 1970, *21 U.S.C § 801*, et seq.; or

(4) Prescribes, administers, or dispenses in a manner which is inconsistent with provisions of the law, or the Comprehensive Drug Abuse Prevention and Control Act of 1970, *21 U.S.C. § 801*, et seq., any controlled substance.

(f) A practitioner may administer a controlled substance prescribed by a practitioner and not prohibited by law for a therapeutic purpose to a person diagnosed and treated by a practitioner for a condition resulting in intractable pain, if this diagnosis and treatment has been documented in the practitioner's medical records. No practitioner shall be subject to disciplinary action by the director solely for administering controlled substances when prescribed or dispensed for a therapeutic purpose for a person diagnosed and treated by a practitioner for a condition resulting in intractable pain, if this diagnosis and treatment has been documented in the practitioner's medical records of the patient.

STATUTES

Pain Assessment Act

R.I. Gen. Laws § 5-37.6-1 – § 5-37.6-8

§ 5-37.6-1. Short title

This chapter shall be known and may be cited as the "Pain Assessment Act."

§ 5-37.6-2. Findings

The general assembly finds and declares that:

(1) Pain affects quality of life, job performance and security;

(2) Nearly thirty percent (30%) of nursing home residents with daily pain were receiving no pain medication of any form;

(3) Pain untreated or under-treated adversely impacts the quality of life for patients;

(4) Up to ninety-five percent (95%) of terminally ill patients' pain can be relieved with adequate pain management; and

(5) Too many Rhode Islanders are suffering and dying in needless pain.

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STATUTES

Pain Assessment Act

[CONTINUED]

§ 5-37.6-3. Definitions

As used in this chapter, the following terms have the following meanings:

(1) "Assessment of pain" means the act of assessing an unpleasant sensation occurring in varying degrees of severity as a consequence of injury, disease, or emotional disorder;

(2) "Director" means the director of the department of health;

(3) "Health care facilities" is defined in the same manner as in § 23-17-2(6);

(4) "Health care provider" means any person licensed by this state to provide or lawfully providing health care services, including, but not limited to, a physician, dentist, optometrist, nurse, podiatrist, physical therapist, nurse practitioner or physician's assistant;

(5) "Person" means any individual, trust or estate, partnership, limited liability corporation, corporation (including associations, joint stock companies, and insurance companies), state, or political subdivision or instrumentality of a state;

(6) "Regular basis" means a procedure done on a customary, usual, normal, orderly, even, or symmetrical schedule.

§ 5-37.6-4. Pain assessment

(a) Health care facilities and health care providers shall conduct an assessment of pain experienced by a patient on a regular basis.

(b) The assessment of pain shall be noted in the patient's chart in a manner consistent with vital signs.

§ 5-37.6-5. Regulations

(a) *Promulgation by department.* The director of the department shall promulgate regulations relating to the assessment of pain requirements of this chapter.

(b) *Educational materials.* The director shall make available educational and informational materials concerning the assessment of pain to health care facilities and health care providers.

§ 5-37.6-6. Enforcement

The director of the department of health shall have the power to enforce the provisions of this chapter.

§ 5-37.6-7. Penalty

(a) Every person who shall willfully and continually violate the provisions of this chapter is subject to a fine up to one hundred dollars ($ 100) for a first violation and any other remedy provided for in the Rhode Island law.

(b) Every person who shall continuously violate this chapter is subject to a fine up to five hundred dollars ($ 500) for each subsequent violation in addition to any other remedy provided for in the Rhode Island law.

§ 5-37.6-8. Severability

If any provision of this chapter or any rule or regulation made under this chapter or the application of any provision of this chapter to any person or circumstance shall be held invalid by any court of competent jurisdiction, the remainder of the chapter, rule or regulation and the application of the provision to other persons or circumstances shall not be affected by that invalidity. The invalidity of any section or sections or parts of any section of this chapter shall not affect the validity of the remainder of this chapter and to this end the provisions of the chapter are declared to be severable.

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for health care facilities to ensure that pain management is an essential part of patient care. (Although not required by this provision, pain assessment should be followed up with appropriate treatment.)

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (regulations) for the Department of Health to improve pain management.

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

CATEGORY C:
Regulatory or policy issues

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

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RHODE ISLAND

REGULATIONS

Controlled Substances Regulations

CRIR 14-060-020

14 060 020 Rules and Regulations Governing Electronic Data Transfer of Controlled Substances in Schedules II and III

INTRODUCTION

These Rules and Regulations Governing Electronic Data Transfer of Controlled Substances in Schedules II and III (R21-28-EDT) are promulgated pursuant to the authority set forth in sections 42-35 and 21-28-3.18 of the General Laws of Rhode Island, as amended. These regulations are established for the purpose of defining minimum standards for the establishment of an electronic data transfer system between the Department of Health and pharmacies in this state for schedules II and III controlled substances.

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Section 3.0 Data Collection

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3.3 The Department shall:

3.3.1 be authorized to provide data in the electronic prescription system to other regulatory, investigative or law enforcement agencies for disciplinary, civil, or criminal purposes, and for the purposes of educating practitioners in lieu of disciplinary, civil or criminal action.

3.3.2 be authorized to provide data to appropriate public or private entities for statistical, research, or educational purposes provided that the privacy and confidentiality of patients and patient information is not compromised.

3.3.3 in using the information for investigative or prosecutorial purposes, consider the nature of the prescriber's or dispenser's practice and the condition(s) for which the patient is being treated.

3.3.4 ensure the privacy and confidentiality of patients and shall ensure that patient information collected, recorded, transmitted, and stored in the prescription system is maintained in accordance with applicable state and federal laws, rules and regulations.

3.3.5 ensure that the EDT program does not infringe on the legal use of any schedule II or III controlled substance.

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

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a responsibility for the Department of Health to consider case-specific details, such as the patient's diagnosis, when reviewing prescription monitoring program information used for investigations.

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

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a responsibility for the Department of Health to ensure that a prescription monitoring program does not interfere with the legitimate medical use of controlled substances, which represents the principle of Balance.

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RHODE ISLAND

REGULATIONS

Medical Board Regulations

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

CRIR 14-140-031

14 140 031 Licensure and Discipline of Physicians

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1.14 "Practice of Medicine", pursuant to section 5-37-1 (1) of the Act, shall include the practice of allopathic and osteopathic medicine. Any person shall be regarded as practicing medicine within the meaning of the act who holds himself or herself out as being able to diagnose, treat, operate, or prescribe for any person ill or alleged to be ill with disease, pain, injury, deformity or abnormal physical or mental condition, or who shall either profess to heal, offer or undertake, by any means or method, to diagnose, treat, operate, or prescribe for any person for disease, pain, injury, deformity or physical or mental condition. In addition, one who attaches the title M.D., physician, surgeon, D.O., osteopathic physician and surgeon, or any other similar word or words or abbreviation to his or her name indicating that he or she is engaged in the treatment or diagnosis of the diseases, injuries or conditions of persons shall be held to be engaged in the practice of medicine.

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RHODE ISLAND

STATUTES

Assisted Suicide

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:* Clarifies for physicians the 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, and the practitioners who provide it.

R.I. Gen. Laws § 11-60-4

(a) A licensed health care professional who administers, prescribes, or dispenses medications or procedures to relieve another person's pain or discomfort, even if the medication or procedure may hasten or increase the risk of death, does not violate the provision of this chapter unless the medications or procedures are knowingly administered, prescribed, or dispensed to cause death.

A licensed health care professional who withholds or withdraws a life-sustaining procedure in compliance with chapter 4.10 or title 23 does not violate the provisions of this chapter.

STATUTES

Drug Abuse Control

R.I. Gen. Laws § 21-28.2-1

§ 21-28.2-1. Definitions

Unless the context otherwise requires, the following terms shall be construed in this chapter to have the following meanings:

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(3) "Narcotic addict" means a person who is at the time of examination dependent upon opium, heroin, morphine, or any derivative or synthetic drug of that group or any other narcotic drug as defined in § 21-28-1.02, or a depressant or stimulant substance, or who by reason of the repeated use of any such drug is in imminent danger of becoming dependent upon opium, heroin, morphine, or any derivative or synthetic drug of that group, or any other narcotic drug as defined in § 21-28-1.02; or any person who is or has been so far addicted to the use of narcotic drugs as to have lost the power of self-control with reference to his or her addiction; provided, that no person shall be deemed a narcotic addict solely by virtue of his or her taking of any of the drugs pursuant to a lawful prescription issued by a physician in the course of professional treatment for legitimate medical purposes.

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

CATEGORY B:
Issues related to patients

COMMENT*:* Ensures that patients with pain would not be labeled as a narcotic addict.

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RHODE ISLAND

STATUTES

Licensing of Health Care Facilities

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for health care facilities to ensure that pain management is an essential part of patient care. (Although not required by this provision, pain assessment should be followed up with appropriate treatment.)

R.I. Gen. Laws § 23-17-19.1

§ 23-17-19.1. Rights of patients

Every health care facility licensed under this chapter shall observe the following standards and any other standards that may be prescribed in rules and regulations promulgated by the licensing agency with respect to each patient who utilizes the facility:

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(17) The patient shall have the right to have his or her pain assessed on a regular basis.

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STATUTES

Rights of Nursing Home Patients

R.I. Gen. Laws § 23-17.5-28

§ 23-17.5-28. Pain assessment

A patient shall have the right to have his or her pain assessed on a regular basis.

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for nursing homes to ensure that pain management is an essential part of patient care. (Although not required by this provision, pain assessment should be followed up with appropriate treatment.)

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RHODE ISLAND

STATUTES

The Rhode Island Palliative Care and Quality of Life Act

R.I. Gen. Laws § 23-89-3

§ 23-89-3. Access to palliative care

(a) As used in this section, the following terms shall have the following meanings:

(1) "Appropriate" means consistent with applicable legal, health and professional standards, the patient's clinical and other circumstances, and the patient's reasonably known wishes and beliefs.

(2) "Medical care" means services provided, requested, or supervised by a physician or advanced practice nurse.

(3) "Palliative care" means patient and family centered medical care that optimizes quality of life by anticipating, preventing, and treating suffering caused by serious illness. Palliative care throughout the continuum of illness involves addressing physical, emotional, social, and spiritual needs and facilitating patient autonomy, access to information, and choice. Palliative care includes, but is not limited to, discussions of the patient's goals for treatment; discussion of treatment options appropriate to the patient, including, where appropriate, hospice care; and comprehensive pain and symptom management.

(4) "Serious illness" means any medical illness or physical injury or condition that substantially impacts quality of life for more than a short period of time. Serious illness includes, but is not limited to, cancer; heart, renal or liver failure; lung disease; and Alzheimer's disease and related dementias.

(b) On or before January 1, 2015, all healthcare organizations which required a license to operate shall:

(1) Consult with the organization's physicians to educate them on how to provide information about appropriate palliative care services for those patients or residents with serious illnesses, who, in their professional medical opinion, would benefit from them.

(c) The department shall carry out this section with the consultation of the palliative care and quality of life interdisciplinary advisory council.

(d) In carrying out this section, the department shall take into account factors that may impact the development of such a system and its ability to facilitate access to palliative care, including the size of the healthcare organization; access and proximity to palliative care services, including the availability of hospice and palliative care board-certified practitioners and related workforce staff; and geographic factors.

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

CATEGORY C:
Regulatory or policy issues

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

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RHODE ISLAND

REGULATIONS

Professional Practice Regulations

CRIR 14-000-029

14 000 029 Pain Assessment

INTRODUCTION

These rules and regulations are promulgated under the authority contained in Chapters 5-37.6 and 42-35 of the General Laws of Rhode Island, as amended, and are established for the purpose of adopting requirements relating to the assessment of pain by health care facilities and health care providers in Rhode Island.

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for health care facilities and health care providers to ensure that pain management is an essential part of patient care. (Although not required by this provision, pain assessment should be followed up with appropriate treatment.)

REGULATIONS

Licensing Hospice Care

CRIR 14-090-017

14 090 017. LICENSING HOSPICE CARE

Section 14.0 Minimum Services Required/Availability and Accessibility of Services.

14.1 Any service available through a hospice program shall be provided to patients/families, with the consent of the terminally ill patient and family.

14.2 Services that are to be provided directly through staff personnel of a hospice program shall include the following core services:

a) physician services (may include attending physicians' or certified registered nurse practitioners' services in accordance with section 17.1 herein);

b) nursing services;

c) social services;

d) counseling services, including spiritual counseling, when required;

e) pain assessment; and

f) availability of drugs and biologicals on a 24-hour basis.

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for hospice facilities to ensure that pain management is an essential part of patient care. (Although not required by this provision, pain assessment should be followed up with appropriate treatment.)

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RHODE ISLAND

REGULATIONS

Licensing Rehabilitation Hospital Centers

CRIR 14-090-018

14 090 018. LICENSING REHABILITATION HOSPITAL CENTERS

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Section 20.0 Plan of Care.

20.1 After initial assessment of patient rehabilitative needs, a written plan of care shall be established by the interdisciplinary team for each patient admitted to the center and at each level of care. Such plan shall designate the intensity of services required in relation to the disability and the individual's response to treatment and shall include provisions pertaining to:

(a) pertinent diagnosis and prognosis;

(b) identification of the intensity of patient care needs including the range of rehabilitation services required; the level of care required; the frequency of therapeutic services required; medications; management of discomfort and pain control; and other rehabilitative needs and prescribed therapies;

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

CATEGORY C:
Regulatory or policy issues

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

REGULATIONS

Licensing of Nursing Facilities

CRIR 14-090-023

14 090 023 Licensing of Nursing Facilities

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Section 19.0 Rights of Residents.

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19.20 The resident shall have the right to have his or her pain assessed on a regular basis.

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Section 25.0 Selected Nursing Care Procedures.

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Pain Assessment

25.15 All health care providers licensed by Rhode Island to provide health care services and all health care facilities licensed under RIGL Chapter 23-17 [Reference 1] shall assess patient pain in accordance with the requirements of the Rules and Regulations Related to Pain Assessment (R5-37.6-PAIN) [Reference 37] promulgated by the Department.

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for nursing facilities to ensure that pain management is an essential part of patient care. (Although not required by this provision, pain assessment should be followed up with appropriate treatment.)

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SOUTH CAROLINA

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 44. Health; Chapter 53. Poisons, Drugs and Other Controlled Substances; Article 3. Narcotics and Controlled Substances

- MEDICAL PRACTICE ACT
  Title 40. Professions and Occupations; Chapter 47. Physicians and Miscellaneous Health Care Professionals

- PHARMACY PRACTICE ACT (*No provisions found*)
  Title 40. Professions and Occupations; Chapter 43. South Carolina Pharmacy Practice Act

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Code of Regulations; Chapter 61. Department of Health and Environmental Control; 61-4. Controlled Substances

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Code of Regulations; Chapter 81. Department of Labor, Licensing and Regulation – State Board of Medical Examiners

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Code of Regulations; Chapter 99. Department of Labor, Licensing and Regulation – State Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
  Board of Medical Examiners of South Carolina. *Pain Management Guidelines*. Adopted: July 2009.

- JOINT BOARD POSITION STATEMENT
  South Carolina Board of Nursing and the South Carolina Board of Pharmacy. *Joint Position Statement on Pain Management*. Adopted: June & July, 2009.

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RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- CRIMES AND OFFENSES
  Title 16. Crimes and Offenses; Chapter 3. Offenses Against the Person;
  Article 11. Miscellaneous Offenses

- STANDARDS FOR LICENSING NURSING HOMES
  Code of Regulations; Chapter 61. Department of Health and Environmental Control

- STANDARDS FOR LICENSING HOSPICES
  Code of Regulations; Chapter 61. Department of Health and Environmental Control

- STANDARDS FOR LICENSING FACILITIES THAT TREAT INDIVIDUALS FOR PSYCHOACTIVE SUBSTANCE ABUSE OR DEPENDENCE
  Code of Regulations; Chapter 61. Department of Health and Environmental Control

SOUTH CAROLINA

STATUTES

Controlled Substances Act

S.C. Code Ann. § 44-53-110

§ 44-53-110. Definitions.

As used in this article and *Sections 44-49-10, 44-49-40,* and *44-49-50*:

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"Practitioner" means:

(1) 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.

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S.C. Code Ann. § 44-53-360

§ 44-53-360. Prescriptions.

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(h) A prescription, in order to be effective in legalizing the possession of a controlled substance and eliminating the need for registration of the recipient, must be issued for legitimate medical purposes. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding liability rests with the pharmacist who fills and ultimately dispenses the prescription. An order purporting to be a prescription issued to a drug dependent person, not in the course of generally accepted medical treatment, but for the purpose of providing the user with controlled substances sufficient to maintain his dependence upon the substance, or to provide him with quantities of controlled substances in great excess of normal dosage ranges as recommended by the manufacturer of the substance, is not a prescription within the meaning and intent of this article; and the person filling or dispensing such an order, as well as the person issuing it, shall be deemed in violation of this section.

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S.C. Code Ann. § 44-53-1620

§ 44-53-1620. Purpose.

This article is intended to improve the state's ability to identify and stop diversion of prescription drugs in an efficient and cost effective manner that will not impede the appropriate medical utilization of licit controlled substances.

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

(+) *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 16:*
Provisions that are ambiguous

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT: Although it is reasonable to expect practitioners to avoid contributing to diversion, "great excess" implies there is a known standard, but the standard is not specified. Also, how would this affect treatment of a person with drug dependence who has pain requiring opioid therapy?

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Madison, Wisconsin

SOUTH CAROLINA

STATUTES

Medical Practice Act

S.C. Code Ann. § 40-47-20

§ 40-47-20. Definitions.

In addition to the definitions provided in ***Section 40-1-20***, as used in this chapter unless the context indicates otherwise:

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(36) "Practice of Medicine" means:

(a) advertising, holding out to the public or representing in any manner that one is authorized to practice medicine in this State;

(b) offering or undertaking to prescribe, order, give, or administer any drug or medicine for the use of any other person;

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

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

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SOUTH CAROLINA

REGULATIONS

Controlled Substances Regulations

S.C. Code Regs. 61-4, Pt. 1

PART 1 Definitions, Information, Payment of Fees, Certain Exemptions, Separate Registrations, Out-of-State Dispensing of Prescriptions

101. Definitions.

As used in this regulation, the following terms shall have the meaning specified:

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(k) Individual practitioner. A physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted by the United States or the State of South Carolina, or by other jurisdiction, or otherwise permitted by the United States or the State of South Carolina, or by any other jurisdiction in which he practices to dispense a controlled substance in the regular course of professional practice, but does not include a pharmacist, a pharmacy, or any institutional practitioner;

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

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SOUTH CAROLINA

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

PAIN MANAGEMENT GUIDELINES

Section I: Preamble

The State Board of Medical Examiners of S. C. recognizes that principles of quality medical practice dictate that the people of the State of South Carolina 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, this policy have been developed to clarify the Boards 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 State Board of Medical Examiners of S. C. is obligated under the laws of the State of South Carolina 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.

[CONTINUED ON NEXT PAGE]

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

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies the potential impact of important barriers on the provision of effective pain care.

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

(+) *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 4:*
Encourages pain management

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Madison, Wisconsin

SOUTH CAROLINA

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

[CONTINUED]

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

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

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

Section II: Guidelines

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

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

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

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).

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 3:*
Opioids are part of professional 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*:* 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 5:*
Addresses fear of regulatory scrutiny

(+) *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 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: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

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SOUTH CAROLINA

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

[CONTINUED]

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

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

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

- 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

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.

[CONTINUED ON NEXT PAGE]

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

CATEGORY B:
Issues related to patients

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

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

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

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Madison, Wisconsin

SOUTH CAROLINA

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

[CONTINUED]

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.

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

SOUTH CAROLINA

OTHER GOVERNMENTAL POLICY

Joint Pain Statement

Joint Position Statement on Pain Management for
The South Carolina Board of Nursing and The South Carolina Board of Pharmacy

Pain management is a national health care concern today for the consumer. Many health care providers and health care agencies are evaluating existing treatment modalities and processes to understand the lack of adequate pain management in the United States. Roughly, there are 50-75 million Americans experiencing some form of pain (Brekken, 2008). Significant percentages of patients undergoing cancer treatments are under treated for pain which could impair quality of life throughout the stages of disease. (National Cancer Institute, 2009).

Inappropriate treatment of pain, including non-treatment, over treatment, and ineffective treatment, can have negative consequences for patients at large. All persons who are experiencing pain have the right to have their pain assessed and managed appropriately. All persons who are experiencing pain also have the right to refuse any undesired treatment. Patients should be encouraged to be active participants in their care. Subjective reporting of pain by the patient and family representatives is the optimal standard upon which all pain management interventions are based. The goal of pain management is to reduce the individual's pain to the lowest level possible, while simultaneously increasing the individual's level of functioning to the greatest extent possible (American Pain Society, 2009).

The South Carolina Boards of Nursing and Pharmacy concur with The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) guideline on pain management which declares that patients have the right to appropriate assessment and management of pain (2008). The application of clinical knowledge and patient-centered treatment modalities improve the quality of life for patients who suffer from pain. All health care providers who treat pain, whether acute or chronic, should become knowledgeable about effective methods of pain management. The management of pain should include the utilization of both pharmacologic and non-pharmacologic modalities. (ASPMN, 2003).

It is therefore incumbent upon South Carolina licensed nurses and pharmacists as health care providers to work cooperatively and effectively to address the dimensions of pain and to assist with providing maximum pain relief measures with the least possible side effects. Patients and families should be assured of competent, safe, comprehensive care during each stage of disease. Nurses and pharmacists should be knowledgeable regarding effective and compassionate pain relief, and patients and families should be confident such pain relief measures will be consistently provided. Communication and collaboration between members of the healthcare team, patient, and family is essential in achieving adequate pain management. In order to effectively communicate guidelines for professional practice and in the interest of public safety, the South Carolina Boards of Nursing and Pharmacy jointly issue the following statement.

(CONTINUED NEXT PAGE)

(+) *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 include improvements in patient functioning and quality of life.

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

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Madison, Wisconsin

SOUTH CAROLINA

OTHER GOVERNMENTAL POLICY

Joint Pain Statement

(CONTINUED)

The Boards acknowledge that healthcare professionals as patient care advocates should, within their scope of practice:

1. Routinely assess all patients for pain symptoms. When patient pain is reported, both the physical assessment and historical patient data should be evaluated. Pain assessment tools utilized should reflect cultural and ethnic diversity to appropriately identify pain for diverse populations.
2. Educate patients who are reluctant to report pain symptoms on safe and effective methods of pain relief. (National Cancer Institute, 2009)
3. Work collaboratively within a multidisciplinary team that involves the patient and family as core participants to develop and implement an individualized written treatment plan of care utilizing both pharmacologic and nonpharmacologic interventions.
4. Anticipate and manage side effects of pain medications when possible;
5. Ensure that adequate pain management is available for all individuals experiencing pain.
6. Provide accurate information to patients and patient representatives to assist them in making informed decisions regarding their health. Continue to encourage and involve patients in their healthcare.
7. Refer and consult with other providers as appropriate;
8. Stay informed of the risks of diversion and abuse of controlled substances and takes appropriate steps to minimize risks. Be knowledgeable about state, federal, and local regulations for controlled substances.
9. Routinely evaluate the effectiveness of the treatment plan utilizing a standardized developmentally appropriate pain tool that reflects cultural and ethnic diversity.
10. Document all aspects of the plan of care regarding pain management in a clear, concise, and accurate manner;
11. Assist in developing organization-appropriate and evidence-based policies and protocols for pain management;
12. Continue to seek out current pain management education regarding safe and effective pain management strategies.
13. Comply with all state and federal laws and regulations regarding prescribing, dispensing, and administering medications, including controlled substances.

(+) *CRITERION 4:*
Encourages pain management

(+) *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 C:
Regulatory or policy issues

COMMENT: Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

SOUTH CAROLINA

STATUTES

Crimes and Offenses

S.C. Code Ann. § 16-3-1090

§ 16-3-1090. Assisted suicide; penalties; injunctive relief.

(A) As used in this section:

(1) "Licensed health care professional" means a duly licensed physician, surgeon, podiatrist, osteopath, osteopathic physician, osteopathic surgeon, physician assistant, nurse, dentist, or pharmacist.

(2) "Suicide" means the act or instance of taking one's life voluntarily and intentionally.

(B) It is unlawful for a person to assist another person in committing suicide. A person assists another person in committing suicide if the person:

(1) by force or duress intentionally causes the other person to commit or attempt to commit suicide; or

(2) has knowledge that the other person intends to commit or attempt to commit suicide and intentionally:

(a) provides the physical means by which the other person commits or attempts to commit suicide; or

(b) participates in a physical act by which the other person commits or attempts to commit suicide.

(C) None of the following may be construed to violate subsection (B):

(1) the withholding or withdrawing of a life sustaining procedure or compliance with any other state or federal law authorizing withdrawal or refusal of medical treatments or procedures;

(2) the administering, prescribing, or dispensing of medications or procedures, by or at the direction of a licensed health care professional, for the purpose of alleviating another person's pain or discomfort, even if the medication or procedure may increase the risk of death, as long as the medication or procedure is not also intentionally administered, prescribed, or dispensed for the purpose of causing death, or the purpose of assisting in causing death, for any reason;

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians the 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, and the practitioners who provide it.

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

SOUTH CAROLINA

REGULATIONS

Standards for Licensing Nursing Homes

S.C. Code Regs. 61-17

61-17 Standards for Licensing Nursing Homes

SECTION 100

DEFINITIONS AND REFERENCES

101. Definitions

For the purpose of this regulation, the following definitions shall apply:

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J. Assessment. A procedure for determining the nature and extent of the problem(s) and needs of a resident and/or a potential resident to ascertain if the facility can adequately address those problems, meet those needs, and to secure information for use in the development of the ICP. Included in the process is an evaluation of the physical, emotional, behavioral, social, spiritual, nutritional, recreational, and, when appropriate, pain management, vocational, educational, legal status/needs of a resident and/or a potential resident. Consideration of each resident's needs, strengths, and weaknesses shall be included in the assessment.

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (patient physical assessment) for nursing homes to ensure that pain management is an essential part of patient care.

REGULATIONS

Standards for Licensing Hospices

S.C. Code Regs. 61-78

61-78. Standards for Licensing Hospices.

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SECTION 1100--PATIENT PHYSICAL ASSESSMENT

1101. General (I)

A. A medical history and physical assessment shall be completed for patients within 30 days prior to or no later than 48 hours after admission. The physical assessment shall address the appropriateness of admission, medications required and self-administration status, and identification of special conditions/care required, e.g., communicable disease, such as tuberculosis, Alzheimer's disease and/or related dementia, pain management, imminent death, etc.

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

CATEGORY C:
Regulatory or policy issues

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

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Madison, Wisconsin

SOUTH CAROLINA

REGULATIONS

Standards for Licensing Facilities that Treat Individuals for Psychoactive Substance Abuse or Dependence

S.C. Code Regs. 61-93

61-93 Standards for Licensing Facilities that Treat Individuals for Psychoactive Substance Abuse or Dependence

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PART V

NARCOTIC TREATMENT PROGRAMS

SECTION 3200

PROGRAM DESCRIPTION.

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3207. Admission (II).

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C. Individuals shall not be admitted to the NTP to receive opioids for pain management only.

1. The NTP shall make the diagnostic distinctions between the disease of opioid addiction and the physical dependence associated with the chronic administration of opioids for the relief of pain, also known as pseudo-addiction. The drug seeking manifestations of persons who are opioid addicted for purpose of euphoria are very similar to the same behavioral manifestations of pseudo-addiction of those with chronic pain seeking only pain relief. Relevant criteria to distinguish pseudo-addiction from opioid addiction include:

a. Unsuccessful efforts to control use, including past failed detoxification efforts;

b. Large amounts of time spent in activities to obtain drugs, including past criminal involvements;

c. Written documentation from a pain management physician attesting to the clients need for NTP medication due to the client's physical dependence, resultant tolerance, and that physician's discontinuance of effective opioid pain relief measures with the client.

d. Continued use, despite having suffered lifestyle consequences of illicit use, e.g., arrests, hospitalizations, family problems, financial setbacks, and employment difficulties.

2. Appropriate referrals by the NTP physician shall be made as necessary, e.g., pain management specialist.

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for OTP staff the important distinction between drug-seeking behaviors resulting from poorly treated pain (i.e., pseudoaddiction) and drug-seeking behaviors related to abuse or addiction; this language identifies a potential clinical situation and attempts to lessen its impact on patient treatment.

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for OTP staff to refer opioid-maintained patients who have chronic pain for treatment of their pain.

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University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

SOUTH DAKOTA

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 34. Public Health and Safety
  Chapter 34-20. Poisons
  Chapter 34-20B. Drugs and Substances Control

- MEDICAL PRACTICE ACT
  Title 36. Professions and Occupations; Chapter 36-4. Physicians and Surgeons

- PHARMACY PRACTICE ACT
  Title 36. Professions and Occupations; Chapter 36-11. Pharmacies and Pharmacists

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Title 44. Department of Health; Article 58. Drug Control

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Title 20. Department of Revenue and Regulation; Article 47. Physicians and Surgeons

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Title 20. Department of Revenue and Regulation; Article 51. Pharmacists

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD POLICY STATEMENT
  South Dakota State Board of Medical and Osteopathic Examiners. *Model Policy for the Use of Controlled Substances for the Treatment of Pain*. Adopted: May, 2004.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- PATIENT OR RESIDENT CARE PLANS AND PROGRAMS
  Title 44. Department of Health; Article 4. Medical Facilities;
  Chapter 6. Nursing and Related Care Services

- QUALITY OF LIFE
  Title 44. Department of Health; Article 4. Medical Facilities;
  Chapter 17. Residents' Rights in Nursing Facilities and Assisted Living Centers

- RESIDENT CARE PLANS AND PROGRAMS
  Title 44. Department of Health; Article 70. Assisted Living Centers;
  Chapter 5. Nursing and Related Care Services

Pain & Policy Studies Group
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Madison, Wisconsin

SOUTH DAKOTA

STATUTES

Controlled Substances Act

S.D. Codified Laws § 34-20B-1

§ 34-20B-1. Definitions -- Generally

Terms as used in this chapter mean:

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(18) "Practitioner," a doctor of medicine, osteopathy, podiatry, optometry, dentistry, or veterinary medicine licensed to practice their profession, or pharmacists licensed to practice their profession; physician assistants certified to practice their profession; nurse practitioners and nurse midwives licensed to practice their profession; government employees acting within the scope of their employment; and persons permitted by certificates issued by the department to distribute, dispense, conduct research with respect to, or administer a substance controlled by this chapter;

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

STATUTES

Medical Practice Act

S.D. Codified Laws § 36-4-30

§ 36-4-30.

The term, unprofessional or dishonorable conduct, as used in this chapter includes:

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(9) Prescribing intoxicants, narcotics, barbiturates, or other habit-forming drugs to any person in quantities and under circumstances making it apparent to the board that the prescription was not made for legitimate medicinal purposes or prescribing in a manner or in amounts calculated in the opinion of the board to endanger the well-being of an individual patient or the public in general;

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

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT: Although it is reasonable to expect physicians to avoid contributing to diversion, "amounts calculated to endanger wellbeing" implies there is a known standard, but the standard is not specified. How is "well-being" defined and what are the criteria for endangerment?

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Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

SOUTH DAKOTA

STATUTES

Pharmacy Practice Act

S.D. Codified Laws § 36-11-2

§ 36-11-2.

Terms used in this chapter mean:

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(20) "Practitioner," an individual licensed, registered or otherwise authorized by the jurisdiction in which he is practicing to prescribe drugs in the course of professional practice;

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

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

SOUTH DAKOTA

REGULATIONS

Controlled Substances Regulations

ARSD 44:58:01:01

44:58:01:01. Definitions

Words defined in SDCL 34-20B-1 have the same meaning when used in this article. In addition, terms used in this article mean:

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(7) "Individual practitioner," a physician, dentist, veterinarian, optometrist, nurse practitioner, nurse midwife, physician's assistant, or podiatrist licensed by the state of South Dakota or the United States to practice, who is registered or exempt from registration with the division to dispense, administer, or prescribe controlled substances in the course of practice;

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

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

SOUTH DAKOTA

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

MODEL POLICY FOR THE USE OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN

Section I: Preamble

The South Dakota State Board of Medical and Osteopathic Examiners recognizes that principles of quality medical practice dictate that the people of the State of South Dakota 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 South Dakota State Board of Medical and Osteopathic Examiners is obligated under the laws of the State of South Dakota 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 healthcare practice

(+) *CRITERION 4:*
Encourages pain management

(+) *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.

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies the potential impact of important barriers on the provision of effective pain care.

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

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Medical Board Guideline

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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.

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 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

(CONTINUED ON NEXT PAGE)

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

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should 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: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

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OTHER GOVERNMENTAL POLICY

Medical Board Guideline

(CONTINUED)

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

CATEGORY B:
Issues related to patients

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

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Medical Board Guideline

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

(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.

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REGULATIONS

Patient or resident care plans and programs

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

CATEGORY C:
Regulatory or policy issues

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

ARSD 44:04:06:05

44:04:06:05. Patient or resident care plans and programs

The nursing service of a health care facility must provide safe and effective care from the day of admission through the ongoing development and implementation of written care plans for each patient or resident. The care plan must address medical, physical, mental, and emotional needs of the patient or resident. The health care facility must establish and implement procedures for assessment and management of symptoms including pain.

The care plan for nursing facility residents must be based on the resident assessments required in §§ 44:04:06:15 and 44:04:06:16 and must be developed and approved by the resident's physician; the resident, the resident's family, or the resident's legal representative; the interdisciplinary team consisting of at least a licensed nurse, the facility's social worker or social service designee, the dietary manager or dietitian, the activities coordinator, and other staff in disciplines determined by the resident's needs. The care plan shall describe the services necessary to meet the resident's medical, physical, mental or cognitive, nursing, and psychosocial needs and shall contain objectives and timetables to attain and maintain the highest level of functioning of the resident. The care plan must be completed within seven days after the completion of each resident assessment required in §§ 44:04:06:15 and 44:04:06:16.

Each nursing facility must provide restorative care services to meet resident needs.

REGULATIONS

Quality of Life

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

CATEGORY C:
Regulatory or policy issues

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

ARSD 44:04:17:09

44:04:17:09. Quality of life

A facility must provide care and an environment that contributes to the resident's quality of life, including:

(1) A safe, clean, comfortable, and homelike environment;

(2) Maintenance or enhancement of the resident's ability to preserve individuality, exercise self-determination, and control everyday physical needs;

(3) Freedom from physical or chemical restraints imposed for purposes of discipline or convenience;

(4) Freedom from verbal, sexual, physical, and mental abuse and from involuntary seclusion, neglect, or exploitation imposed by anyone, and theft of personal property;

(5) Retention and use of personal possessions, including furnishings and clothing, as space permits, unless to do so would infringe upon the rights or health and safety of other residents; and

(6) Support and coordination to assure pain is recognized and addressed appropriately.

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REGULATIONS

Resident Care Plans and Programs

ARSD 44:70:05:02

44:70:05:02. Resident care plans and programs

The nursing service of a facility shall provide safe and effective care from the day of admission through the ongoing development and implementation of written care plans for each resident. The care plan shall address medical, physical, mental, and emotional needs of the resident. The facility shall establish and implement procedures for assessment and management of symptoms including pain.

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

CATEGORY C:
Regulatory or policy issues

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

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STATUTES

- CONTROLLED SUBSTANCES ACT (*No provisions found*)
  Title 53. Food, Drugs, and Cosmetics; Chapter 11. Narcotic Drugs and Drug Control

- MEDICAL PRACTICE ACT
  Title 63. Professions and the Healing Arts; Chapter 6.Medicine and Surgery

- INTRACTABLE PAIN TREATMENT ACT (*Part of Medical Practice Act*)
  Title 63. Professions and the Healing Arts; Chapter 6.Medicine and Surgery;
  Part 11. Intractable Pain Treatment

- OSTEOPATHIC PRACTICE ACT
  Title 63. Professions and the Healing Arts; Chapter 9. Osteopathic Physicians

- PHARMACY PRACTICE ACT (*No provisions found*)
  Title 63. Professions and the Healing Arts; Chapter 10. Pharmacy

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*No provisions found*)
  Rules of the Tennessee Department of Mental Health and Developmental Disabilities; Alcohol and Drug Abuse Services Division; Chapter 0940-6-1. Controlled Substances

- MEDICAL BOARD REGULATIONS
  Rules of the Tennessee State Board of Medical Examiners; Division of Health Related Boards

- OSTEOPATHIC BOARD REGULATIONS
  Rules of the Tennessee State Board of Osteopathic Examination

- PHARMACY BOARD REGULATIONS
  Rules of the Tennessee Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD POLICY STATEMENT
  Tennessee State Boards of Medical Examiners. *Management of Prescribing with Emphasis on Addictive or Dependence-Producing Drugs*. Approved: September 19, 1995.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- CRIMINAL OFFENSES
  Title 39. Criminal Offenses; Chapter 13. Offenses Against Person; Part 2. Criminal Homicide

- PROFESSIONAL PRACTICE
  Title 63. Professions and the Healing Arts; Chapter 1. Division of Health Related Boards

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- Opioid Treatment Program Facilities

  Rules of the Tennessee Department of Mental Health and Developmental Disabilities; Office of Licensure; Chapter 0940-05-42. Minimum Program Requirements for Non-Residential Opioid Treatment Program Facilities

- Standards for Hospitals

  Rules of the Tennessee Department of Health and Tennessee Department of Environment and Conservation; Bureau of Manpower and Facilities; Division of Health Care Facilities; Chapter 1200-8-1. Standards for Hospitals

- Standards for Nursing Homes

  Rules of the Tennessee Department of Health and Tennessee Department of Environment and Conservation; Bureau of Manpower and Facilities; Division of Health Care Facilities; Chapter 1200-8-6. Standards for Nursing Homes

- Standards for Residential Hospices

  Rules of the Tennessee Department of Health and Tennessee Department of Environment and Conservation; Bureau of Manpower and Facilities; Division of Health Care Facilities; Chapter 1200-8-15. Standards for Residential Hospices

- Standards for Home Care Organizations Providing Home Health Services

  Rules of the Tennessee Department of Health and Tennessee Department of Environment and Conservation; Bureau of Manpower and Facilities; Division of Health Care Facilities; Chapter 1200-8-26. Standards for Home Care Organizations Providing Home Health Services

- Standards for Home Care Organizations Providing Hospice Services

  Rules of the Tennessee Department of Health and Tennessee Department of Environment and Conservation; Bureau of Manpower and Facilities; Division of Health Care Facilities; Chapter 1200-8-27. Standards for Home Care Organizations Providing Hospice Services

- Standards for HIV Supportive Living Facilities

  Rules of the Tennessee Department of Health and Tennessee Department of Environment and Conservation; Bureau of Manpower and Facilities; Division of Health Care Facilities; Chapter 1200-8-28. Standards for HIV Supportive Living Facilities

- Standards for Home Care Organizations Providing Professional Support Services

  Rules of the Tennessee Department of Health and Tennessee Department of Environment and Conservation; Bureau of Manpower and Facilities; Division of Health Care Facilities; Chapter 1200-8-34. Standards for Home Care Organizations Providing Professional Support Services

- Standards for Outpatient Diagnostic Centers

  Rules of the Tennessee Department of Health and Tennessee Department of Environment and Conservation; Bureau of Manpower and Facilities; Division of Health Care Facilities; Chapter 1200-8-35. Standards for Outpatient Diagnostic Centers

TENNESSEE

STATUTES

Medical Practice Act

Tenn. Code Ann. § 63-6-214

63-6-214. Grounds for license denial, suspension or revocation -- Reporting misconduct

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(b) The grounds upon which the board shall exercise such power include, but are not limited to:

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(12) Dispensing, prescribing or otherwise distributing any controlled substance or any other drug not in the course of professional practice, or not in good faith to relieve pain and suffering, or not to cure an ailment, physical infirmity or disease, or in amounts and/or for durations not medically necessary, advisable or justified for a diagnosed condition;

(13) Dispensing, prescribing or otherwise distributing to any person a controlled substance or other drug if such person is addicted to the habit of using controlled substances without making a bona fide effort to cure the habit of such patient;

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.

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

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT: Although it is reasonable to expect physicians to avoid contributing to diversion, "amounts and/or for durations not medically necessary, advisable or justified " implies there is a known standard, but the standard is not specified.

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

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: Although it is reasonable to expect physicians to avoid contributing to abuse or addiction, it is unclear what actions would constitute a "bona fide effort to cure the habit" and, thus, fulfill the standard required to avoid grounds for license denial, suspension, or revocation when medically using controlled substances to treat pain or other symptoms in a person with a history of substance abuse or an addictive disease.

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TENNESSEE

STATUTES

Intractable Pain Treatment Act

Tenn. Code Ann. § 63-6-1101 -- 1109

63-6-1101. Short title

This part may be known and cited as the "Intractable Pain Treatment Act."

63-6-1102. Definitions

For the purposes of this part:

(1) "Board" means the board of medical examiners.

(2) "Chemical dependency" means:

(A) The abuse of alcohol or a controlled substance;
(B) A pathological use of alcohol or a controlled substance that chronically impairs the applicant's ability to competently provide legal advice or services; or
(C) A physiological or physical dependence on alcohol or a controlled substance.

(3) "Intractable pain" 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.

(4) "Physician" means a physician licensee of the board of medical examiners or an osteopathic physician.

63-6-1103. Legislative declarations

The general assembly finds and declares all of the following:
(1) The state has a right and duty to control the illegal use of opiate drugs.
(2) Inadequate treatment of acute and chronic pain originating from cancer or noncancerous conditions is a significant health problem.
(3) For some patients, pain management is the single most important treatment a physician can provide.
(4) A patient suffering from severe chronic intractable pain should have access to proper treatment of such patient's pain.
(5) 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.
(6) In the hands of knowledgeable, ethical, and experienced pain management practitioners, opiates administered for severe acute and severe chronic intractable pain can be safe.
(7) Opiates can be an accepted treatment for patients in severe chronic intractable pain who have not obtained relief from any other means of treatment.
(8) A patient suffering from severe chronic intractable pain has the option to request or reject the use of any or all modalities to relieve such patient's severe chronic intractable pain.
(9) 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 physician is in conformance with the provisions of this part.
(10) 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 a physician has first determined that such treatment is appropriate and medically necessary and the prescribing is in conformance with the provisions of this part.
11) 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 whose primary practices are the treatment of severe chronic intractable pain with methods that include the use of opiates.

[CONTINUED ON NEXT PAGE]

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

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: Although similar language is used in Federal regulation, in the context of this statute this definition suggests that physicians would qualify for the immunity and, thus, relief from concerns about regulatory scrutiny provided by this statute only if they prescribe opioids after other treatments have been tried and failed, regardless of other clinical considerations.

(+) *CRITERION 4:*
Encourages pain management

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

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

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

(+) *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 include improvements in patient functioning and quality of life.

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TENNESSEE

STATUTES

Intractable Pain Treatment Act

(+) *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: How does this qualify as a "Pain Patient's Bill of Rights" ? This language falls short of providing any rights to specific treatment and may establish a false expectation for pain management.

[CONTINUED]

63-6-1104. Pain patient's bill of rights

a) This section may be known and cited as the "Pain Patient's Bill of Rights."
b) 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 such patient's severe chronic intractable pain.
c) 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 this part.
d) 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.
e) 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 physician is in conformance with this part.
f) A patient may voluntarily request that such patient's physician provide an identifying notice of the prescription for purposes of emergency treatment or law enforcement identification.
g) 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 this chapter or the regulations adopted thereunder; or
(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.

[CONTINUED ON NEXT PAGE]

(-) *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, and intractable? Is there a greater risk of discipline for a physician who would prescribe opioids to a patient with pain which was not severe, chronic, and intractable?

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STATUTES

Intractable Pain Treatment Act

[CONTINUED]

63-6-1105. Physician authorized to write prescriptions

Notwithstanding any other provision of law, a physician may prescribe or administer dangerous drugs or controlled substances to a person in the course of the physician's treatment of a person for intractable pain to provide adequate pain treatment.

63-6-1106. Disciplinary action against physicians

a) No physician may be subject to disciplinary action by the board for prescribing or administering appropriate amounts, combinations, or durations of dangerous drugs or controlled substances in the course of treatment of a person for intractable pain.
b) The board is authorized to set by rule guidelines to govern treatment under this part. Such guidelines may include requirements for documented medical history, written treatment plans, discussion of benefits and risks of the treatment, periodic review, and the keeping of appropriate records. Such guidelines may be in addition to specific requirements for persons with substance abuse issues governed by § 63-6-1107.

63-6-1107. Treatment of chemically dependent individuals

a) Notwithstanding any other provision of this part, subsections c and d shall govern the treatment of persons for chemical dependency by a physician because of their use of dangerous drugs or controlled substances.
b) The provisions of this part provide no authority to a physician to prescribe or administer dangerous drugs or controlled substances to a person for other than legitimate medical purposes as defined by the board and who the physician knows or should know to be using drugs for nontherapeutic purposes.
c) The provisions of this part authorize a physician to treat a patient who develops an acute or chronic painful medical condition with a dangerous drug or a controlled substance to relieve the patient's pain using appropriate doses, for an appropriate length of time, and for as long as the pain persists.

A patient under this subsection includes a person who:
1) Is a current drug abuser;
2) Is not currently abusing drugs but has a history of drug abuse; or
3) Lives in an environment that poses a risk for drug misuse or diversion of the drug to illegitimate use.

d) A physician who treats a patient under subsection c shall monitor the patient to ensure the prescribed dangerous drug or controlled substance is used only for the treatment of the patient's painful medical condition. To ensure that the prescribed dangerous drug or controlled substance is not being diverted to another use and the appropriateness of the treatment of the patient's targeted symptoms, the physician shall:

1) Specifically document the:
A)Understanding between the physician and patient about the patient's prescribed treatment;
B) Name of the drug prescribed;
C) Dosage and method of taking the prescribed drug;
D) Number of dose units prescribed; and
E) Frequency of prescribing and dispensing the drug; and
2) Consult with a psychologist, psychiatrist, expert in the treatment of addictions, or other health care professional, as appropriate.

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

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

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

CATEGORY C:
Regulatory or policy issues

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

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TENNESSEE

STATUTES

Intractable Pain Treatment Act

[CONTINUED]

63-6-1109. Use of physician's assistants or other personnel – Licensing – Continued education

a) Any physician who practices pain management shall also be able to hire physician assistants to assist such physician's in such physician's practice. Any of these assistants shall be a licensed physician assistant according to the requirements in § 63-19-105(a) except for any person who meets the following requirements;

(1) Is sixty-five (65) years of age or older;
(2) Was granted a degree in pre-medical studies in 1960;
(3) Was granted a master of science degree from the University of Tennessee in 1991;
(4) Was an instructor and assistant professor during the time period 1977-97 at East Tennessee State University in Surgical Technology;
(5) Was an instructor in surgical techniques and instruments to medical students and surgical residents at the Quillen College of Medicine at East Tennessee State University;
(6) Met the standards and qualifications of the American Association of Physician Assistants in March of 1976 and was rated as "physicians assistant – SP-2";
(7) Satisfactorily completed the postgraduate course "clinical skills for physicians' assistants V" in September 1977 from the Hahnemann Medical College and Hospital in Philadelphia, Pennsylvania:
(8) Held an "assistants renewal certificate" issued by the Virginia Board of Medicine from July 1, 1977, to June 30, 1978; and
(9) Was recognized as a "certified surgical assistant" by the National Surgical Assistant Association in May of 1987.

b) Such person shall be issued a license within sixty (60) days upon submission of evidence to the board of medical examiners that such person met all of the above criteria; provided, however, that such person shall only work under the supervision of one (1) physician who is in the sole practice of pain management and rehabilitation medicine. Such person's duties shall only include helping the physician examine the patients in the physician's office, doing diagnostic EMGs, ordering appropriate lab x-rays studies, seeing the physician's hospital patients on hospital rounds and writing orders to be countersigned by such physician, but, at no time shall this person be allowed to prescribe medicine. Such person shall also have the ability to work under a physician, who is in the sole practice of pain management and rehabilitation medicine, while performing extensive medical missionary trips in underpriviledged countries. Any continuing education requirements for a person meeting the above criteria shall not be waived.

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STATUTES

Osteopathic Practice Act

Tenn. Code Ann. § 63-9-111

63-9-111. Denial, suspension and revocation of licenses or certificates -- Enjoining violations -- Enforcement –Investigations

(a) The board has the power to:

(1) Deny an application for a license to any applicant who applies for the same through reciprocity or otherwise;

(2) Permanently or temporarily withhold issuance of a license;

(3) Suspend or limit or restrict a previously issued license for such time and in such manner as the board may determine;

(4) Reprimand or take such action in relation to disciplining an applicant or licensee as the board in its discretion may deem proper; or

(5) Permanently revoke a license.

(b) The grounds upon which the board shall exercise the powers set forth in subsection (a) include, but are not limited to:

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(12) Dispensing, prescribing or otherwise distributing to any person a controlled substance or other drug if such person is addicted to the habit of using controlled substances without making a bona fide effort to cure the habit of such patient;

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(-) CRITERION 16:
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: Although it is reasonable to expect physicians to avoid contributing to abuse or addiction, it is unclear what actions would constitute a "bona fide effort to cure the habit" and, thus, fulfill the standard required to avoid grounds for license denial, suspension, or revocation when medically using controlled substances to treat pain or other symptoms in a person with a history of substance abuse or an addictive disease.

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REGULATIONS

Medical Board Regulations

Tenn. Comp. R. & Regs. R. 0880-2-.14

0880-02-.14 SPECIALLY REGULATED AREAS AND ASPECTS OF MEDICAL PRACTICE.

(1) Policy Statement - The scope of practice of physicians in Tennessee is broadly defined and includes many aspects which if not particularly regulated could lead to serious ramifications for the consuming public. This Rule is to designate specific areas in the practice of medicine for regulation the violation of which may result in disciplinary action pursuant to either T.C.A. §§ 63-6-214(b)(1) or 63-6-214(b)(4) or 63-6-214(b)(12).

(2) Pharmaceutical Dispensing - Physicians who elect to dispense medication for remuneration must comply with the following:

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(d) Dispensing or prescribing controlled substances in amounts or for durations not medically necessary, advisable or justified is considered to be practicing beyond the scope of the professional practice.

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(6) Authority of Physician to Prescribe for the Treatment of Pain - Purpose - The purpose of this chapter is to recognize that some dangerous drugs and controlled substances are indispensable for the treatment of pain, and are useful for relieving and controlling many other related symptoms that patients may suffer. It is the position of the board that these drugs may be prescribed for the treatment of pain and other related symptoms after a reasonably based medical diagnosis has been made, in adequate doses, and for appropriate lengths of time, which in some cases may be as long as the pain or related symptoms persist. The board recognizes that pain, including intractable pain, and many other related symptoms are subjective complaints and that the appropriateness and the adequacy of drug and dose will vary from individual to individual. The practitioner is expected to exercise sound medical judgment in treating pain and related symptoms with dangerous drugs and controlled substances.

(a) Definitions. The following words and terms, as used in this rule shall have the following meanings in the context of providing medications for pain and related symptoms.

1. Abuser of narcotic drugs, controlled substances and dangerous drugs - A person who takes a drug or drugs for other than legitimate medical purposes.

2. Intractable pain - 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.

3. Non-therapeutic in nature or manner - A medical use or purpose that is not legitimate.

4. Prescribing pharmaceuticals or practicing consistent with the public health and welfare - Prescribing pharmaceuticals and practicing medicine for a legitimate medical purpose in the usual course of professional practice.

(b) No physician is required to provide treatment to patients with intractable pain with opiate medications but when refusing to do so shall inform the patient that there are physicians whose primary practice is in the treatment of severe, chronic, intractable pain with methods including the use of opiates. If the patient requests a referral to such a physician, and the physician makes such a referral that referral shall be noted in the patient's medical records.

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

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

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: Although similar language is used in Federal regulation, in the context of this statute this definition suggests that physicians would qualify for the immunity and, thus, relief from concerns about regulatory scrutiny provided by this statute only if they prescribe opioids after other treatments have been tried and failed, regardless of other clinical considerations.

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

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT: Although it is reasonable to expect physicians to avoid contributing to diversion, "amounts or for durations not medically necessary, advisable or justified " implies there is a known standard, but the standard is not specified.

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

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(c) If a physician provides medical care for persons with intractable pain, with or without the use of opiate medications, to the extent that those patients become the focus of the physician's practice the physician must be prepared to document specialized medical education in pain management sufficient to bring the physician within the current standard of care in that field which shall include education on the causes, different and recommended modalities for treatment, chemical dependency and the psycho/social aspects of severe, chronic intractable pain.

(d) The treatment of persons with an acute or chronic painful medical condition who also require treatment for chemical dependency by a physician shall be governed by T.C.A. § 63-6-1107 (c) and (d).

(e) Guidelines - The Tennessee Board of Medical Examiners will use the following guidelines to determine whether a physician's conduct violates T.C.A. § 63-6-214 (b) (12) through (14) in regard to the prescribing, administering, ordering, or dispensing of pain medications and other drugs necessary to address their side effects.

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

1. The treatment of pain, including intractable pain, with dangerous drugs and controlled substances is a legitimate medical purpose when done in the usual course of professional practice.

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

2. A physician or surgeon duly authorized to practice medicine in Tennessee and to prescribe controlled substances and dangerous drugs in this state shall not be subject to disciplinary action by the board for prescribing, ordering, administering, or dispensing dangerous drugs or controlled substances for the treatment and relief of pain, including intractable pain, in the usual course of professional practice for a legitimate medical purpose in compliance with applicable state and federal law.

3. Prescribing, ordering, administering, or dispensing dangerous drugs or controlled substances for pain will be considered to be for a legitimate medical purpose if based upon accepted scientific knowledge of the treatment of pain, including intractable pain, not in contravention of applicable state or federal law, and if prescribed, ordered, administered, or dispensed in compliance with the following guidelines where appropriate and as is necessary to meet the individual needs of the patient:

(i) After a documented medical history, which may be provided orally or in writing by the patient, and physical examination by the physician providing the medication including an assessment and consideration of the pain, physical and psychological function, any history and potential for substance abuse, coexisting diseases and conditions, and the presence of a recognized medical indication for the use of a dangerous drug or controlled substance;

(+) *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 include improvements in patient functioning and quality of life.

(ii) Pursuant to a written treatment plan tailored for the individual needs of the patient by which treatment progress and success can be evaluated with stated objectives such as pain relief and/or improved physical and psychosocial function. Such a written treatment plan shall consider pertinent medical history and physical examination as well as the need for further testing, consultations, referrals, or use of other treatment modalities;

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

(iii) The physician should discuss the risks and benefits of the use of controlled substances with the patient or guardian;

(iv) Subject to documented periodic review of the care by the physician at reasonable intervals in view of the individual circumstances of the patient in regard to progress toward reaching treatment objectives which takes into consideration the course of medications prescribed, ordered, administered, or dispensed as well as any new information about the etiology of the pain;

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(v) Complete and accurate records of the care provided as set forth in parts (i)-(iv) of this paragraph should be kept. When controlled substances are prescribed, names, quantities prescribed, dosages, and number of authorized refills of the drugs should be recorded, keeping in mind that pain patients with a history of substance abuse or who live in an environment posing a risk for medication misuse or diversion require special consideration. Management of these patients may require closer monitoring by the physician managing the pain and consultation with appropriate health care professionals.

4. A decision by a physician not to strictly adhere to the provisions of paragraph 3 of this section will, for good cause shown, be grounds for the board to take no disciplinary action in regard to the physician. Each case of prescribing for pain will be evaluated on an individual basis. 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.

5. If the provisions as set out in subparagraphs (1)-(4) of this section 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.

6. Quantity of pharmaceutical and chronicity of prescribing will be evaluated on the basis of the documented appropriate diagnosis and treatment of the recognized medical indication, documented persistence of the recognized medical indication, and properly documented follow-up evaluation with appropriate continuing care as set out in this rule.

7. A physician may use any number of treatment modalities for the treatment of pain, including intractable pain, which are consistent with legitimate medical purposes.

8. These rules shall not be construed so as to apply to the treatment of acute pain with dangerous drugs or controlled substances for purposes of short-term care.

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

CATEGORY B:
Issues related to patients

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

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

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Osteopathic Board Regulations

Tenn. Comp. R. & Regs. R. 1050-2-.13

1050-2-.13 SPECIFICALLY REGULATED AREAS AND ASPECTS OF MEDICAL PRACTICE

(1) The scope of practice of osteopathic physicians in Tennessee is broadly defined in the Osteopathic Medical Act and promulgated rules and includes many aspects which if not particularly regulated could lead to serious ramifications for the consuming public. This rule is to designate specific areas in the practice of osteopathic medicine for regulation the violation of which may result in disciplinary action pursuant to T.C.A. § 63-9-111.

(2) Pharmaceutical Dispensing - Osteopathic physicians who elect to dispense medication for remuneration must comply with the following:

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(d) Dispensing or prescribing controlled substances in amounts or for durations not medically necessary, advisable or justified is considered to be practicing beyond the scope of the professional practice.

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(5) Guidelines for the Use of Controlled Substances for the Treatment of Pain --

(a) Purposes and Intent

1. The Board recognizes that principles of quality medical practice dictate that the people of the State of Tennessee 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.

2. 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 pursuant to the Tennessee Intractable Pain Treatment Act 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.

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

4. The Board is obligated under the laws of the State of Tennessee 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.

[CONITINUED ON NEXT PAGE]

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

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies the potential impact of important barriers on the provision of effective pain care.

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

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

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT: Although it is reasonable to expect physicians to avoid contributing to diversion, "amounts or durations not medically necessary, advisable, or justified" implies there is a known standard, but the standard is not specified.

(+) *CRITERION 4:*
Encourages pain management

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Osteopathic Board Regulations

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5. Physicians should not fear disciplinary action from the Board for prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice. The Board will consider prescribing, ordering, administering or dispensing controlled substances for pain to be for a legitimate medical purpose 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 federal law.

6. 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.

7. 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.

(b) Guidelines - The Board adopts the following guidelines when evaluating the use of controlled substances for pain control:

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

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

3. Informed Consent and Agreement for Treatment - The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is incompetent. The patient should receive prescriptions from one physician and one pharmacy where possible.

[CONITINUED ON NEXT PAGE]

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

(+) *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.

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

(+) *CRITERION 3:*
Opioids are part of professional 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 goal of pain treatment should include improvements in patient functioning and quality of life.

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REGULATIONS

Osteopathic Board Regulations

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

5. Consultation - The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. The management of pain in patients 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; 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.

(c) No physician is required to provide treatment to patients with intractable pain with opiate medications but when refusing to do so shall inform the patient that there are physicians whose primary practice is in the treatment of severe, chronic, intractable pain with methods including the use of opiates. If the patient requests a referral to such a physician, and the physician makes such a referral that referral shall be noted in the patient's medical records.

(d) If a physician provides medical care for persons with intractable pain, with or without the use of opiate medications, to the extent that those patients become the focus of the physician's practice the physician must be prepared to document specialized medical education in pain management sufficient to bring the physician within the current standard of care in that field which shall include education on the causes, different and recommended modalities for treatment, chemical dependency and the psycho/social aspects of severe, chronic intractable pain.

(e) The treatment of persons with an acute or chronic painful medical condition who also require treatment for chemical dependency by a physician shall be governed by subsections T.C.A. § 63-6-1107 (c) and (d).

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REGULATIONS

Pharmacy Board Regulations

Tenn. Comp. R. & Regs. R. 1140-11-.01

1140-11-.01 DEFINITIONS

(1) The following definitions shall be applicable to this chapter:

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(m) "Healthcare practitioner" means:

1. a physician, dentist, optometrist, veterinarian, or other person licensed, registered, or otherwise permitted to prescribe, distribute, dispense or administer a controlled substance in the course of professional practice; or

2. a pharmacy, hospital or other institution licensed, registered, or otherwise permitted to distribute, dispense, or administer a controlled substance in the course of professional practice;

(n) "Healthcare practitioner extender" means any registered or licensed healthcare professional, and up to two (2) unlicensed persons designated by the prescriber or dispenser, who act as agents of the prescriber or dispenser. The prescriber or dispenser shall be responsible for all actions taken by the agents, pursuant to this part;

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

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TENNESSEE

OTHER GOVERNMENTAL POLICY

Medical Board Policy Statement

MANAGEMENT OF PRESCRIBING WITH EMPHASIS ON
ADDICTIVE OR DEPENDENCE-PRODUCING DRUGS

The Tennessee Board of Medical Examiners is charged by the General Assembly 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 or herself 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 Tennessee consider and reevaluate their prescribing practice of controlled substances. Practicing physicians have often mentioned the abrupt education they received in their own prescribing patterns. Moreover, there have been many request to the Board from physicians requesting detailed information on prescribing in certain specific situations.

It is not what you prescribe, but how well you manage the patient's care, and document that care in legible form, that is 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 had followed the steps that are being outlined here.

To prevent any misunderstanding, it is necessary to state what the Board **does not** have.

It **does not** have a list of "bad" or "disallowed" drugs, except in certain circumstances, amphetamines, amphetamine-like substances and central nervous system stimulants. (See, Board of Medical Examiner Rule 0880-2-.14, a copy of which is available to you by contacting the Board's administrative office at (615) 367-6231.) All formulary drugs, except as previously noted, are good if prescribed and administered when properly indicated. Conversely, all drugs are ineffective, dangerous, or even lethal when used inappropriately.

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

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 is 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 based on follow-up visits; and
- All rationale for continuing or modifying the therapy.

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OTHER GOVERNMENTAL POLICY

Medical Board Policy Statement

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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 result 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 are not appropriate or they do not work.** A finding of intolerance or allergy to NSAIDs 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.

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 is 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 a prolonged drug use, it is very important to monitor the patient for the root 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 dependence.

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

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

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

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

CATEGORY D:
Undue prescription limitations

COMMENT: Although it is reasonable to expect physicians to periodically review treatment efficacy and continued analgesia, "drug holidays" are no longer recognized as appropriate medical practice.

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OTHER GOVERNMENTAL POLICY

Medical Board Policy Statement

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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 the cumulative dosage and average daily dosage are especially valuable. A thumbnail sketch of three hypothetical cases will illustrate our point here. In the first case, a physician prescribes Tussionex to a patient for approximately five years for a cumulative dosage of nineteen and one half gallons. In the second case, a physician prescribes, Tylenol 3's to a patient for slightly more than a year at the average daily rate of 30 per day! The third case is very similar, except that 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 reselling 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 and other health care providers may tell you whether a patient is obtaining extra drugs or the patient is doctor shopping. If you are aware it is occurring, contact other physicians and health professionals in your area.

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 a symptom of 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 is 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.

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

TENNESSEE

STATUTES

Criminal Offenses

Tenn. Code Ann. § 39-13-216

39-13-216. Assisted suicide

(a) The board has the power to:

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(b) It is not an offense under this section to:

(1) Withhold or withdraw medical care as defined by *§ 32-11-103*;

(2) Prescribe, dispense, or administer medications or perform medical procedures calculated or intended to relieve another person's pain or discomfort (but not calculated or intended to cause death), even if the medications or medical procedures may hasten or increase the risk of death;

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Tenn. Code Ann. § 39-17-402

39-17-402. Definitions.

As used in this part and title 53, chapter 11, parts 3 and 4, unless the context otherwise requires:

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(23) "Practitioner" means:

(A) A physician, dentist, optometrist, 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

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians the 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 lessens its impact on patient treatment, and the practitioners who provide it.

Pain & Policy Studies Group
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Madison, Wisconsin

TENNESSEE

STATUTES

Professional Practice

Tenn. Code Ann. § 63-1-102

63-1-102. Chapter definitions

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(2) "Practice of the healing arts" means offering or undertaking to diagnose, treat, operate on, or prescribe for any human pain, injury, disease, deformity, or physical or mental condition. The practice of acupuncture is hereby declared to be included within the definition of "practice of the healing arts" as defined by this section; and

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63-1-303. Regulation of licensed healthcare practitioners -- Rules and regulations.

(a) Each licensed healthcare practitioner who provides services at a pain management clinic shall continue to be regulated only by the board which has issued a license to that practitioner.

(b) On or before October 1, 2011, the commissioner of health, in consultation with the board of medical examiners, the board of osteopathic examination, the board of nursing, and the committee on physician assistants, shall promulgate rules necessary to implement this part, in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

(c) The rules adopted pursuant to subsection (b) shall address the following topics, among others:

(1) The operation of the clinic, including requirements:

(A) That patients have current and valid government issued identification or current health insurance card issued by either a government or private carrier; and

(B) That providers conduct urine drug screening in accordance with a written drug screening and compliance plan, which may include testing on initial assessment or upon new admission;

(2) Personnel requirements for the clinic;

(3) Training requirements for clinic providers who are regulated by that board;

(4) Patient records;

(5) Standards to ensure quality of patient care;

(6) Infection control;

(7) Health and safety requirements;

(8) Certificate application and renewal procedures and requirements;

(9) Data collection and reporting requirements;

(10) Inspections and complaint investigations; and

(11) Patient billing procedures.

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

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

CATEGORY A:
Issues related to healthcare professionals

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

2013

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Madison, Wisconsin

TENNESSEE

REGULATIONS

Opioid Treatment Program Facilities

Tenn. Comp. R. & Regs. R. 0940-05-42-.12

0940-05-42-.12 SPECIAL POPULATIONS

(1) The OTP shall ensure that physicians are knowledgeable in the management of opioid dependence in a context of chronic pain and pain management. The OTP may not prohibit a service recipient diagnosed with chronic pain from receiving medication-assisted therapy for either maintenance or withdrawal in a program setting.

(a) The OTP shall ensure continuity of care and communication between programs or physicians regarding service recipients receiving treatment in both an opioid treatment program and a facility or physician's office for purposes of pain management, with service recipient consent.

(b) If the service recipient refuses consent for the two entities to communicate and coordinate care, the OTP shall document refusal and may make clinically appropriate decisions regarding take-home medication privileges, an increase in counseling, and continuation in treatment.

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Tenn. Comp. R. & Regs. R. 0940-05-42-.29

0940-05-42-.29 PERSONNEL AND STAFFING REQUIREMENTS

(1) A personnel record for each staff member of a Facility shall include an application for employment and/or resume and a record of any disciplinary action taken. A licensee shall maintain written records for each employee and each individual file shall include:

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(5) Staff Training and Orientation. Prior to working with service recipients, all staff providing treatment or services shall be oriented in accordance with these rules and shall thereafter receive additional training with these rules.

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(b) Additional training consisting of a minimum of eight clock hours of training or instruction shall be provided annually for each staff member who provides treatment or services to service recipients. Such training shall be in subjects that relate to the employee's assigned duties and responsibilities, and in subjects about current clinical practice guidelines for opioid replacement treatment. In-house training for staff may be substituted for external training with the approval of the SOTA. The following areas shall receive emphasis during training:

1. Dosage level as determined through a physician's clinical decision-making and the individual service recipient's needs;
2. Counseling;
3. Drug screens and urinalysis;
4. Phases of treatment;
5. Treating multiple substance abuse;
6. Opioid treatment during pregnancy and diseases;
7. HIV and other infectious diseases;
8. Co-morbid psychiatric conditions;
9. FDA-approved drugs for the treatment of opioid addiction, including methadone and buprenorphine;
10. Take-home medication practices;
11. Chronic pain and pain management; and

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

CATEGORY B:
Issues related to patients

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

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for OTP staff to permit methadone-maintained patients treatment for pain.

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (staff training and orientation) for OTP to ensure that pain management is an essential part of patient care.

2013

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University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

TENNESSEE

REGULATIONS

Standards for Hospitals

Tenn. Comp. R. & Regs. R. 1200-8-1-.04

1200-8-01-.04 ADMINISTRATION

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(8) The hospital shall provide a process that assesses pain in all patients. There shall be an appropriate and effective pain management program.

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Tenn. Comp. R. & Regs. R. 1200-8-1-.12

1200-8-1-.12 PATIENT RIGHTS.

(1) Each patient has at least the following rights:

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(g) To have appropriate assessment and management of pain;

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

CATEGORY C:
Regulatory or policy issues

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

REGULATIONS

Standards for Nursing Homes

Tenn. Comp. R. & Regs. R. 1200-8-6

1200-8-06-.04 ADMINISTRATION

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(19) The nursing home shall provide a process that assesses pain in all patients. There shall be an appropriate and effective pain management program.

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1200-8-6-.12 RESIDENT RIGHTS.

(1) The nursing home shall establish and implement written policies and procedures setting forth the rights of residents for the protection and preservation of dignity, individuality and, to the extent medically feasible, independence. Residents and their families or other representatives shall be fully informed and documentation shall be maintained in the resident's file of the following rights:

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(x) To have appropriate assessment and management of pain;

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

CATEGORY C:
Regulatory or policy issues

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

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Madison, Wisconsin

TENNESSEE

REGULATIONS

Standards for Residential Hospices

Tenn. Comp. R. & Regs. R. 1200-8-15

1200-8-15-.04 ADMINISTRATION

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(4) The residential hospice shall provide a process that assesses pain in all patients. There shall be an appropriate and effective pain management program.

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1200-8-15-.12 PATIENT/RESIDENT RIGHTS.

(1) The residential hospice shall establish and implement written policies and procedures setting forth the rights of patients and residents for the protection and preservation of dignity and individuality. Each patient and resident has at least the following rights:

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(m) To have appropriate assessment and management of pain;

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

CATEGORY C:
Regulatory or policy issues

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

REGULATIONS

Standards for Home Care Organizations Providing Home Health Services

Tenn. Comp. R. & Regs. R. 1200-8-26-.04

1200-8-26-.04 ADMINISTRATION

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(3) The home health agency shall provide a process that assesses pain in all patients. There shall be an appropriate and effective pain management program.

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Tenn. Comp. R. & Regs. R. 1200-8-26-.12

1200-8-26-.12 PATIENT RIGHTS

(1) Each patient has at least the following rights:

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(b) To have appropriate assessment and management of pain;

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

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a responsibility for home care organizations providing home health services to ensure that pain management is an essential part of patient care.

2013

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Madison, Wisconsin

TENNESSEE

REGULATIONS

Standards for Home Care Organizations Providing Hospice Services

Tenn. Comp. R. & Regs. R. 1200-8-27-.04

1200-8-27-.04 ADMINISTRATION

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(4) The hospice agency shall provide a process that assesses pain in all patients. There shall be an appropriate and effective pain management program.

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1200-8-27-.12 PATIENT RIGHTS.

(1) Each patient has at least the following rights:

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(c) To have appropriate assessment and management of pain;

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.

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for home care organizations providing hospice services to ensure that pain management is an essential part of patient care.

REGULATIONS

Standards for HIV Supportive Living Facilities

Tenn. Comp. R. & Regs. R. 1200-8-28-.04

1200-8-28-.04 ADMINISTRATION

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(4) The HIV supportive living facility shall provide a process that assesses pain in all patients. There shall be an appropriate and effective pain management program.

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Tenn. Comp. R. & Regs. R. 1200-8-28-.12

1200-8-28-.12 RESIDENT RIGHTS

(1) The HIV supportive living facility shall establish and implement written policies and procedures setting forth the rights of residents for the protection and preservation of dignity and individuality. Each resident has at least the following rights:

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(m) To have appropriate assessment and management of pain;

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

CATEGORY C:
Regulatory or policy issues

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

2013

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Madison, Wisconsin

TENNESSEE

REGULATIONS

Standards for Home Care Organizations Providing Professional Support Services

Tenn. Comp. R. & Regs. R. 1200-8-34-.12

1200-8-34-.12 CONSUMER RIGHTS

(1) Each consumer has at least the following rights:

(a) To privacy in treatment and personal care;

(b) To have appropriate assessment and management of pain;

. . .

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for home care organizations providing professional support services to ensure that pain management is an essential part of patient care.

REGULATIONS

Standards for Outpatient Diagnostic Centers

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

CATEGORY C:
Regulatory or policy issues

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

Tenn. Comp. R. & Regs. R. 1200-8-35-.12

1200-8-35-.12 PATIENT RIGHTS.

(1) Each patient has at least the following rights:

. . .

(f) To have appropriate assessment and management of pain;

. . .

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Madison, Wisconsin

TEXAS

STATUTES

- CONTROLLED SUBSTANCES ACT
  Health and Safety Code; Title 6. Food, Drugs, Alcohol, and Hazardous Substances; Subtitle C. Substance Abuse Regulation and Crimes; Chapter 481. Texas Controlled Substances Act

- MEDICAL PRACTICE ACT
  Occupations Code; Title 3. Health Professions; Subtitle B. Physicians

- PHARMACY PRACTICE ACT
  Occupations Code; Title 3. Health Professions; Subtitle J. Pharmacy and Pharmacists

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Title 37. Public Safety and Corrections; Part 1. Texas Department of Public Safety; Chapter 13. Controlled Substances

- MEDICAL BOARD REGULATIONS
  Title 22. Examining Boards; Part 9. Texas Medical Board

- PHARMACY BOARD REGULATIONS
  Title 22. Examining Boards; Part 15. Texas State Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- PHARMACY BOARD POLICY STATEMENT
  Texas State Board of Pharmacy. *Texas State Board of Pharmacy Position Statement on the Treatment of Pain*. Adopted: August 29, 2001.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- PAIN TREATMENT EDUCATION
  Education Code; Title 3. Higher Education; Subtitle A. Higher Education in General; Chapter 51. Provisions Generally Applicable to Higher Education; Subchapter F. Required and Elective Courses

- INTRACTABLE PAIN TREATMENT ACT
  Occupations Code; Title 3. Health Professions; Subtitle A. Provisions Applying to Health Professions Generally; Chapter 107. Intractable Pain Treatment

- LICENSING OF HOSPITALS
  Title 25. Health Services; Part 1. Department of State Health Services; Chapter 133. Hospital Licensing; Subchapter C. Operational Requirements

- STANDARDS FOR LICENSURE

  Title 40. Social Services and Assistance; Part 1. Department of Aging and Disability Services; Chapter 92. Licensing Standards for Assisted Living Facilities; Subchapter C. Standards for Licensure

- STANDARDS SPECIFIC TO AGENCIES LICENSED TO PROVIDE HOSPICE SERVICES

  Title 40. Social Services and Assistance; Part 1. Department of Aging and Disability Services; Chapter 97. Licensing Standards for Home and Community Support Services Agencies; Subchapter H. Standards Specific to Agencies Licensed to Provide Hospice Services

TEXAS

STATUTES

Controlled Substances Act

Tex. Health & Safety Code § 481.002

§ 481.002. Definitions

In this chapter:

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(39) "Practitioner" means:

(A) a physician, dentist, veterinarian, podiatrist, scientific investigator, or other person licensed, registered, or otherwise permitted to distribute, dispense, analyze, 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

Tex. Health & Safety Code § 481.351

§ 481.351. Interagency Prescription Monitoring Work Group

The interagency prescription monitoring work group is created to evaluate the effectiveness of prescription monitoring under this chapter and offer recommendations to improve the effectiveness and efficiency of recordkeeping and other functions related to the regulation of dispensing controlled substances by prescription.

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (interagency work group) to evaluate effectiveness of prescription monitoring program.

2013

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

TEXAS

STATUTES

Medical Practice Act

Tex. Occ. Code § 153.014

§ 153.014. Information Provided to License Holders

At least once each biennium, the board shall provide to license holders information on:

(1) prescribing and dispensing pain medications, with particular emphasis on Schedule II and Schedule III controlled substances;

(2) abusive and addictive behavior of certain persons who use prescription pain medications;

(3) common diversion strategies employed by certain persons who use prescription pain medications, including fraudulent prescription patterns; and

(4) the appropriate use of pain medications and the differences between addiction, pseudo-addiction, tolerance, and physical dependence.

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

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (board responsibility) to provide practitioners information/education about pain management.

Tex. Occ. Code § 156.055

§ 156.055. Continuing Education in Pain Treatment

A physician licensed under this subtitle who submits an application for renewal of a license that designates a direct patient care practice and whose practice includes treating patients for pain is encouraged to include continuing medical education in pain treatment among the hours of continuing medical education completed to comply with Section 156.051(a)(2).

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

CATEGORY C:
Regulatory or policy issues

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

Tex. Occ. Code § 164.053

§ 164.053. Unprofessional or Dishonorable Conduct

(a) For purposes of Section 164.052(a)(5), unprofessional or dishonorable conduct likely to deceive or defraud the public includes conduct in which a physician:

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(3) writes prescriptions for or dispenses to a person who:

(A) is known to be an abuser of narcotic drugs, controlled substances, or dangerous drugs; or

(B) the physician should have known was an abuser of narcotic drugs, controlled substances, or dangerous drugs;

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(c) Subsection (a)(3) does not apply to a person the physician is treating for:

(1) the person's use of narcotics after the physician notifies the board in writing of the name and address of the person being treated; or

(2) intractable pain under the Intractable Pain Treatment Act (Article 4495c, Revised Statutes).

(-) *CRITERION 14:*
Undue prescription requirements

COMMENT: This provision requires reporting. Submission to the medical board of the names of all patients, for whom the physician writes or dispenses any prescription to a patient the physician "knows or should have known was an abuser of narcotic drugs", may reinforce concerns about regulatory scrutiny.

2013

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University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

TEXAS

STATUTES

Pharmacy Practice Act

Tex. Occ. Code § 551.003

§ 551.003. Definitions

In Chapters 551-566:

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(34) "Practitioner" means:

(A) a person licensed or registered to prescribe, distribute, administer, or dispense a prescription drug or device in the course of professional practice in this state, including a physician, dentist, podiatrist, or veterinarian but excluding a person licensed under this subtitle;

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

Tex. Occ. Code § 554.014

§ 554.014. Information Provided to License Holders

At least once each biennium, the board shall provide to license holders information on:

(1) prescribing and dispensing pain medications, with particular emphasis on Schedule II and Schedule III controlled substances;

(2) abusive and addictive behavior of certain persons who use prescription pain medications;

(3) common diversion strategies employed by certain persons who use prescription pain medications, including fraudulent prescription patterns; and

(4) the appropriate use of pain medications and the differences between addiction, pseudo-addiction, tolerance, and physical dependence.

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

CATEGORY C:
Regulatory or policy issues

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

Tex. Occ. Code § 559.0525

§ 559.0525. Continuing Education Relating to Opioid Drugs

(a) The board shall develop a continuing education program regarding opioid drug abuse and the delivery, dispensing, and provision of tamper-resistant opioid drugs after considering input from interested persons.

(b) The board by rule may require a license holder to satisfy a number of the continuing education hours required by Section 559.053 through attendance of a program developed under this section.

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (continuing education) to provide practitioners information/education about opioid medications.

2013

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

TEXAS

REGULATIONS

Controlled Substances Regulations

37 TAC § 13.1

§ 13.1. Chapter Definitions

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise.

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(14) Individual practitioner--A physician, dentist, veterinarian, optometrist, podiatrist, or other individual licensed, registered, or otherwise permitted 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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37 TAC § 13.72

§ 13.72. Prescriptions

(a) Schedule II Prescriptions.
(1) A practitioner, as defined in the Act, § 481.002(39)(A), must issue a written prescription for a Schedule II con-trolled substance only on an official Texas prescription form or through an electronic prescription that includes the con-trolled substances registration number issued by the department and meets all requirements of the Act. This subsection also applies to a prescription issued in an emergency situation.

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

(-) *CRITERION 14:*
Undue prescription requirements

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

TEXAS

REGULATIONS

Medical Board Regulations

22 TAC § 170.1 - .3

§ 170.1. Purpose

The treatment of pain is a vital part of the practice of medicine. Patients look to physicians not only to cure disease, but also to try to relieve their pain. Physicians should be able to treat their patients' pain using sound clinical judgment without fear that the board will pursue disciplinary action. This Rule sets forth the board's policy for the proper treatment of pain. The board's intent is to protect the public and give guidance to physicians. The principles underlying this policy include:

(1) Pain is a medical condition that every physician sees regularly. It is an integral part of the practice of medicine. Patients deserve to have medical treatment for their pain, whether the pain is acute or chronic, mild or severe. The goal of pain management is to treat the patient's pain in relation to overall health, including physical function, psychological, social, and work-related factors.

(2) The regulatory atmosphere must support a physician's ability to treat pain, no matter how difficult the case, using whatever tools are most appropriate. Drugs, including opiates, are essential tools for the treatment of pain.

(3) The board is charged by the Legislature with the responsibility to assure that drugs are used in a therapeutic manner. A license to practice medicine gives a physician legal authority to prescribe drugs for pain. The physician has a duty to use that authority to help, and not to harm patients and the public.

(4) Harm can result when a physician does not use sound clinical judgment in using drug therapy. If the physician fails to apply sufficient drug therapy, the patient will likely suffer continued pain and may demonstrate relief-seeking behavior, known as pseudoaddiction. On the other hand, non-therapeutic drug therapy may lead to or contribute to abuse, addiction, and/or diversion of drugs. As with everything in the practice of medicine, physicians must be well informed of and carefully assess the risks and the benefits as they apply to each case.

(5) Physicians should not fear board action if they provide proper pain treatment. The board will not look solely at the quantity or duration of drug therapy. Proper pain treatment is not a matter of how much drug therapy is used, as long as that therapy is based on sound clinical judgment. Sound clinical judgment results from evidence-based medicine and/or the use of generally accepted standards.

(6) A physician can demonstrate sound clinical judgment by recording the physician's rationale for the treatment plan and maintaining medical records that are legible, complete, accurate and current for each patient.

(7) The extent of medical records should be reasonable for each case. A treatment plan for acute, episodic pain may note only the dosage and frequency of drugs prescribed and that no further treatment is planned.

(8) Treatment of chronic pain requires a reasonably detailed and documented plan to assure that the treatment is monitored. An explanation of the physician's rationale is especially required for cases in which treatment with scheduled drugs is difficult to relate to the patients objective physical, radiographic, or laboratory findings.

(9) The intent of these guidelines is not to impose regulatory burdens on the practice of medicine. Rather, these guidelines are intended to set forth those items expected to be done by any reasonable physician involved in the treatment of pain. The use of the word "shall" in these guidelines is used to identify those items a physician is required to perform in all such cases. The word "should" and the phrase "it is the responsibility of the physician" in these guidelines are used to identify those actions that a prudent physician will either do and document in the treatment of pain or be able to provide a thoughtful explanation as to why the physician did not do so.

[CONTINUED ON NEXT PAGE]

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

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians the important distinction between drug-seeking behaviors resulting from poorly treated pain (i.e., pseudoaddiction) and drug-seeking behaviors related to abuse or addiction; this language identifies a potential clinical situation and attempts to lessen its impact on patient treatment.

(+) *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 include improvements in patient functioning and quality of life.

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

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

2013

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

TEXAS

REGULATIONS

Medical Board Regulations

[CONTINUED]

§ 170.2. Definitions

In this Chapter:

(1) "Abuse" or "substance abuse"--the essential feature of substance abuse is a maladaptive pattern of substance use manifested by recurrent and significant adverse consequences related to the repeated use of substances.

(2) "Acute pain"--the normal, predicted, physiological response to a stimulus such as trauma, disease, and operative procedures. Acute pain is time limited.

(3) "Addiction"--a primary, chronic, neurobiological disease characterized by craving and compulsive use of drugs. Addiction is often characterized by impaired control over drug use, including taking more drugs more often than prescribed by a physician. It may also be characterized by continued use despite harm to oneself or others. Genetic, psychosocial, and environmental factors may influence the development and manifestation of addiction. Physical dependence and tolerance are normal physiological consequences of extended drug therapy for pain and, alone, do not indicate addiction.

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

(4) "Chronic pain"--a state in which pain persists beyond the usual course of an acute disease or healing of an injury. Chronic pain may be associated with a chronic pathological. process that causes continuous or intermittent pain over months or years.

(5) "Dangerous drugs"--medications defined by the Texas Dangerous Drug Act, Chapter 483, Texas Health and Safety Code. Dangerous drugs require a prescription, but are not included in the list of scheduled drugs. A dangerous drug bears the legend "Caution: federal law prohibits dispensing without a prescription" or "Prescription Only."

(6) "Diversion"--the use of drugs by anyone other than the person for whom the drug was prescribed.

(7) "Escalation"--increasing the dosage and/or frequency of the use of drugs.

(+) *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.

(8) "Improper pain treatment"--includes over treatment, under treatment, no treatment, and the prescription of drugs for purposes other than the proper treatment of pain.

(9) "Non-therapeutic"--is defined in *§ 164.053(a)(5), Texas Occupations Code* and includes improper pain treatment.

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

(11) "Physical dependence"--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, alone, does not indicate addiction.

(12) "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.

(13) "Scheduled drugs" (sometimes referred to as "Controlled Substances")--medications defined by the Texas Controlled Substances Act, Chapter 481, Texas Health and Safety Code. This Act establishes five categories, or schedules of drugs, based on risk of abuse and addiction. (Schedule I includes drugs that carry an extremely high risk of abuse and addiction and have no legitimate medical use. Schedule V includes drugs that have the lowest abuse/addiction risk).

(14) "Tolerance" (tachyphylaxis)--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 does not necessarily occur during opioid treatment and does not, alone, indicate addiction.

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Medical Board Regulations

[CONTINUED]

(15) "Withdrawal"--the physiological and mental readjustment that accompanies discontinuation of a drug for which a person has established a physical dependence.

§ 170.3. Guidelines

(a) The Texas Medical Board will use these guidelines to assess a physician's treatment of pain.

(1) Evaluation of the patient.

(A) A physician is responsible for obtaining a medical history and a physical examination that includes a problem-focused exam specific to the chief presenting complaint of the patient.

(B) The medical record shall document the medical history and physical examination. In the case of chronic pain, the medical record should document:

(i) the nature and intensity of the pain,

(ii) current and past treatments for pain,

(iii) underlying or coexisting diseases and conditions,

(iv) the effect of the pain on physical and psychological function,

(v) any history and potential for substance abuse, and

(vi) the presence of one or more recognized medical indications for the use of a dangerous or scheduled drug.

(2) Treatment plan for chronic pain. The physician is responsible for a written treatment plan that is documented in the medical records. The medical record should include:

(A) How the medication relates to the chief presenting complaint of chronic pain;

(B) dosage and frequency of any drugs prescribed,

(C) further testing and diagnostic evaluations to be ordered,

(D) other treatments that are planned or considered,

(E) periodic reviews planned, and

(F) objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function.

(3) Informed consent. It is the physician's responsibility to discuss the risks and benefits of the use of controlled substances for the treatment of chronic pain 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. This discussion should be documented by either a written signed document maintained in the records or a contemporaneous notation included in the medical records. Discussion of risks and benefits should include an explanation of the:

(A) diagnosis;

(B) treatment plan;

(C) anticipated therapeutic results, including the realistic expectations for sustained pain relief and improved functioning and possibilities for lack of pain relief

[CONTINUED ON NEXT PAGE]

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

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Medical Board Regulations

[CONTINUED]

(D) therapies in addition to or instead of drug therapy, including physical therapy or psychological techniques;

(E) potential side effects and how to manage them;

(F) adverse effects, including the potential for dependence, addiction, tolerance, and withdrawal; and

(G) potential for impairment of judgment and motor skills.

(4) Agreement for treatment of chronic pain. A proper patient-physician relationship for treatment of chronic pain requires the physician to establish and inform the patient of the physician's expectations that are necessary for patient compliance. If the treatment plan includes extended drug therapy, the physician should consider the use of a written pain management agreement between the physician and the patient outlining patient responsibilities, including the following provisions:

(A) the physician may require laboratory tests for drug levels upon request;

(B) the physician may limit the number and frequency of prescription refills;

(C) only one physician will prescribe dangerous and scheduled drugs;

(D) only one pharmacy will be used for prescriptions, and

(E) reasons for which drug therapy may be discontinued (e.g. violation of agreement).

(5) Periodic review of the treatment of chronic pain.

(A) The physician should see the patient for periodic review at reasonable intervals in view of the individual circumstances of the patient.

(B) Periodic review should assess progress toward reaching treatment objectives, taking into consideration the history of medication usage, as well as any new information about the etiology of the pain.

(C) Each periodic visit shall be documented in the medical records.

(D) Contemporaneous to the periodic reviews, the physician should note in the medical records any adjustment in the treatment plan based on the individual medical needs of the patient.

(E) A physician should continue or modify the use of dangerous and scheduled drugs for pain management based on an evaluation of progress toward treatment objectives.

(i) Progress or the lack of progress in relieving pain should be documented in the patient's record.

(ii) Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, and/or improved quality of life.

(iii) Objective evidence of improved or diminished function should be monitored. Information from family members or other caregivers should be considered in determining the patient's response to treatment.

(iv) If the patient's progress is unsatisfactory, the physician should reassess the current treatment plan and consider the use of other therapeutic modalities.

(6) Consultation and Referral. The physician should refer a patient with chronic pain for further evaluation and treatment as necessary. Patients who are at-risk for abuse or addiction require special attention. Patients with chronic pain and histories of substance abuse or with co-morbid psychiatric disorders require even more care. A consult with or referral to an expert in the management of such patients should be considered in their treatment.

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Medical Board Regulations

[CONTINUED]

(7) Medical records. The medical records shall document the physician's rationale for the treatment plan and the prescription of drugs for the chief complaint of chronic pain and show that the physician has followed these guidelines. Specifically the records should include:

(A) the medical history and the physical examination;

(B) diagnostic, therapeutic and laboratory results;

(C) evaluations and consultations;

(D) treatment objectives;

(E) discussion of risks and benefits;

(F) informed consent;

(G) treatments;

(H) medications (including date, type, dosage and quantity prescribed);

(I) instructions and agreements; and

(J) periodic reviews.

(b) It is not the board's policy to take disciplinary action against a physician solely for not adhering strictly to these guidelines if the physician's rationale for the treatment indicates sound clinical judgment documented in the medical records. Each case of prescribing for pain will be evaluated on an individual basis. The physician's conduct will be evaluated by considering:

(1) the treatment objectives, including any improvement in functioning,

(2) whether the drug used is pharmacologically recognized to be appropriate for the diagnosis as determined by a consensus of medical practitioners in the State or by recognized experts in the field for which the drug is being used,

(3) the patient's individual needs, and

(4) that some types of pain cannot be completely relieved.

22 TAC § 195.4

§ 195.4. Operation of Pain Management Clinics

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(f) Standards to Ensure Quality of Patient Care. The medical director of a pain management clinic shall:

(1) be on-site at the clinic at least 33 percent of the clinic's total number of operating hours;

(2) review at least 33 percent of the total number of patient files of the clinic, including the patient files of a clinic employee or contractor to whom authority for patient care has been delegated by the clinic;

(3) establish protocols consistent with Chapter 170 of this title (relating to Pain Management); and

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[CONTINUED ON NEXT PAGE]

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (written protocols) for pain management clinics to guide patient pain care.

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Allows for additional flexibility for physicians as long as their prescribing maintains the standards of good medical practice.

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REGULATIONS

Medical Board Regulations

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (ongoing assessments) for pain management clinics to ensure that pain relief is an essential part of patient care.

[CONTINUED]

(4) establish quality assurance procedures to include at a minimum:

(A) a practice quality plan that requires the medical director to complete at least 10 hours of continuing medical education in the area of pain management;

(B) documentation of the background, training, and certifications for all clinical staff;

(C) a written drug screening policy and compliance plan for patients receiving chronic opioids;

(D) performance of periodic quality measures of medical and procedural outcomes and complications that may include questionnaires or surveys for activities of daily living scores, pain scores, and standardized scales.

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (education requirement) for pain management clinics to ensure that pain relief is an essential part of patient care.

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TEXAS

REGULATIONS

Pharmacy Board Regulations

22 TAC § 281.7

§ 281.7. Grounds for Discipline for a Pharmacist License

(a) For the purposes of the Act, § 565.001(a)(2), "unprofessional conduct" shall include, but not be limited to:

(1) dispensing a prescription drug pursuant to a forged, altered, or fraudulent prescription;

(2) dispensing a prescription drug order pursuant to a prescription from a practitioner as follows:

(A) the dispensing of a prescription drug order not issued for a legitimate medical purpose or in the usual course of professional practice shall include the following:

(i) dispensing controlled substances or dangerous drugs to an individual or individuals in quantities, dosages, or for periods of time which grossly exceed standards of practice, approved labeling of the federal Food and Drug Administration, or the guidelines published in professional literature; or

(ii) dispensing controlled substances or dangerous drugs when the pharmacist knows or reasonably should have known that the controlled substances or dangerous drugs are not necessary or required for the patient's valid medical needs or for a valid therapeutic purpose;

(B) the provisions of subparagraph (A)(i) and (ii) of this paragraph are not applicable for prescriptions dispensed to persons with intractable pain in accordance with the requirements of the Intractable Pain Treatment Act, or to a narcotic drug dependent person in accordance with the requirements of *Title 21, Code of Federal Regulations, § 1306.07*, and the Regulation of Narcotic Drug Treatment Programs Act;

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22 TAC § 291.31

§ 291.31. Definitions

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

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(39) Practitioner--

(A) a person licensed or registered to prescribe, distribute, administer, or dispense a prescription drug or device in the course of professional practice in this state, including a physician, dentist, podiatrist, or veterinarian but excluding a person licensed under this subtitle;

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22 TAC § 291.34

§ 291.34. Records

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(E) Prescription drug orders for Schedule II controlled substances. No Schedule II controlled substance may be dispensed without a written prescription drug order of a practitioner on an official prescription form as required by the Texas Controlled Substances Act, § 481.075.

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(+) *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 pain.

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

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

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT: Although it is reasonable to expect pharmacists to avoid contributing to diversion, "grossly exceeds" implies there is a known standard, but the standard is not specified.

(-) *CRITERION 14:*
Undue prescription requirements

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TEXAS

OTHER GOVERNMENTAL POLICIES

Pharmacy Board Policy Statement

Texas State Board of Pharmacy
Position Statement on the Treatment of Pain

The Texas State Board of Pharmacy recognizes that quality care dictates that the people of the State of Texas have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages pharmacists to view effective pain management as a part of quality care 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 dispensing controlled substances.

Inadequate pain control may result from physicians' and pharmacists' lack of knowledge about pain management or an inadequate understanding of addiction. 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 also recognizes that controlled substances are subject to abuse by individuals who seek them for mood altering and other psychological effects rather than their legitimate medical uses. When dispensing controlled substances, the pharmacist should be diligent in preventing them from being diverted from legitimate to illegitimate use. Tolerance and physical dependence are normal consequences of sustained use of these drugs and are not synonymous with psychological dependency (addiction). Psychological dependency is characterized by the compulsion to take the drug despite its harmful and destructive effect on the individual.

Pharmacists should not fear disciplinary action from the Board for dispensing controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice. The Board will consider dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain and sound clinical grounds. All such dispensing must be based on clear documentation of the patient's medical condition and pertinent discussions with the prescribing physician.

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

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

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

(+) *CRITERION 4:*
Encourages pain management

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies the potential impact of important barriers on the provision of effective pain care.

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

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TEXAS

STATUTES

Pain Treatment Education

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

CATEGORY C:
Regulatory or policy issues

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

Tex. Educ. Code § 51.309

§ 51.309. Pain Treatment Medical Education Course Work

(a) Each medical school shall determine the extent to which pain treatment medical education course work is meeting the instructional elements described in Subsection (b) and is offered to all students enrolled in medical schools.

(b) Pain treatment medical education course work should include instruction in:

(1) pain assessment in adults, children, and special populations, including elderly and impaired individuals;

(2) pain anatomy, physiology and pathophysiology, and pharmacology of opioid and nonopioid analgesic drugs, including pharmacokinetics and pharmacodynamics;

(3) the advantages and disadvantages of various methods of drug administration, side effects, treatment outcome, and the outcome of behavioral and other psychological therapy for pain;

(4) the psychological, social, economic, and emotional impact of malignant and nonmalignant acute and chronic pain on patients;

(5) indications for and outcomes of anesthetic and neurosurgical pain-relieving techniques, including nerve blocks and neuroaugmentative and neuroablative techniques; and

(6) the outcome of treatment of pain emanating from a damaged nervous system and neuropathic pain.

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TEXAS

STATUTES

Intractable Pain Treatment Act

Tex. Occ. Code § 107.001

§ 107.001. Short Title

This chapter may be cited as the Intractable Pain Treatment Act.

§ 107.002. Definitions

In this chapter:

(1) "Board" means the Texas State Board of Medical Examiners.

(2) "Intractable pain" means a state of pain for which:

(A) the cause of the pain cannot be removed or otherwise treated; and

(B) in the generally accepted course of medical practice, relief or cure of the cause of the pain:

(i) is not possible; or

(ii) has not been found after reasonable efforts.

(3) "Physician" means a physician licensed by the board.

§ 107.003. Nonapplicability of Chapter to Certain Chemically Dependent Persons

Except as provided by Subchapter C , this chapter does not apply to a person being treated by a physician for chemical dependency because of the person's use of a dangerous drug or controlled substance.

§ 107.051. Authority to Prescribe or Administer Dangerous Drug or Controlled Substance

Notwithstanding any other law, a physician may prescribe or administer a dangerous drug or controlled substance to a person in the course of the physician's treatment of the person for intractable pain.

§ 107.052. Limitations on Prescription or Administration of Dangerous Drug or Controlled Substance

This chapter does not authorize a physician to prescribe or administer to a person a dangerous drug or controlled substance:

(1) for a purpose that is not a legitimate medical purpose as defined by the board; and

(2) if the physician knows or should know the person is using drugs for a nontherapeutic purpose.

§ 107.053. Limitation on Authority of Hospital or Other Health Care Facility Regarding Use of Dangerous Drug or Controlled Substance

A hospital or other health care facility may not prohibit or restrict the use of a dangerous drug or controlled substance prescribed or administered by a physician who holds staff privileges at the hospital or facility for a person diagnosed and treated by a physician for intractable pain.

[CONITINUED ON NEXT PAGE]

(+) *CRITERION 2:*
Pain management is part of healthcare 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: Attempts to provide a secure environment for physicians prescribing in their healthcare facility. However, this only applies to prescribing for intractable pain patients and not patients in general.

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

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

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: Although similar language is used in Federal regulation, in the context of this statute this definition suggests that physicians would qualify for the immunity and, thus, relief from concerns about regulatory scrutiny provided by this statute only if they prescribe opioids after other treatments have been tried and failed, regardless of other clinical considerations.

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STATUTES

Intractable Pain Treatment Act

[CONTINUED]

§ 107.101. Patient

In this subchapter, "patient" includes a person who:

(1) is currently abusing a dangerous drug or controlled substance;

(2) is not currently abusing such a drug or substance but has a history of such abuse; or

(3) lives in an environment that poses a risk for misuse or diversion to illegitimate use of such a drug or substance.

§ 107.102. Authority To Treat

This chapter authorizes a physician to treat a patient with an acute or chronic painful medical condition with a dangerous drug or controlled substance to relieve the patient's pain using appropriate doses, for an appropriate length of time, and for as long as the pain persists.

§ 107.103. Duty to Monitor Patient

A physician who treats a patient under this subchapter shall monitor the patient to ensure that a prescribed dangerous drug or controlled substance is used only for the treatment of the patient's painful medical condition.

§ 107.104. Documentation and Consultation Required

To ensure that a prescribed dangerous drug or controlled substance is not diverted to another use and to ensure the appropriateness of the treatment of the patient's targeted symptoms, the physician shall:

(1) specifically document:

(A) the understanding between the physician and patient about the patient's prescribed treatment;

(B) the name of the drug or substance prescribed;

(C) the dosage and method of taking the prescribed drug or substance;

(D) the number of dose units prescribed; and

(E) the frequency of prescribing and dispensing the drug or substance; and

(2) consult with a psychologist, psychiatrist, expert in the treatment of addictions, or other health care professional, as appropriate.

[CONITINUED ON NEXT PAGE]

(+) *CRITERION 4:*
Encourages pain management

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

CATEGORY B:
Issues related to patients

COMMENT: Acknowledges that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management, which is authorized for all patients in §107.102.

(-) *CRITERION 14:*
Undue prescription requirements

COMMENT: Although it is reasonable to expect physicians to avoid knowingly contributing to diversion, an absolute requirement is unrealistic. What are the ramifications to the physician if diversion does occur despite monitoring?

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TEXAS

STATUTES

Intractable Pain Treatment Act

[CONTINUED]

§ 107.151. Disciplinary Action Prohibited

A physician is not subject to disciplinary action by the board for prescribing or administering a dangerous drug or controlled substance in the course of treatment of a person for intractable pain.

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

§ 107.152. Authority of Board to Revoke or Suspend License

(a) This chapter does not affect the authority of the board to revoke or suspend the license of a physician who:

(1) prescribes, administers, or dispenses a drug or treatment:

(A) for a purpose that is not a legitimate medical purpose as defined by the board; and

(B) that is nontherapeutic in nature or nontherapeutic in the manner the drug or treatment is administered or prescribed;

(2) fails to keep a complete and accurate record of the purchase and disposal of:

(A) a drug listed in Chapter 481, Health and Safety Code; or

(B) a controlled substance scheduled in the Comprehensive Drug Abuse Prevention and Control Act of 1970 *(21 U.S.C. Section 801* et seq.);

(3) writes a false or fictitious prescription for:

(A) a dangerous drug as defined by Chapter 483, Health and Safety Code;

(B) a controlled substance listed in a schedule under Chapter 481, Health and Safety Code; or

(C) a controlled substance scheduled in the Comprehensive Drug Abuse Prevention and Control Act of 1970 *(21 U.S.C. Section 801* et seq.); or

(4) prescribes, administers, or dispenses in a manner inconsistent with public health and welfare:

(A) a dangerous drug as defined by Chapter 483, Health and Safety Code;

(B) a controlled substance listed in a schedule under Chapter 481, Health and Safety Code; or

(C) a controlled substance scheduled in the Comprehensive Drug Abuse Prevention and Control Act of 1970 *(21 U.S.C. Section 801* et seq.).

(b) For purposes of Subsection (a)(2), the physician's records must include a record of:

(1) the date of purchase;

(2) the sale or disposal of the drug or substance by the physician;

(3) the name and address of the person receiving the drug or substance; and

(4) the reason for the disposal or dispensing of the drug or substance to the person.

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TEXAS

REGULATIONS

Licensing of Hospitals

25 TAC § 133.42

§ 133.42. Patient Rights

(a) Patient rights requirements for all hospitals.

(1) A hospital shall adopt, implement, and enforce a policy to ensure patients' rights. The written policy shall include:

(A) the right of the patient to the hospital's reasonable response to his or her requests and needs for treatment or service, within the hospital's capacity, its stated mission, and applicable law and regulation;

(B) the right of the patient to considerate and respectful care:

(i) the care of the patient includes consideration of the psychosocial, spiritual, and cultural variables that influence the perceptions of illness;

(ii) the care of the dying patient optimizes the comfort and dignity of the patient through:

(I) treating primary and secondary symptoms that respond to treatment as desired by the patient or surrogate decision maker;

(II) effectively managing pain;

. . .

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

CATEGORY C:
Regulatory or policy issues

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

REGULATIONS

Standards for Licensure

40 TAC § 92.41

§ 92.41. Standards for Type A, Type B, and Type E Assisted Living Facilities

. . .

(a) Employees.

. . .

(4) Staff training. The facility must document that staff members are competent to provide personal care before assuming responsibilities and have received the following training.

. . .

(D) Facilities that employ licensed nurses, certified nurse aides, or certified medication aides must provide annual in-service training, appropriate to their job responsibilities, from one or more of the following areas:

. . .

(iii) geriatric pharmacology, including treatment for pain management, food and drug interactions, and sleep disorders;

. . .

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (staff training) for assisted living facilities to ensure that pain management is an essential part of patient care.

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TEXAS

REGULATIONS

Standards Specific to Agencies Licensed to Provide Hospice Services

40 TAC § 97.821

§ 97.821. Hospice Plan of Care

(a) A hospice must designate an interdisciplinary team (IDT) to prepare a written plan of care for a client in consultation with the client's attending practitioner, if any, the client or the client's legal representative, and the primary caregiver, if any of them so desire.

(b) The IDT must develop an individualized written plan of care for each client. The plan of care must reflect client and family goals and interventions based on the problems identified in the initial, comprehensive, and updated comprehensive assessments.

(c) The hospice must provide care and services to a client and the client's family in accordance with an individualized written plan of care established by the hospice IDT.

(d) The client's plan of care must include all services necessary for the palliation and management of the terminal illness and related conditions. The plan of care must include:

(1) interventions to manage pain and symptoms;

(2) a detailed statement of the scope and frequency of services necessary to meet the specific client and family needs;

(3) measurable outcomes anticipated from implementing and coordinating the plan of care;

(4) drugs and treatments necessary to meet the needs of the client;

(5) medical supplies and equipment necessary to meet the needs of the client; and

(6) the IDT's documentation in the client record of the client's or the client's legal representative's level of understanding, involvement, and agreement with the plan of care, in accordance with the hospice's policies.

(e) The hospice must ensure that the client and the client's primary caregiver receives education and training provided by hospice staff as appropriate to the client's and the client's primary caregiver's responsibilities for providing the care and services specified in the client's plan of care.

40 TAC § 97.859

§ 97.859. Hospice Discharge or Transfer of Care

(a) If a hospice transfers the care of a client to another facility or agency, the hospice must provide a copy of the hospice discharge summary and, if requested, a copy of the client's record to the receiving facility or agency.

(b) If a client revokes the election of hospice care, or is discharged by the hospice for any reason listed in subsection (d) of this section, the hospice must provide a copy of the hospice discharge summary and, if requested, a copy of the client's record to the client's attending practitioner.

(c) A hospice discharge summary must include:

(1) a summary of the client's stay, including treatments, symptoms, and pain management;

(2) the client's current plan of care;

(3) the client's latest physician orders; and

(4) any other documentation needed to assist in post-discharge continuity of care or that is requested by the attending practitioner or receiving facility or agency.

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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 to prepare a written plan of care) for hospices to ensure that pain management is an essential part of patient care.

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

CATEGORY C:
Regulatory or policy issues

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

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TEXAS

REGULATIONS

Standards Specific to Agencies Licensed to Provide Hospice Services

40 TAC § 97.861

§ 97.861. Hospice Short-term Inpatient Care

(a) A hospice must make inpatient care available when needed for pain control, symptom management, and respite purposes.

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40 TAC § 97.870

§ 97.870. Staffing in a Hospice Inpatient Unit

(a) A hospice is responsible for staffing its inpatient unit with the numbers and types of qualified, trained, and experienced staff to meet the care needs of every client in the inpatient unit to ensure that plan of care outcomes are achieved and negative outcomes are avoided.

(b) A hospice inpatient unit must provide 24-hour nursing services that meet the nursing needs of all clients and are furnished in accordance with each client's plan of care.

(1) A client must receive all nursing services as prescribed in the plan of care and must be kept comfortable, clean, well-groomed, and protected from accident, injury, and infection.

(2) If at least one client in the hospice inpatient unit is receiving general inpatient care for pain control or symptom management, then each shift must include a registered nurse who provides direct client care.

(3) A hospice inpatient unit must have a nurse call system. The hospice must install in a client's room a system that:

(A) is equipped with an easily activated, functioning device accessible to the client; and

(B) allows the client to call for assistance from a staff person on the unit.

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

CATEGORY C:
Regulatory or policy issues

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

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

CATEGORY C:
Regulatory or policy issues

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

2013

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University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

TEXAS

REGULATIONS

Standards Specific to Agencies Licensed to Provide Hospice Services

40 TAC § 97.880

§ 97.880. Providing Hospice Care to a Resident of a Skilled Nursing Facility, Nursing Facility, or Intermediate Care Facility for Individuals with an Intellectual Disability or Related Conditions

(a) Professional management. A hospice must assume responsibility for professional management of the hospice services it provides to a resident of a skilled nursing facility (SNF), nursing facility (NF), or an intermediate care facility for individuals with an intellectual disability or related conditions (ICF/IID), in accordance with the hospice plan of care. The hospice must make arrangements as necessary for hospice-related inpatient care in a participating Medicare or Medicaid facility in accordance with § 97.850 of this subchapter (relating to Organization and Administration of Hospice Services) and § 97.861 of this subchapter (relating to Hospice Short-term Inpatient Care).

(b) Written contract. A hospice and SNF, NF, or ICF/IID must have a written contract that allows the hospice to provide services in the facility. The contract must be signed by an authorized representative of the hospice and the SNF, NF, or ICF/IID before hospice services are provided. In addition to the requirements in § 97.289(b) of this chapter (relating to Independent Contractors and Arranged Services), the written contract must include:

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(7) a delineation of the hospice's responsibilities, which include providing medical direction and management of the client; nursing; counseling, including spiritual, dietary and bereavement counseling; social work; medical supplies, durable medical equipment, and drugs necessary for the palliation of pain and symptoms associated with the terminal illness and related conditions; and all other hospice services that are necessary for the care of the resident's terminal illness and related conditions;

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(e) Orientation and training of staff. Hospice personnel must assure that SNF, NF or ICF/IID staff who provide care to the hospice's clients have been oriented and trained in the hospice philosophy, including the hospice's policies and procedures regarding methods of comfort, pain control, symptom management, as well as principles about death and dying, how a person may respond to death, the hospice's client rights, the hospice's forms, and the hospice's record keeping requirements.

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

CATEGORY C:
Regulatory or policy issues

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

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

CATEGORY C:
Regulatory or policy issues

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

2013

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Madison, Wisconsin

UTAH

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 58. Occupations and Professions; Chapter 37. Controlled Substances

- MEDICAL PRACTICE ACT
  Title 58. Occupations and Professions; Chapter 67. Utah Medical Practice Act

- OSTEOPATHIC PRACTICE ACT
  Title 58. Occupations and Professions; Chapter 68. Utah Osteopathic Medical Practice Act

- PHARMACY PRACTICE ACT
  Title 58. Occupations and Professions; Chapter 17b. Pharmacy Practice Act

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*No provisions found*)
  Commerce; R156. Occupational and Professional Licensing;
  R156-37. Utah Controlled Substances Act Rule

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Commerce; R156. Occupational and Professional Licensing;
  R156-67. Utah Medical Practice Act Rule

- OSTEOPATHIC BOARD REGULATIONS (*No provisions found*)
  Commerce; R156. Occupational and Professional Licensing;
  R156-68. Utah Osteopathic Medical Practice Act Rule

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Commerce; R156. Occupational and Professional Licensing;
  R156-17b. Pharmacy Practice Act Rule

OTHER GOVERNMENTAL POLICIES

No policies found

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Madison, Wisconsin

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- HARM REDUCTION PROGRAM
  Title 26. Utah Health Code; Chapter 1. Department of Health Organization

- PROFESSIONAL BOARD MODEL POLICY
  Commerce; R156. Occupational and Professional Licensing;
  R156-1. General Rule of the Division of Occupational and Professional Licensing

- PATIENT RECORDS
  Health; R432. Health Systems Improvement, Licensing; R432-750. Hospice Rule

UTAH

STATUTES

Controlled Substances Act

Utah Code Ann. § 58-37-2

§ 58-37-2. Definitions

(1) As used in this chapter:

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(jj) "Practitioner" means a physician, dentist, veterinarian, pharmacist, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted 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 in this state.

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

Utah Code Ann. § 58-37-6

§ 58-37-6. License to manufacture, produce, distribute, dispense, administer, or conduct research — Issuance by department — Denial, suspension, or revocation — Records required — Prescriptions

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(B) A Schedule II controlled substance may not be filled in a quantity to exceed a one-month's supply, as directed on the daily dosage rate of the prescriptions.

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(i) A practitioner licensed under this chapter may not prescribe or administer dosages of a controlled substance in excess of medically recognized quantities necessary to treat the ailment, malady, or condition of the ultimate user.

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

***CATEGORY C*:**
Restrictions regarding quantity prescribed or dispensed

COMMENT: Although it is reasonable to expect practitioners to avoid contributing to diversion, "in excess" implies there is a known standard, but the standard is not specified.

Utah Code Ann. § 58-37-6.5

§ 58-37-6.5. Continuing education for controlled substance prescribers

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(4) A controlled substance prescriber shall complete at least 3.5 hours of continuing education hours in one or more controlled substance prescribing classes, except dentists who shall complete at least 2 such hours, that satisfy the requirements of Subsections (5) and (7).

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(7) The 3.5 hours of the controlled substance prescribing classes under Subsection (4) shall include educational content covering the following:

(a) the scope of the controlled substance abuse problem in Utah and the nation;

(b) all elements of the FDA Blueprint for Prescriber Education under the FDA's Extended-Release and Long-Acting Opioid Analgesics Risk Evaluation and Mitigation Strategy, as published July 9, 2012, or as it may be subsequently revised;

(c) the national and Utah-specific resources available to prescribers to assist in appropriate controlled substance and opioid prescribing;

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

CATEGORY C:
Regulatory or policy issues

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

2013

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University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

UTAH

STATUTES

Medical Practice Act

Utah Code Ann. § 58-67-102

§ 58-67-102. Definitions

In addition to the definitions in Section 58-1-102, as used in this chapter:

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(12)(a) "Practice of medicine" means:

(i) to diagnose, treat, correct, or prescribe for any human disease, ailment, injury, infirmity, deformity, pain or other condition, physical or mental, real or imaginary, or to attempt to do so, by any means or instrumentality, and by an individual in Utah or outside the state upon or for any human within the state;

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

STATUTES

Osteopathic Practice Act

Utah Code Ann. § 58-68-102

§ 58-68-102. Definitions

In addition to the definitions in Section 58-1-102, as used in this chapter:

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(12)(a) "Practice of osteopathic medicine" means:

(i) to diagnose, treat, correct, administer anesthesia, or prescribe for any human disease, ailment, injury, infirmity, deformity, pain, or other condition, physical or mental, real or imaginary, or to attempt to do so, by any means or instrumentality, which in whole or in part is based upon emphasis of the importance of the musculoskeletal system and manipulative therapy in the maintenance and restoration of health, by an individual in Utah or outside of the state upon or for any human within the state, except that conduct described in this Subsection (8)(a) that is performed by a person legally and in accordance with a license issued under another chapter of this title does not constitute the practice of medicine;

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

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University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

UTAH

STATUTES

Pharmacy Practice Act

Utah Code Ann. § 58-17b-102

§ 58-17b-102. Definitions

In addition to the definitions in Section 58-1-102, as used in this chapter:

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(57) "Practitioner" means an individual currently licensed, registered, or otherwise authorized by the appropriate jurisdiction to prescribe and administer drugs in the course of professional practice.

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

2013

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Madison, Wisconsin

UTAH

STATUTES

Harm Reduction Program

Utah Code Ann. § 26-1-36

§ 26-1-36. Duty to establish program to reduce deaths and other harm from prescription opiates used for chronic noncancer pain

(1) As used in this section, "opiate" means any drug or other substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability.

(2) In addition to the duties listed in *Section 26-1-30*, the department shall develop and implement a two-year program in coordination with the Division of Professional Licensing, the Utah Labor Commission, and the Utah attorney general, to:

(a) investigate the causes of and risk factors for death and nonfatal complications of prescription opiate use and misuse in Utah for chronic pain by utilizing the Utah Controlled Substance Database created in *Section 58-37f-201*;

(b) study the risks, warning signs, and solutions to the risks associated with prescription opiate medications for chronic pain, including risks and prevention of misuse and diversion of those medications;

(c) provide education to health care providers, patients, insurers, and the general public on the appropriate management of chronic pain, including the effective use of medical treatment and quality care guidelines that are scientifically based and peer reviewed; and

(d) educate the public regarding:

(i) the purpose of the Controlled Substance Database established in *Section 58-37f-201*; and

(ii) the requirement that a person's name and prescription information be recorded on the database when the person fills a prescription for a schedule II, III, IV, or V controlled substance.

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

CATEGORY C:
Regulatory or policy issues

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

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University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

UTAH

REGULATIONS

Professional Board Model Policy

U.A.C. R156-1-502

The "Model Policy for the Use of Controlled Substances for the Treatment of Pain", 2004, established by the Federation of State Medical Boards, is adopted and incorporated by reference.

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

Section I: Preamble

The (name of board) recognizes that principles of quality medical practice dictate that the people of the State of (name of state) have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of this policy, the inappropriate treatment of pain includes nontreatment, 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, 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.

(CONTINUED ON NEXT PAGE)

(+) *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 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 healthcare practice

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies the potential impact of important barriers on the provision of effective pain care.

2013

Pain & Policy Studies Group
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Madison, Wisconsin

UTAH

REGULATIONS

Professional Board Model Policy

(CONTINUED)

The (name of board) is obligated under the laws of the State of (name of state) to protect the public health and safety. The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes pose a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, the Board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

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

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

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

Section II: Guidelines

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

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.

(CONTINUED ON NEXT PAGE)

(+) *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 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 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 goal of pain treatment should include improvements in patient functioning and quality of life.

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University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

UTAH

REGULATIONS

Professional Board Model Policy

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

(CONTINUED)

3. Informed Consent and Agreement for Treatment—The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is 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

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 (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, 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.

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

a. the medical history and physical examination,
b. diagnostic, therapeutic and laboratory results,
c. evaluations and consultations,
d. treatment objectives,
e. discussion of risks and benefits,
f. informed consent,
g. treatments,
h. medications (including date, type, dosage and quantity prescribed),
i. instructions and agreements and
j. periodic reviews.

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

(CONTINUED ON NEXT PAGE)

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

CATEGORY B:
Issues related to patients

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

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

UTAH

REGULATIONS

Professional Board Model Policy

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

(CONTINUED)

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

Section III: Definitions

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

Acute 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.

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

UTAH

REGULATIONS

Patient Records

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (record keeping policies and procedures) for hospices to ensure that pain management is an essential part of patient care. (Although not required by this provision, pain assessment should be followed up with appropriate treatment.)

U.A.C. R432-750-12

R432-750-12. Patient Records.

(1) The administrator shall develop and implement record keeping policies and procedures that address the use of patient records by authorized staff, content, confidentiality, retention, and storage.

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(3) Each patient's record shall contain at least the following information:

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(h) a signed, dated patient assessment which includes the following:

(i) a description of the patient's functional limitations;

(ii) a physical assessment noting chronic or acute pain and other physical symptoms and their management;

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University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

VERMONT

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 18. Health; Part 5. Foods and Drugs
  Chapter 84. Possession and Control of Regulated Drugs
  Chapter 84A. Vermont Prescription Monitoring Program

- MEDICAL PRACTICE ACT
  Title 26. Professions and Occupations; Chapter 23. Medicine

- OSTEOPATHIC PRACTICE ACT
  Title 26. Professions and Occupations; Chapter 33. Osteopathy

- PHARMACY PRACTICE ACT
  Title 26. Professions and Occupations; Chapter 35. Pharmacy

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Agency 13. Agency of Human Services; Sub-Agency 140. Department of Health; Chapter 011. Regulated Drugs

- MEDICAL BOARD REGULATIONS
  Agency 13. Agency of Human Services; Sub-Agency 141. Department of Health; Board of Medical Practice; Chapter 001. Rules of the Board of Medical Practice

- OSTEOPATHIC BOARD REGULATIONS (*No provisions found*)
  Agency 04. Secretary of State; Sub-Agency 030. Office of Professional Regulation; Chapter 220. Rules of the Board of Osteopathic Physicians and Surgeons

- PHARMACY BOARD REGULATIONS
  Agency 04. Secretary of State; Sub-Agency 030. Office of Professional Regulation; Chapter 230. Board of Pharmacy Administrative Rules

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
  Vermont Board of Medical Practice. *Policy for the Use of Controlled Substances for the Treatment of Pain*. Adopted: December 7, 2005.

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- CHRONIC CARE AND PAIN MANAGEMENT
  Title 18. Health; Part 1. State and Local Health Agencies;
  Chapter 13. Chronic Care Infrastructure and Prevention Measures

- BILL OF RIGHTS FOR HOSPITAL PATIENTS
  Title 18. Health; Part 3. Hospitals, Health Centers, Nursing Homes;
  Chapter 42. Bill of Rights for Hospital Patients

- PATIENT'S BILL OF RIGHTS FOR PALLIATIVE CARE AND PAIN MANAGEMENT
  Title 18. Health; Part 3. Hospitals, Health Centers, Nursing Homes;
  Chapter 42A. Patient's Bill of Rights for Palliative Care and Pain Management

- NURSING HOME RESIDENT BILL OF RIGHTS
  Title 33. Human Services; Part 5. Programs and Services for Vulnerable Adults;
  Chapter 73. Nursing Home Residents' Bill of Rights

- HOMES FOR THE TERMINALLY ILL
  Agency 13. Agency of Human Services; Sub-Agency 110. Department of Aging and Disabilities;
  Chapter 006. Licensing Regulations for Homes of the Terminally Ill

VERMONT

STATUTES

Controlled Substances Act

18 V.S.A. § 4201

§ 4201. Definitions

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

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(24) "Practitioner" includes a physician, dentist, veterinarian, surgeon or any other person who may be lawfully entitled under this chapter to distribute, dispense, prescribe, or administer regulated drugs to patients.

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18 V.S.A. § 4281

§ 4281. Legislative intent

The general assembly recognizes the important public health benefits of the legal medical use of controlled substances and also the significant risk to public health that can arise due to the abuse of those substances. It is the intent of this chapter to create the Vermont prescription monitoring system, which will provide an electronic database and reporting system for electronic monitoring of prescriptions for Schedules II, III, and IV controlled substances, as defined in 21 C.F.R. Part 1308, as amended and as may be amended, to promote the public health through enhanced opportunities for treatment for and prevention of abuse of controlled substances, without interfering with the legal medical use of those substances.

18 V.S.A. § 4284

§ 4284. Protection and disclosure of information

(a) The data collected pursuant to this chapter and all related information and records shall be confidential, except as provided in this chapter, and shall not be subject to the Public Records Act. The Department shall maintain procedures to protect patient privacy, ensure the confidentiality of patient information collected, recorded, transmitted, and maintained, and ensure that information is not disclosed to any person except as provided in this section.

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(h) Following consultation with the Unified Pain Management System Advisory Council and an opportunity for input from stakeholders, the Department shall develop a policy that will enable it to evaluate the prescription of regulated drugs by prescribers.

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

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (Advisory Council) to assist with the appropriate interpret ion of prescription monitoring program information.

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (record keeping policies and procedures) for hospices to ensure that pain management is an essential part of patient care. (Although not required by this provision, pain assessment should be followed up with appropriate treatment.)

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

VERMONT

STATUTES

Medical Practice Act

26 V.S.A. § 1311

§ 1311. Definitions

For the purposes of this chapter:

(1) Practice of medicine means:

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(D) offering or undertaking to prevent, diagnose, correct, or treat in any manner or by any means, methods, or devices any disease, illness, pain, wound, fracture, infirmity, defect, or abnormal physical or mental condition of any person, including the management of pregnancy and parturition;

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

26 V.S.A. § 1400

§ 1400. Renewal of license; continuing medical education

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(b) A licensee for renewal of an active license to practice medicine shall have completed continuing medical education which shall meet minimum criteria as established by rule, by the board, by August 31, 2012 and which shall be in effect for the renewal of licenses to practice medicine expiring after August 31, 2014. The board shall require a minimum of ten hours of continuing medical education by rule. The training provided by the continuing medical education shall be designed to assure that the licensee has updated his or her knowledge and skills in his or her own specialties and also has kept abreast of advances in other fields for which patient referrals may be appropriate. The board shall require evidence of current professional competence in recognizing the need for timely appropriate consultations and referrals to assure fully informed patient choice of treatment options, including treatments such as those offered by hospice, palliative care, and pain management services.

(+) *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.

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Madison, Wisconsin

VERMONT

STATUTES

Osteopathic Practice Act

26 V.S.A. § 1750

§ 1750. Definitions

As used in this chapter:

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(10) "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 neuromusculoskeletal structure and manipulative treatment in the maintenance and restoration of health.

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

STATUTES

Pharmacy Practice Act

26 V.S.A. § 2022

§ 2022. Definitions

As used in this chapter:

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(15) "Practitioner" shall mean a physician, dentist, nurse, veterinarian, scientific investigator, or other person (other than pharmacists) licensed by this state or adjoining states or the province of Quebec and permitted by such license to dispense, conduct research with respect to or administer drugs in the course of professional practice or research in their respective state or province.

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

2013

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REGULATIONS

Controlled Substances Regulations

CVR 13-140-069

13 140 069. PRESCRIPTION MONITORING SYSTEM

Part I.
General Provisions

Section 1.1 Purpose.

This rule implements the Vermont Prescription Monitoring System ("VPMS") created by 18 V.S.A. Chapter 84A, which authorizes the Department to establish an electronic database and reporting system for electronic monitoring of prescriptions of certain controlled substances to promote the public health through enhanced opportunities for treatment for and prevention of abuse of controlled substances, without interfering with the legal medical use of those substances.

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Section 3.4 Disclosures from the VPMS Database.

Disclosures from the VPMS database pursuant to the provisions in this rule 3.4 will be in accordance with a protocol approved by the Commissioner to identify when disclosures should be made pursuant to this subsection. The protocol will be developed, and periodically reviewed and updated, in consultation with the Advisory Committee and with health care providers designated by the Commissioner with particular expertise in relevant clinical specialties including the use of controlled substances for the treatment of acute and chronic pain, palliative care, end-of-life care and the treatment for and prevention of abuse of controlled substances and will be consistent with current standards of care and practice in those clinical specialties. Disclosures from the VPMS database pursuant to subsections 1, 2 or 3 below shall occur only in accordance with the protocol and as otherwise permitted by this rule.

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Requires an expertise in pain management on a Technical Advisory Committee that reviews requests for PMP information.

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Madison, Wisconsin

VERMONT

REGULATIONS

Medical Board Regulations

CVR 13-141-001

13 141 001. RULES OF THE BOARD OF MEDICAL PRACTICE

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SECTION VII
CONTINUING MEDICAL EDUCATION RULES

PART 22
RULES REGARDING CONTINUING MEDICAL EDUCATION

Rule 22.1 Introduction and Definitions.

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(e) Required Subject: Hospice, Palliative Care, Pain Management. 26 V.S.A. § 1400(b) mandates that the Board of Medical Practice shall require licensees to provide "evidence of current professional competence in recognizing the need for timely appropriate consultations and referrals to assure fully informed patient choice of treatment options, including treatments such as those offered by hospice, palliative care, and pain management services." Accordingly, all licensees who are required under these rules to complete CME shall certify at the time of each renewal that at least one of the hours of qualifying CME activity has been on the topics of hospice, palliative care, or pain management services.

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(+) *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, hospice, and palliative care.

REGULATIONS

Pharmacy Board Regulations

CVR 04-030-230

Part I. General Information

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1.10 Definitions

(a) As used in these rules:

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(40) "Practitioner" means an individual currently licensed, registered, or otherwise authorized by the appropriate jurisdiction to prescribe and administer drugs in the course of professional practice.

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

2013

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

VERMONT

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

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

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

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

Introduction

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

Since adoption in April 1998, the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain have been widely distributed to state medical boards, medical professional organizations, other health care regulatory boards, patient advocacy groups, pharmaceutical companies, state and federal regulatory agencies, and practicing physicians and other health care providers. The Model Guidelines have been endorsed by the American Academy of Pain Medicine, the Drug Enforcement Administration, the American Pain Society, and the National Association of State Controlled Substances Authorities. Many states have adopted pain policy using all or part of the Model Guidelines. 1 Despite increasing concern in recent years regarding the abuse and diversion of controlled substances, pain policies have improved due to the efforts of medical, pharmacy, and nursing regulatory boards committed to improving the quality of and access to appropriate pain care.

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

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VERMONT

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

(CONTINUED)

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

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

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

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

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

1. As of January 2004, 22 of 70 state medical boards have policy, rules, regulations or statutes reflecting the Federation's Model Guidelines for the Use of Controlled Substances for the Treatment of Pain and two (2) states have formally endorsed the Model Guidelines.

2. SUPPORT Study Principal Investigators. A controlled trial to improve care for seriously ill hospitalized patients: JAMA, 274(20) (1995): p. 1591-1598.

3. A.M. Gilson, D.E. Joranson, and M.A. Mauer, Improving Medical Board Policies: Influence of a Model, J. of Law, Medicine, and Ethics, 31 (2003): p. 128.

(CONTINUED ON NEXT PAGE)

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

CATEGORY C:
Regulatory or policy issues

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

Pain & Policy Studies Group
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Madison, Wisconsin

VERMONT

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

(CONTINUED)

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

Section I: Preamble
The Vermont Board of Medical Practice recognizes that principles of quality medical practice dictate that patients 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, 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 (name of board) is obligated under the laws of the State of (name of state) to protect the public health and safety. The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes pose a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, the Board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

(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 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies the potential impact of important barriers on the provision of effective pain care.

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

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

(+) *CRITERION 4:*
Encourages pain management

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Madison, Wisconsin

VERMONT

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

(CONTINUED)

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

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

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

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

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

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

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).

(CONTINUED ON NEXT PAGE)

(+) *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 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 to good 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 the goal of pain treatment should 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: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

2013

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

VERMONT

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

(CONTINUED)

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

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

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

1. the medical history and physical examination,
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.

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

CATEGORY B:
Issues related to patients

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

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

VERMONT

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

(CONTINUED)

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.

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University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

VERMONT

STATUTES

Chronic Care and Pain Management

18 V.S.A. § 701

§ 701. Definitions

For the purposes of this chapter:

(1) "Blueprint for Health" or "Blueprint" means the state's program for integrating a system of health care for patients, improving the health of the overall population, and improving control over health care costs by promoting health maintenance, prevention, and care coordination and management.

(2) "Board" means the Green Mountain Care board established in chapter 220 of this title.

(3) "Chronic care" means health services provided by a health care professional for an established clinical condition that is expected to last a year or more and that requires ongoing clinical management attempting to restore the individual to highest function, minimize the negative effects of the condition, prevent complications related to chronic conditions, engage in advanced care planning, and promote appropriate access to palliative care and pain and symptom management. Examples of chronic conditions include diabetes, hypertension, cardiovascular disease, cancer, asthma, pulmonary disease, substance abuse, mental illness, spinal cord injury, hyperlipidemia, dementia, and chronic pain.

(4) "Chronic care information system" means the electronic database developed under the Blueprint for Health that shall include information on all cases of a particular disease or health condition in a defined population of individuals.

(5) "Chronic care management" means a system of coordinated health care interventions and communications for individuals with chronic conditions, including significant patient self-care efforts, systemic supports for licensed health care practitioners and their patients, and a plan of care emphasizing, on an ongoing basis and with the goals of improving overall health and meeting patients' needs:

(A) prevention of complications utilizing evidence-based practice guidelines;

(B) patient empowerment strategies;

(C) evaluation of clinical, humanistic, and economic outcomes; and

(D) advance care planning, palliative care, pain management, and hospice services, as appropriate.

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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.

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

VERMONT

STATUTES

Bill of Rights for Hospital Patients

18 V.S.A. § 1852

§ 1852. Patients' bill of rights; adoption

(a) The general assembly hereby adopts the "Bill of Rights for Hospital Patients" as follows:

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(16) The patient has the right to receive professional assessment of pain and professional pain management.

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

CATEGORY C:
Regulatory or policy issues

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

STATUTES

Patient's Bill of Rights for Palliative Care and Pain Management

18 V.S.A. § 1871

§ 1871. Patient's bill of rights for palliative care and pain management

(a) A patient has the right to be informed of all evidence-based options for care and treatment, including palliative care, in order to make a fully informed patient choice.

(b) A patient with a terminal illness has the right to be informed by a clinician of all available options related to terminal care; to be able to request any, all, or none of these options; and to expect and receive supportive care for the specific option or options available.

(c) A patient suffering from pain has the right to request or reject the use of any or all treatments in order to relieve his or her pain.

(d) A patient suffering from a chronic condition has the right to competent and compassionate medical assistance in managing his or her physical and emotional symptoms.

(e) A pediatric patient suffering from a serious or life-limiting illness or condition has the right to receive palliative care while seeking and undergoing potentially curative treatment.

(+) *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.

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VERMONT

STATUTES

Nursing Home Resident Bill of Rights

33 V.S.A. § 7301

§ 7301. Nursing home residents' bill of rights

The general assembly hereby adopts the Nursing Home Residents' Bill of Rights as follows:

(1) The governing body of the facility shall establish written policies regarding the rights and responsibilities of residents and, through the administrator, is responsible for development of, and adherence to, procedures implementing such policies. These policies and procedures shall be made available to residents, to any guardians, next of kin, reciprocal beneficiaries, sponsoring agency, or representative payees selected pursuant to subsection 205(j) of the Social Security Act, and Subpart Q of 20 CFR Part 404, and to the public.

(2) The staff of the facility shall ensure that, at least, each individual admitted to the facility:

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(T) is provided with professional assessment of pain and its management.

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

CATEGORY C:
Regulatory or policy issues

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

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

VERMONT

REGULATIONS

Homes for the Terminally Ill

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

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (staff training) for homes for the terminally ill to ensure that pain management is an essential part of patient care.

CVR 13-110-006

13 110 006. Licensing Regulations for Homes for the Terminally Ill

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5.9 Medication Management

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(e) Staff responsible for assisting residents with medications must receive training from the registered nurse in the following areas before assisting with any medications:

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(5) Pain assessment and management.

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2013

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VIRGINIA

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 54.1. Professions and Occupations; Subtitle III. Professions and Occupations Regulated by Boards Within the Department of Health Professions; Chapter 34. Drug Control Act

- MEDICAL PRACTICE ACT
  Title 54.1. Professions and Occupations; Subtitle III. Professions and Occupations Regulated by Boards Within the Department of Health Professions; Chapter 29. Medicine and Other Healing Arts

- PHARMACY PRACTICE ACT
  Title 54.1. Professions and Occupations; Subtitle III. Professions and Occupations Regulated by Boards Within the Department of Health Professions; Chapter 33. Pharmacy

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*Part of Pharmacy Board Regulations*) (*No provisions found*)
  Title 18. Professional and Occupational Licensing; Agency No. 110. Board of Pharmacy

- MEDICAL BOARD REGULATIONS
  Title 18. Professional and Occupational Licensing; Agency No. 85. Board of Medicine

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Title 18. Professional and Occupational Licensing; Agency No. 110. Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
  Virginia Board of Medicine. *Guidance on the Use of Opioid Analgesics in the Treatment of Chronic Pain*. Adopted: July 24, 2004; Amended: October 25, 2013.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- INJUNCTION AGAINST ASSISTED SUICIDE
  Title 8.01. Civil Remedies and Procedures; Chapter 24. Injunctions

- REGULATIONS FOR THE LICENSURE OF HOSPICE
  Title 12. Health; Agency Number 5. Department of Health; Hospitals, Nursing Homes, and Related Institutions and Services; Chapter 391. Regulations for the Licensure of Hospice; Part II. Administrative Services

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

VIRGINIA

STATUTES

Controlled Substances Act

Va. Code Ann. § 54.1-3401

§ 54.1-3401. Definitions

As used in this chapter, unless the context requires a different meaning:

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"Practitioner" means a physician, dentist, licensed nurse practitioner pursuant to *§ 54.1-2957.01*, licensed physician assistant pursuant to *§ 54.1-2952.1*, pharmacist pursuant to *§ 54.1-3300*, TPA-certified optometrist pursuant to Article 5 (*§ 54.1-3222* et seq.) of Chapter 32, veterinarian, scientific investigator, or other person licensed, registered or otherwise permitted to distribute, dispense, prescribe and administer, or conduct research with respect to, a controlled substance in the course of professional practice or research in the Commonwealth.

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Va. Code Ann. § 54.1-3408.1

§ 54.1-3408.1. Prescription in excess of recommended dosage in certain cases

In the case of a patient with intractable pain, a physician may prescribe a dosage in excess of the recommended dosage of a pain relieving agent if he certifies the medical necessity for such excess dosage in the patient's medical record. Any person who prescribes, dispenses or administers an excess dosage in accordance with this section shall not be in violation of the provisions of this title because of such excess dosage, if such excess dosage is prescribed, dispensed or administered in good faith for accepted medicinal or therapeutic purposes.

Nothing in this section shall be construed to grant any person immunity from investigation or disciplinary action based on the prescription, dispensing or administration of an excess dosage in violation of this title.

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

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

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Medical Practice Act

Va. Code Ann. § 54.1-2900

§ 54.1-2900. Definitions

As used in this chapter, unless the context requires a different meaning:

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"Healing arts" means the arts and sciences dealing with the prevention, diagnosis, treatment and cure or alleviation of human physical or mental ailments, conditions, diseases, pain or infirmities.

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"Practice of medicine or osteopathic medicine" means the prevention, diagnosis and treatment of human physical or mental ailments, conditions, diseases, pain or infirmities by any means or method.

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Va. Code Ann. § 54.1-2912.2

§ 54.1-2912.2. Board may endorse certain document

In the furtherance of its responsibility to ensure continued practitioner competency, the Board of Medicine may endorse the Medical Society of Virginia's Guidelines for the Use of Opioids in the Management of Chronic, Non-Cancer Pain, developed and adopted in 1997.

For the purpose of this section, ***"endorse"*** means to publicize and distribute such guidelines as providing an appropriate standard of care; however, the Board's endorsement shall not be construed to mean that the guidelines must be followed or are regulations or are in any way intended to be enforceable law.

Va. Code Ann. § 54.1-2971.01

§ 54.1-2971.01. Prescription in excess of recommended dosage in certain cases

A. Consistent with § 54.1-3408.1, a physician may prescribe a dosage of a pain-relieving agent in excess of the recommended dosage upon certifying the medical necessity for the excess dosage in the patient's medical record. Any practitioner who prescribes, dispenses or administers an excess dosage in accordance with this section and § 54.1-3408.1 shall not be in violation of the provisions of this title because of such excess dosage, if such excess dosage is prescribed, dispensed or administered in good faith for recognized medicinal or therapeutic purposes.

B. The Board of Medicine shall advise physicians of the provisions of this section and § 54.1-3408.1.

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

(+) *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.

(+) *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

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STATUTES

Pharmacy Practice Act

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

Va. Code Ann. § 54.1-3303

§ 54.1-3303. Prescriptions to be issued and drugs to be dispensed for medical or therapeutic purposes only

A. A prescription for a controlled substance may be issued only by a practitioner of medicine, osteopathy, podiatry, dentistry or veterinary medicine who is authorized to prescribe controlled substances, or by a licensed nurse practitioner pursuant to *§ 54.1-2957.01*, a licensed physician assistant pursuant to *§ 54.1-2952.1*, or a TPA-certified optometrist pursuant to Article 5 (*§ 54.1-3222* et seq.) of Chapter 32 of this title. The prescription shall be issued for a medicinal or therapeutic purpose and may be issued only to persons or animals with whom the practitioner has a bona fide practitioner-patient relationship.

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REGULATIONS

Medical Board Regulations

18 VAC 85-20-10.

18 VAC 85-20-10. Definitions.

A. The following words and terms when used in this chapter shall have the meanings ascribed to them in *§ 54.1-2900 of the Code of Virginia*:

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Practice of medicine or osteopathic medicine (by reference: means the prevention, diagnosis and treatment of human physical or mental ailments, conditions, diseases, pain or infirmities by any means or method)

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

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OTHER GOVERNMENTAL POLICY

Medical Board Guideline

Virginia Board of Medicine
Guidance on the Use of Opioid Analgesics in the Treatment of Chronic Pain

Section I: Preamble

The Idaho Board of Medicine is obligated under the laws of the State of Idaho to protect the public health and safety. The Idaho Board of Medicine recognizes that principles of high-quality medical practice dictate that the people of the State of Idaho have access to appropriate, safe and effective pain management. The application of up-to-date knowledge and treatment modalities can help to restore function and thus improve the quality of life of patients who suffer from pain, particularly chronic pain [4,8,26].

This policy has been developed to articulate the Board's position on the use of controlled substances for pain, particularly the use of opioid analgesics and with special attention to the management of chronic pain. The policy thus is intended to encourage physicians to be knowledgeable about best clinical practices as regards the prescribing of opioids and be aware of associated risks. For the purposes of this policy, inappropriate treatment of pain includes nontreatment, inadequate treatment, overtreatment, and continued use of ineffective treatments.

The Board recognizes that opioid analgesics are useful and can be essential in the treatment of acute pain that results from trauma or surgery, as well as in the management of certain types of chronic pain, whether due to cancer or non-cancer causes [20,26,28]. The Board will refer to current clinical practice guidelines and expert reviews in approaching allegations of possible mismanagement of pain [8,10,12,14,26-41,80].

Responsibility for Appropriate Pain Management: All physicians and other providers should be knowledgeable about assessing patients' pain and function, and familiar with methods of managing pain [4,16]. Physicians also need to understand and comply with federal and state requirements for prescribing opioid analgesics [3,12,19]. Whenever federal laws and regulations differ from those of a particular state, the more stringent rule is the one that should be followed [42].

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, when current best clinical practices are met.

The Board will consider the use of opioids for pain management to be for a legitimate medical purpose if it is based on sound clinical judgment and current best clinical practices, is appropriately documented, and is of demonstrable benefit to the patient. To be within the usual course of professional practice, a legitimate physician-patient relationship must exist and the prescribing or administration of medications should be appropriate to the identified diagnosis, should be accompanied by careful follow-up monitoring of the patient's response to treatment as well as his or her safe use of the prescribed medication, and should demonstrate that the therapy has been adjusted as needed [7,38,43]. There should be documentation of appropriate referrals as necessary [36-37].

The medical management of pain should reflect current knowledge of evidence-based or best clinical practices for the use of pharmacologic and nonpharmacologic modalities, including the use of opioid analgesics and non-opioid therapies [14,16,27]. Such prescribing must be based on careful assessment of the patient and his or her pain (see the discussion on risk stratification, below) [33].

[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 4:*
Encourages pain management

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

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

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Pain should be assessed and treated promptly, and the selection of therapeutic modalities (including the quantity and frequency of medication doses) should be adjusted according to the nature of the pain, the patient's response to treatment, and the patient's risk level relative to the use of medications with abuse potential [8,10,12,14,26-38].

Preventing Opioid Diversion and Abuse: The Board also recognizes that individuals' use of opioid analgesics for other than legitimate medical purposes poses a significant threat to the health and safety of the individual as well as to the public health [3]. The Board further recognizes that inappropriate prescribing of controlled substances by physicians may contribute to drug misuse and diversion by individuals who seek opioids for other than legitimate medical purposes [5,19,44]. Accordingly, the Board expects physicians to incorporate safeguards into their practices to minimize the risk of misuse and diversion of opioid analgesics and other controlled substances [19-23,38,45-46].

Allegations of inappropriate pain management will be evaluated on an individual basis. The Board may use a variety of sources to determine the appropriateness of treatment including prescribing information obtained from the State Prescription Drug Monitoring Program. The Board will not take disciplinary action against a physician for deviating from this Model Policy when contemporaneous medical records show reasonable cause for such a deviation.

The Board will judge the validity of the physician's treatment of a patient on the basis of available documentation, rather than solely on the quantity and duration of medication administered. The goal is the management of the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors, and mitigating risk of misuse, abuse, diversion and overdose [4,29].

The Board will consider the unsafe or otherwise inappropriate treatment of pain to be a departure from best clinical practice, taking into account whether the treatment is appropriate to the diagnosis and the patient's level of risk.

Section II: Guidelines

The Board has adopted the following criteria for use in evaluating a physician's management of a patient with pain, including the physician's prescribing of opioid analgesics:

Understanding Pain: The diagnosis and treatment of pain is integral to the practice of medicine [4,34-37]. In order to cautiously prescribe opioids, physicians must understand the relevant pharmacologic and clinical issues in the use of such analgesics, and carefully structure a treatment plan that reflects the particular benefits and risks of opioid use for each individual patient. Such an approach should be employed in the care of every patient who receives chronic opioid therapy [4,8].

Patient Evaluation and Risk Stratification: The medical record should document the presence of one or more recognized medical indications for prescribing an opioid analgesic [7] and reflect an appropriately detailed patient evaluation [38]. Such an evaluation should be completed before a decision is made as to whether to prescribe an opioid analgesic.

The nature and extent of the evaluation depends on the type of pain and the context in which it occurs. For example, meaningful assessment of chronic pain, including pain related to cancer or non-cancer origins, usually demands a more detailed evaluation than an assessment of acute pain. Assessment of the patient's pain typically would include the nature and intensity of the pain, past and current treatments for the pain, any underlying or co-occurring disorders and conditions, and the effect of the pain on the patient's physical and psychological functioning [31].

[CONTINUED ON NEXT PAGE]

(+) *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 goal of pain treatment should include improvements in patient functioning and quality of life.

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

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OTHER GOVERNMENTAL POLICY

Medical Board Guideline

[CONTINUED]

For every patient, the initial work-up should include a systems review and relevant physical examination, as well as laboratory investigations as indicated [33,36,48-53]. Such investigations help the physician address not only the nature and intensity of the pain, but also its secondary manifestations, such as its effects on the patient's sleep, mood, work, relationships, valued recreational activities, and alcohol and drug use.

Social and vocational assessment is useful in identifying supports and obstacles to treatment and rehabilitation; for example: Does the patient have good social supports, housing, and meaningful work? Is the home environment stressful or nurturing? [14].

Assessment of the patient's personal and family history of alcohol or drug abuse and relative risk for medication misuse or abuse also should be part of the initial valuation [11,14,21-23,45], and ideally should be completed prior to a decision as to whether to prescribe opioid analgesics [56-58]. This can be done through a careful clinical interview, which also should inquire into any history of physical, emotional or sexual abuse, because those are risk factors for substance misuse [31]. Use of a validated screening tool (such as the Screener and Opioid Assessment for Patients with Pain [SOAPP-R; 48] or the Opioid Risk Tool [ORT; 49]), or other validated screening tools, can save time in collecting and evaluating the information and determining the patient's level of risk.

All patients should be screened for depression and other mental health disorders, as part of risk evaluation. Patients with untreated depression and other mental health problems are at increased risk for misuse or abuse of controlled medications, including addiction, as well as overdose.

Patients who have a history of substance use disorder (including alcohol) are at elevated risk for failure of opioid analgesic therapy to achieve the goals of improved comfort and function, and also are at high risk for experiencing harm from this therapy, since exposure to addictive substances often is a powerful trigger of relapse [11,31,45]. Therefore, treatment of a patient who has a history of substance use disorder should, if possible, involve consultation with an addiction specialist before opioid therapy is initiated (and follow-up as needed). Patients who have an active substance use disorder should not receive opioid therapy until they are established in a treatment/recovery program [31] or alternatives are established such as co-management with an addiction professional. Physicians who treat patients with chronic pain should be encouraged to also be knowledgeable about the treatment of addiction, including the role of replacement agonists such as methadone and buprenorphine. For some physicians, there may be advantages to becoming eligible to treat addiction using office-based buprenorphine treatment.

Information provided by the patient is a necessary but insufficient part of the evaluation process. Reports of previous evaluations and treatments should be confirmed by obtaining records from other providers, if possible. Patients have occasionally provided fraudulent records, so if there is any reason to question the truthfulness of a patient's report, it is best to request records directly from the other providers [54-55].

If possible, the patient evaluation should include information from family members and/or significant others [22-23,49-50]. Where available, the state prescription drug monitoring program (PDMP) should be consulted to determine whether the patient is receiving prescriptions from any other physicians, and the results obtained from the PDMP should be documented in the patient record [34].

[CONTINUED ON NEXT PAGE]

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

CATEGORY B:
Issues related to patients

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

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

[CONTINUED]

Development of a Treatment Plan and Goals: The goals of pain treatment include reasonably attainable improvement in pain and function; improvement in pain-associated symptoms such as sleep disturbance, depression, and anxiety; and avoidance of unnecessary or excessive use of medications [4,8]. Effective means of achieving these goals vary widely, depending on the type and causes of the patient's pain, other concurrent issues, and the preferences of the physician and the patient.

The treatment plan and goals should be established as early as possible in the treatment process and revisited regularly, so as to provide clear-cut, individualized objectives to guide the choice of therapies [38]. The treatment plan should contain information supporting the selection of therapies, both pharmacologic (including medications other than opioids) and nonpharmacologic. It also should specify the objectives that will be used to evaluate treatment progress, such as relief of pain and improved physical and psychosocial function [14,36,47].

The plan should document any further diagnostic evaluations, consultations or referrals, or additional therapies that have been considered [21-23,45].

Informed Consent and Treatment Agreement: The decision to initiate opioid therapy should be a shared decision between the physician and the patient. The physician should discuss the risks and benefits of the treatment plan (including any proposed use of opioid analgesics) with the patient, with persons designated by the patient, or with the patient's surrogate or guardian if the patient is without medical decision-making capacity [32,35]. If opioids are prescribed, the patient (and possibly family members) should be counseled on safe ways to store and dispose of medications [3,37].

Use of a written informed consent and treatment agreement (sometimes referred to as a "treatment contract") is recommended [21-23,35,38].

Informed consent documents typically address:

- The potential risks and anticipated benefits of chronic opioid therapy.
- Potential side effects (both short- and long-term) of the medication, such as constipation and cognitive impairment.
- The likelihood that tolerance to and physical dependence on the medication will develop.
- The risk of drug interactions and over-sedation.
- The risk of impaired motor skills (affecting driving and other tasks).
- The risk of opioid misuse, dependence, addiction, and overdose.
- The limited evidence as to the benefit of long-term opioid therapy.
- The physician's prescribing policies and expectations, including the number and frequency of prescription refills, as well as the physician's policy on early refills and replacement of lost or stolen medications.
- Specific reasons for which drug therapy may be changed or discontinued (including violation of the policies and agreements spelled out in the treatment agreement).

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Treatment agreements outline the joint responsibilities of physician and patient [35-37] and are indicated for opioid or other abusable medications. They typically discuss:

- The goals of treatment, in terms of pain management, restoration of function, and safety.
- The patient's responsibility for safe medication use (e.g., by not using more medication than prescribed or using the opioid in combination with alcohol or other substances; storing medications in a secure location; and safe disposal of any unused medication).
- The patient's responsibility to obtain his or her prescribed opioids from only one physician or practice.
- The patient's agreement to periodic drug testing (as of blood, urine, hair, or saliva).
- The physician's responsibility to be available or to have a covering physician available to care for unforeseen problems and to prescribe scheduled refills.

Informed consent documents and treatment agreements can be part of one document for the sake of convenience.

Initiating an Opioid Trial: Generally, safer alternative treatments should be considered before initiating opioid therapy for chronic, non-malignant pain. Opioid therapy should be presented to the patient as a therapeutic trial or test for a defined period of time (usually no more than 90 days) and with specified evaluation points. The physician should explain that progress will be carefully monitored for both benefit and harm in terms of the effects of opioids on the patient's level of pain, function, and quality of life, as well as to identify any adverse events or risks to safety [51]. When initiating opioid therapy, the lowest dose possible should be given to an opioid naïve patient and titrate to affect. It is generally suggested to begin opioid therapy with a short acting opioid and rotate to a long acting/extended release if indicated.

A decision to continue opioid therapy beyond the trial period should reflect a careful evaluation of benefits versus adverse events [29] and/or potential risks.

Ongoing Monitoring and Adapting the Treatment Plan: The physician should regularly review the patient's progress, including any new information about the etiology of the pain or the patient's overall health and level of function [35,49-50]. When possible, collateral information about the patient's response to opioid therapy should be obtained from family members or other close contacts, and the state PDMP. The patient should be seen more frequently while the treatment plan is being initiated and the opioid dose adjusted [44-51]. As the patient is stabilized in the treatment regimen, follow-up visits may be scheduled less frequently. (However, if the patient is seen less than monthly and an opioid is prescribed, arrangements must be made for the patient to obtain a refill or new prescription when needed.)

At each visit, the results of chronic opioid therapy should be monitored by assessing what have been called the "5As" of chronic pain management; these involve a determination of whether the patient is experiencing a reduction in pain (**A**nalgesia), has demonstrated an improvement in level of function (**A**ctivity), whether there are significant **A**dverse effects, whether there is evidence of **A**berrant substance-related behaviors, and mood of the individual (**A**ffect) [38,52]. Validated brief assessment tools that measure pain and function, such as the three-question "Pain, Enjoyment and General Activity" (PEG) scale [47] or other validated assessment tools, may be helpful and time effective.

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Continuation, modification or termination of opioid therapy for pain should be contingent on the physician's evaluation of (1) evidence of the patient's progress toward treatment objectives and (2) the absence of substantial risks or adverse events, such as overdose or diversion [21-23,45]. A satisfactory response to treatment would be indicated by a reduced level of pain, increased level of function, and/or improved quality of life [29]. Information from family members or other caregivers should be considered in evaluating the patient's response to treatment [14,35-36]. Use of measurement tools to assess the patient's level of pain, function, and quality of life (such as a visual analog or numerical scale) can be helpful in documenting therapeutic outcomes [14,49].

Periodic Drug Testing: Periodic drug testing may be useful in monitoring adherence to the treatment plan, as well as in detecting the use of non-prescribed drugs [53-54]. Drug testing is an important monitoring tool because self-reports of medication use is not always reliable and behavioral observations may detect some problems but not others [55-59]. Patients being treated for addiction should be tested as frequently as necessary to ensure therapeutic adherence, but for patients being treated for pain, clinical judgment trumps recommendations for frequency of testing.

Urine may be the preferred biologic specimen for testing because of its ease of collection and storage and the cost-effectiveness of such testing [53]. When such testing is conducted as part of pain treatment, forensic standards are generally not necessary and not in place, so collection is not observed and chain-of-custody protocols are not followed. Initial testing may be done using class-specific immunoassay drug panels (point-of-care or laboratory-based), which typically do not identify particular drugs within a class unless the immunoassay is specific for that drug. If necessary, this can be followed up with a more specific technique, such as gas chromotography/mass spectrometry (GC/MS) or other chromatographic tests to confirm the presence or absence of a specific drug or its metabolites [53]. In drug testing in a pain practice, it is important to identify the specific drug not just the class of the drug.

Physicians need to be aware of the limitations of available tests (such as their limited sensitivity for many opioids) and take care to order tests appropriately [54]. For example, when a drug test is ordered, it is important to specify that it include the opioid being prescribed [53]. Because of the complexities involved in interpreting drug test results, it is advisable to confirm significant or unexpected results with the laboratory toxicologist or a clinical pathologist [59-60].

While immunoassay, point of care (POC) testing has its utility in the making of temporary and "on the spot" changes in clinical management, its limitations with regard to accuracy have recently been the subject of study. These limitations are such that the use of point of care testing for the making of more long term and permanent changes in management of people with the disease of addiction and other clinical situations may not be justified until the results of confirmatory testing with more accurate methods such as LC-MS/MS are obtained. A recent study on LC-MS/MS results following immunoassay POC testing in addiction treatment settings and found very high rates of "false negatives and positives" [53,81].

Test results that suggest opioid misuse should be discussed with the patient. It is helpful to approach such a discussion in a positive, supportive fashion, so as to strengthen the physician-patient relationship and encourage healthy behaviors (as well as behavioral change where that is needed). Both the test results and subsequent discussion with the patient should be documented in the medical record [53].

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Periodic pill counting is also a useful strategy to confirm medication adherence and to minimize diversion (e.g., selling, sharing or giving away medications). As noted earlier and where available, consulting the state's PDMP before prescribing opioids for pain and during ongoing use is highly recommended. A PDMP can be useful in monitoring compliance with the treatment agreement as well as identifying individuals obtaining controlled substances from multiple prescribers [21-23,55,62].

If the patient's progress is unsatisfactory, the physician must decide whether to revise or augment the treatment plan, whether other treatment modalities should be added to or substituted for the opioid therapy, or whether a different approach—possibly involving referral to a pain specialist or other health professional—should be employed [35-37,62-63].

Evidence of misuse of prescribed opioids demands prompt intervention by the physician [19,21-23,32,35]. Patient behaviors that require such intervention typically involve recurrent early requests for refills, multiple reports of lost or stolen prescriptions, obtaining controlled medications from multiple sources without the physician's knowledge, intoxication or impairment (either observed or reported), and pressuring or threatening behaviors [23]. The presence of illicit or unprescribed drugs, (drugs not prescribed by a physician) in drug tests similarly requires action on the part of the prescriber. Some aberrant behaviors are more closely associated with medication misuse than others [62-63]. Most worrisome is a pattern of behavior that suggests recurring misuse, such as unsanctioned dose escalations, deteriorating function, and failure to comply with the treatment plan [64].

Documented drug diversion or prescription forgery, obvious impairment, and abusive or assaultive behaviors require a firm, immediate response [22-23,38,46]. Indeed, failure to respond can place the patient and others at significant risk of adverse consequences, including accidental overdose, suicide attempts, arrests and incarceration, or even death [23,65-67]. For this reason, physicians who prescribe chronic opioid therapy should be knowledgeable in the diagnosis of substance use disorders and able to distinguish such disorders from physical dependence—which is expected in chronic therapy with opioids and many sedatives.

Consultation and Referral: The treating physician should seek a consultation with, or refer the patient to, a pain, psychiatry, addiction or mental health specialist as needed [37-38]. For example, a patient who has a history of substance use disorder or a co-occurring mental health disorder may require specialized assessment and treatment, if available [31,66].

Physicians who prescribe chronic opioid therapy should be familiar with treatment options for opioid addiction (including those available in licensed opioid treatment programs [OTPs]) and those offered by an appropriately credentialed and experienced physician through office-based opioid treatment [OBOT]), so as to make appropriate referrals when needed [23,31,37,39].

Discontinuing Opioid Therapy: Throughout the course of opioid therapy, the physician and patient should regularly weigh the potential benefits and risks of continued treatment and determine whether such treatment remains appropriate [46].

If opioid therapy is continued, the treatment plan may need to be adjusted to reflect the patient's changing physical status and needs, as well as to support safe and appropriate medication use [22-23].

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Reasons for discontinuing opioid therapy include resolution of the underlying painful condition, emergence of intolerable side effects, inadequate analgesic effect, failure to improve the patient's quality of life despite reasonable titration, deteriorating function, or significant aberrant medication use [38, 45].

If opioid therapy is discontinued, the patient who has become physically dependent should be provided with a safely structured tapering regimen. Withdrawal can be managed either by the prescribing physician or by referring the patient to an addiction specialist [63]. The termination of opioid therapy should not mark the end of treatment, which should continue with other modalities, either through direct care or referral to other health care specialists, as appropriate [21-23].

Additionally, providers should not continue opioid treatment unless the patient has received a benefit, including demonstrated functional improvement.

Medical Records: Every physician who treats patients for chronic pain must maintain accurate and complete medical records. Information that should appear in the medical record includes the following [22-23,38,43-44]:

- Copies of the signed informed consent and treatment agreement.
- The patient's medical history.
- Results of the physical examination and all laboratory tests.
- Results of the risk assessment, including results of any screening instruments used.
- A description of the treatments provided, including all medications prescribed or administered (including the date, type, dose and quantity).
- Instructions to the patient, including discussions of risks and benefits with the patient and any significant others.
- Results of ongoing monitoring of patient progress (or lack of progress) in terms of pain management and functional improvement.
- Notes on evaluations by and consultations with specialists.
- Any other information used to support the initiation, continuation, revision, or termination of treatment and the steps taken in response to any aberrant medication use behaviors [21-23,30,38,45,68]. These may include actual copies of, or references to, medical records of past hospitalizations or treatments by other providers.
- Authorization for release of information to other treatment providers.

The medical record must include all prescription orders for opioid analgesics and other controlled substances, whether written or telephoned. In addition, written instructions for the use of all medications should be given to the patient and documented in the record [25]. The name, telephone number, and address of the patient's pharmacy also should be recorded to facilitate contact as needed [23]. Records should be up-to-date and maintained in an accessible manner so as to be readily available for review [25].

Good records demonstrate that a service was provided to the patient and establish that the service provided was medically necessary. Even if the outcome is less than optimal, thorough records protect the physician as well as the patient [23,38,45,68].

Compliance with Controlled Substance Laws and Regulations: To prescribe, dispense or administer controlled substances, the physician must be registered with the DEA, licensed by the state in which he or she practices, and comply with applicable federal and state regulations [25].

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 and regulations governing the use of controlled substances. Additional resources are available on the DEA's website (at www.deadiversion.usdoj.gov), as well as from (*any relevant documents issued by the state medical board*).

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

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Section III: Definitions

For the purposes of this Model Policy, the following terms are defined as shown.

Aberrant Substance Use Behaviors: Behaviors that are outside the boundaries of the agreed-upon treatment plan may constitute aberrant substance use behaviors [22-23]. For example, obtaining prescriptions for the same or similar drugs from more than one physician or other health care provider without the treating physician's knowledge is aberrant behavior, as is use of illicit drugs.

Abuse: Abuse has been described as a maladaptive pattern of drug use that results in harm or places the individual at risk of harm [29]. Abuse of a prescription medication involves its use in a manner that deviates from approved medical, legal, and social standards, generally to achieve a euphoric state ("high") or to sustain opioid dependence that is opioid addiction or that is other than the purpose for which the medication was prescribed [28].

Addiction: A longstanding definition of addiction is that it is "a primary, chronic, neurobiologic disease, whose development and manifestations are influenced by genetic, psychosocial, and environmental factors" [28]. Addiction often is said to be characterized by behaviors that include impaired control over drug use, craving, compulsive use, and continued use despite harm [28].

A newer definition, adopted by the American Society of Addiction Medicine in 2011, describes addiction as "a primary, chronic disease of brain reward, motivation, memory and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors. Addiction is characterized by inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one's behaviors and interpersonal relationships, and a dysfunctional emotional response. Like other chronic diseases, addiction often involves cycles of relapse and remission. Without treatment or engagement in recovery activities, addiction is progressive and can result in disability or premature death" [40].

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

(As discussed below, physical dependence and tolerance are expected physiological consequences of extended opioid therapy for pain and in this context do not indicate the presence of addiction.)

Controlled Substance: A controlled substance is a drug that is subject to special requirements under the federal Controlled Substances Act of 1970 (CSA) [25], which is designed to ensure both the availability and control of regulated substances. Under the CSA, availability of regulated drugs for medical purposes is accomplished through a system that establishes quotas for drug production and a distribution system that closely monitors the importation, manufacture, distribution, prescribing, dispensing, administering, and possession of controlled drugs. Civil and criminal sanctions for serious violations of the statute are part of the government's control apparatus. The Code of Federal Regulations (Title 21, Chapter 2) implements the CSA.

The CSA provides that responsibility for scheduling controlled substances is shared between the Food and Drug Administration (FDA) and the DEA. In granting regulatory authority to these agencies, the Congress noted that both public health and public safety needs are important and that neither takes primacy over the other. To accomplish this, the Congress provided guidance in the form of factors that must be considered by the FDA and DEA when assessing public health and safety issues related to a new drug or one that is being considered for rescheduling or removal from control.

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OTHER GOVERNMENTAL POLICY

Medical Board Guideline

[CONTINUED]

The CSA does ***not*** limit the amount of drug prescribed, the duration for which it is prescribed, or the period for which a prescription is valid (although some states do impose such limits).

Most potent opioid analgesics are classified in ***Schedules II or III*** under the CSA, indicating that they have a significant potential for abuse and a currently accepted medical use in treatment in the U.S. (with certain restrictions), and that abuse of the drug may lead to severe psychological or physical dependence. Although the scheduling system provides a rough guide to abuse potential, it should be recognized that all controlled medications have some potential for abuse.

Dependence: Physical dependence is a state of biologic adaptation that is evidenced by a class-specific withdrawal syndrome when the drug is abruptly discontinued or the dose rapidly reduced, and/or by the administration of an antagonist [28]. It is important to distinguish addiction from the type of physical dependence that can and does occur within the context of good medical care, as when a patient on long-term opioid analgesics for pain becomes physically dependent on the analgesic. This distinction is reflected in the two primary diagnostic classification systems used by health care professionals: the ***International Classification of Mental and Behavioural Disorders, 10th Edition (ICD10)*** of the World Health Organization [70], and the ***Diagnostic and Statistical Manual (DSM)*** of the American Psychiatric Association [71]. In the DSM-IV-TR, a diagnosis of "substance dependence" meant addiction. In the upcoming DSM V, the term ***dependence*** is reestablished in its original meaning of physiological dependence. When symptoms are sufficient to meet criteria for substance misuse or addiction, the term "substance use disorder" is used, accompanied by severity ratings [69].

It may be important to clarify this distinction during the informed consent process, so that the patient (and family) understands that physical dependence and tolerance are likely to occur if opioids are taken regularly over a period of time, but that the risk of addiction is relatively low, although estimates do vary. Discontinuing chronic opioid therapy may be difficult, even in the absence of addiction. According to the World Health Organization, "The development of tolerance and physical dependence denote normal physiologic adaptations of the body to the presence of an opioid" [70]. Consequently, physical dependence alone is neither necessary nor sufficient to diagnose addiction [71,72].

Diversion: Drug diversion is defined as the intentional transfer of a controlled substance from authorized to unauthorized possession or channels of distribution [73-74]. The federal Controlled Substances Act (21 U.S.C. §§ 801 et seq.) establishes a closed system of distribution for drugs that are classified as controlled substances. Records must be kept from the time a drug is manufactured to the time it is dispensed. Health care professionals who are authorized to prescribe, dispense, and otherwise control access to such drugs are required to register with the DEA [25,75].

Pharmaceuticals that make their way outside this closed distribution system are said to have been "diverted" [75], and the individuals responsible for the diversion (including patients) are in violation of federal law.

Experience shows that the degree to which a prescribed medication is misused depends in large part on how easily it is redirected (diverted) from the legitimate distribution system [17,19,74].

Misuse: The term *misuse* (also called ***nonmedical use***) encompasses all uses of a prescription medication other than those that are directed by a physician and used by a patient within the law and the requirements of good medical practice [28].

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Opioid: An opioid is any compound that binds to an opioid receptor in the central nervous system (CNS) [4]. The class includes both naturally occurring and synthetic or semi-synthetic opioid drugs or medications, as well as endogenous opioid peptides [35].

Most physicians use the terms "opiate" and "opioid" interchangeably, but toxicologists (who perform and interpret drug tests) make a clear distinction between them. "Opioid" is the broader term because it includes the entire class of agents that act at opioid receptors in the CNS, whereas "opiates" refers to natural compounds derived from the opium plant but not semisynthetic opioid derivatives of opiates or completely synthetic agents. Thus, drug tests that are "positive for opiates" have detected one of these compounds or a metabolite of heroin, 6-monoacetyl morphine (MAM). Drug tests that are "negative for opiates" have found no detectable levels of opiates in the sample, even though other opioids that were not tested for—including the most common currently used and misused prescription opioids—may be present in the sample that was analyzed [53,59-260].

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

Acute pain is the normal, predictable physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. Acute pain generally is time-limited, lasting six weeks or less [4].

Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury (e.g., more than three months). It may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over a period of months or years.

Chronic noncancer related pain is chronic pain that is not associated with active cancer and does not occur at the end of life [4,76].

Opioid-induced hyperalgesia may develop as a result of long-term opioid use in the treatment of chronic pain. *Primary hyperalgesia* is pain sensitivity that occurs directly in the damaged tissues, while *secondary hyperalgesia* occurs in surrounding undamaged tissues. Human and animal studies have demonstrated that primary or secondary hyperalgesia can develop in response to both chronic and acute exposure to opioids. Hyperalgesia can be severe enough to warrant discontinuation of opioid treatment [77].

Prescription Drug Monitoring Program: Almost all states have enacted laws that establish prescription drug monitoring programs (PDMPs) to facilitate the collection, analysis, and reporting of information on the prescribing and dispensing of controlled substances. Most such programs employ electronic data transfer systems, under which prescription information is transmitted from the dispensing pharmacy to a state agency, which collates and analyzes the information [3,24].

After analyzing the efficacy of PDMPs, the GAO concluded that such programs have the potential to help law enforcement and regulatory agencies rapidly identify and investigate activities that may involve illegal prescribing, dispensing or consumption of controlled substances. Where real-time data are available, PDMPs also can help to prevent prescription drug misuse and diversion by allowing physicians to determine whether a patient is receiving prescriptions for controlled substances from other physicians, as well as whether the patient has filled or refilled an order for an opioid the physician has prescribed [24,78-79].

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OTHER GOVERNMENTAL POLICY

Medical Board Guideline

[CONTINUED]

Tolerance: Tolerance is a state of physiologic adaptation in which exposure to a drug induces changes that result in diminution of one or more of the drug's effects over time. Tolerance is common in opioid treatment, has been demonstrated following a single dose of opioids, and is not the same as addiction [28].

Trial Period: A period of time during which the efficacy of an opioid for treatment of an individual's pain is tested to determine whether the treatment goals can be met in terms of reduction of pain and restoration of function. If the goals are not met, the opioid dose may be adjusted, a different opioid substituted, an adjunctive therapy added, or use of opioids discontinued and an alternative approach to pain management selected [36].

Universal Precautions: The concept of *universal precautions* is borrowed from an infectious disease model of the same name to underscore its comparability to practices in other areas of medicine. The concept recognizes that all patients have a level of risk that can only be estimated initially, with the estimate modified over time as more information is obtained. The 10 essential steps of universal precautions can be summarized as follows [38]:

1. Make a diagnosis with an appropriate differential.
2. Conduct a patient assessment, including risk for substance use disorders.
3. Discuss the proposed treatment plan with the patient and obtain informed consent.
4. Have a written treatment agreement that sets forth the expectations and obligations of both the patient and the treating physician.
5. Initiate an appropriate trial of opioid therapy, with or without adjunctive medications.
6. Perform regular assessments of pain and function.
7. Reassess the patient's pain score and level of function.
8. Regularly evaluate the patient in terms of the "5 A's": **A**nalgesia, **A**ctivity, **A**dverse effects, **A**berrant behaviors, and **A**ffect.
9. Periodically review the pain diagnosis and any comorbid conditions, including substance use disorders, and adjust the treatment regimen accordingly.
10. Keep careful and complete records of the initial evaluation and each follow-up visit.

By acknowledging the fact that there are no signs that invariably point to substance use disorder [41], the universal precautions encourage a consistent and respectful approach to the assessment and management of pain patients, thereby minimizing stigma, improving patient care, and reducing overall risk [38].

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VIRGINIA

STATUTES

Injunction Against Assisted Suicide

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:* Clarifies for physicians the 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, and the practitioners who provide it.

Va. Code Ann. § 8.01-622.1

§ 8.01-622.1. Injunction against assisted suicide; damages; professional sanctions

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E. Nothing in this section shall be construed to limit or conflict with § 54.1-2971.01 or the Health Care Decisions Act (§ 54.1-2981 et seq.). This section shall not apply to a licensed health care provider who (i) administers, prescribes or dispenses medications or procedures to relieve another person's pain or discomfort and without intent to cause death, even if the medication or procedure may hasten or increase the risk of death, or (ii) withholds or withdraws life-prolonging procedures as defined in § 54.1-2982. This section shall not apply to any person who properly administers a legally prescribed medication without intent to cause death, even if the medication may hasten or increase the risk of death.

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VIRGINIA

REGULATIONS

Regulations for the Licensure of Hospice

12 VAC 5-391-190.

12 VAC 5-391-190. Written policies and procedures.

A. The hospice program shall implement written policies and procedures approved by the governing body.

B. All policies and procedures shall be reviewed at least annually, with recommended changes submitted to the governing body for approval, as necessary.

C. Administrative and operational policies and procedures shall include, but are not limited to:

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6. Pain assessment and management;

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12 VAC 5-391-240.

12 VAC 5-391-240. Patient rights.

A. The hospice program shall establish and implement written policies and procedures regarding the rights of patients. A copy of the patient's rights shall be displayed in the hospice office for public review.

B. Written procedures to implement the policies shall ensure that each patient is:

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5. Assured the right to participate in the planning of his care, including appropriate assessment and management of pain and the right to refuse services;

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12 VAC 5-391-260.

12 VAC 5-391-260. Quality improvement.

A. The hospice program shall implement an on-going, comprehensive, integrated, self-assessment program of the quality and appropriateness of care provided, including services provided under contract. The quality improvement program shall address actual patient outcomes (results of care), clinical, administrative, and cost-of-care issues. The findings shall be used to correct identified problems and revise policies and practices, as necessary. Exclusive concentration on administrative or cost-of-care issues does not fulfill this requirement.

B. The following areas shall be evaluated to identify unacceptable or unexpected trends or occurrences that influence patient outcomes (results of care):

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6. Appropriateness and effectiveness of pain management;

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12 VAC 5-381-280.

12 VAC 5-381-280. Client record system.

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F. An accurate and complete client record shall be maintained for each client receiving services and shall include, but shall not be limited to:

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10. A medical plan of care including appropriate assessment and pain management;

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

CATEGORY C:
Regulatory or policy issues

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

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility and various mechanisms for hospices 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 the patient's right to request or reject different types of treatments.

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VIRGINIA

REGULATIONS

Regulations for the Licensure of Hospice

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

CATEGORY C:
Regulatory or policy issues

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

12 VAC 5-391-320.

12 VAC 5-391-320. Plan of care.

A. At the time of a patient's admission to the hospice program, the IDG shall develop and maintain a plan of care, including but not limited to:

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4. A comprehensive assessment of pain, as warranted by the patient's condition and the scope of services provided by the hospice program;

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12 VAC 5-391-330.

12 VAC 5-391-330. Medical direction.

A. There shall be a medical director, who shall be a physician licensed by the Virginia Board of Medicine, responsible for the overall direction and management of the medical component of care. The individual shall have training and experience in the psychological and medical needs of the terminally ill.

B. The medical director shall have admitting privileges at one or more hospitals and nursing facilities that provide inpatient service to the hospice program's patients.

C. The duties and responsibilities of the medical director shall include at least the following:

1. Consulting with attending physicians regarding pain and symptom management;

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

CATEGORY C:
Regulatory or policy issues

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

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STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 69. Food, Drugs, Cosmetics, and Poisons; Chapter 69.50. Uniform Controlled Substances Act

- MEDICAL PRACTICE ACT
  Title 18. Businesses and Professions;
  Chapter 18.71. Physicians
  Chapter 18.72. Medical Disciplinary Board

- OSTEOPATHIC PRACTICE ACT
  Title 18. Businesses and Professions; Chapter 18.57. Osteopathy – Osteopathic Medicine and Surgery

- PHARMACY PRACTICE ACT (*No provisions found*)
  Title 18. Businesses and Professions; Chapter 18.64. Pharmacists

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*No provisions found*)
  Title 246. Health, Department of Professional Standards and Licensing;
  Chapter 887. Pharmacy -- Regulations Implementing the Uniform Controlled Substances Act

- MEDICAL BOARD REGULATIONS
  Title 246. Health, Department of Professional Standards and Licensing;
  Chapter 919. Medical Quality Assurance Commission

- OSTEOPATHIC BOARD REGULATIONS
  Title 246. Health, Department of Professional Standards and Licensing;
  Chapter 853. Osteopathic Physicians and Surgeons

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Title 246. Health, Department of Professional Standards and Licensing; Chapters 856-907

OTHER GOVERNMENTAL POLICIES

No policies found

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RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- PROFESSIONAL PRACTICE
  Title 18. Businesses and Professions; Chapter 18.130. Regulation of Health Professions – Uniform Disciplinary Act

- HOSPICE PLAN OF CARE
  Title 246. Health, Department of Facility Standards and Licensing;
  Chapter 335. In-Home Services Agencies; Part 1. Requirements for In-Home Services Agencies Licensed to Provide Home Health, Home Care, Hospice, and Hospice Care Center Services

- ADULT RESIDENTIAL CARE SERVICE
  Title 388. Social and Health Services, Department of Aging and Adult Services;
  Chapter 110. Contracted Residential Care Services; Part III. Enhanced Adult Residential Care

WASHINGTON

STATUTES

Controlled Substances Act

Rev. Code Wash. (ARCW) § 69.50.101

§ 69.50.101. Definitions

Unless the context clearly requires otherwise, definitions of terms shall be as indicated where used in this chapter:

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(dd) "Practitioner" means:

(1) A physician under chapter 18.71 RCW, a physician assistant under chapter 18.71A RCW, an osteopathic physician and surgeon under chapter 18.57 RCW, an optometrist licensed under chapter 18.53 RCW who is certified by the optometry board under ***RCW 18.53.010*** subject to any limitations in ***RCW 18.53.010***, a dentist under chapter 18.32 RCW, a podiatric physician and surgeon under chapter 18.22 RCW, a veterinarian under chapter 18.92 RCW, a registered nurse, advanced registered nurse practitioner, or licensed practical nurse under chapter 18.79 RCW, a pharmacist under chapter 18.64 RCW or a scientific investigator under this chapter, licensed, registered or otherwise permitted insofar as is consistent with those licensing laws to distribute, dispense, conduct research with respect to or administer a controlled substance in the course of their professional practice or research in this state.

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

Rev. Code Wash. (ARCW) § 69.50.308

§ 69.50.308. Prescriptions

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(i) 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. Medical treatment includes dispensing or administering a narcotic drug for pain, including intractable pain.

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

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WASHINGTON

STATUTES

Medical Practice Act

Rev. Code Wash. (ARCW) § 18.71.011

§ 18.71.011. Definition of practice of medicine — Engaging in practice of chiropractic prohibited, when

A person is practicing medicine if he does one or more of the following:

(1) Offers or undertakes to diagnose, cure, 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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Rev. Code Wash. (ARCW) § 18.71.450

§ 18.71.450. Pain management rules -- Repeal -- Adoption of new rules

(1) By June 30, 2011, the commission shall repeal its rules on pain management, *WAC 246-919-800* through *246-919-830*.

(2) By June 30, 2011, the commission shall adopt new rules on chronic, noncancer pain management that contain the following elements:

(a) (i) Dosing criteria, including:

(A) A dosage amount that must not be exceeded unless a physician first consults with a practitioner specializing in pain management; and

(B) Exigent or special circumstances under which the dosage amount may be exceeded without consultation with a practitioner specializing in pain management.

(ii) The rules regarding consultation with a practitioner specializing in pain management must, to the extent practicable, take into account:

(A) Circumstances under which repeated consultations would not be necessary or appropriate for a patient undergoing a stable, ongoing course of treatment for pain management;

(B) Minimum training and experience that is sufficient to exempt a physician from the specialty consultation requirement;

(C) Methods for enhancing the availability of consultations;

(D) Allowing the efficient use of resources; and

(E) Minimizing the burden on practitioners and patients;

(b) Guidance on when to seek specialty consultation and ways in which electronic specialty consultations may be sought;

(c) Guidance on tracking clinical progress by using assessment tools focusing on pain interference, physical function, and overall risk for poor outcome; and

(d) Guidance on tracking the use of opioids, particularly in the emergency department.

(3) The commission shall consult with the agency medical directors' group, the department of health, the University of Washington, and the largest professional association of physicians in the state.

(4) The rules adopted under this section do not apply:

(a) To the provision of palliative, hospice, or other end-of-life care; or

(b) To the management of acute pain caused by an injury or a surgical procedure.

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

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (regulations) for the board to improve 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.

(+) *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 include improvements in patient functioning and quality of life.

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STATUTES

Osteopathic Practice Act

Rev. Code Wash. (ARCW) § 18.57.285

§ 18.57.285. Pain management rules -- Repeal -- Adoption of new rules

(1) By June 30, 2011, the commission shall repeal its rules on pain management, *WAC 246-919-800* through *246-919-830*.

(2) By June 30, 2011, the commission shall adopt new rules on chronic, noncancer pain management that contain the following elements:

(a) (i) Dosing criteria, including:

(A) A dosage amount that must not be exceeded unless a physician first consults with a practitioner specializing in pain management; and

(B) Exigent or special circumstances under which the dosage amount may be exceeded without consultation with a practitioner specializing in pain management.

(ii) The rules regarding consultation with a practitioner specializing in pain management must, to the extent practicable, take into account:

(A) Circumstances under which repeated consultations would not be necessary or appropriate for a patient undergoing a stable, ongoing course of treatment for pain management;

(B) Minimum training and experience that is sufficient to exempt a physician from the specialty consultation requirement;

(C) Methods for enhancing the availability of consultations;

(D) Allowing the efficient use of resources; and

(E) Minimizing the burden on practitioners and patients;

(b) Guidance on when to seek specialty consultation and ways in which electronic specialty consultations may be sought;

(c) Guidance on tracking clinical progress by using assessment tools focusing on pain interference, physical function, and overall risk for poor outcome; and

(d) Guidance on tracking the use of opioids, particularly in the emergency department.

(3) The commission shall consult with the agency medical directors' group, the department of health, the University of Washington, and the largest professional association of physicians in the state.

(4) The rules adopted under this section do not apply:

(a) To the provision of palliative, hospice, or other end-of-life care; or

(b) To the management of acute pain caused by an injury or a surgical procedure.

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (regulations) for the board to improve 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 include improvements in patient functioning and quality of life.

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WASHINGTON

REGULATIONS

Medical Board Regulations

WAC 246-919-850. Pain management -- Intent.

These rules govern the use of opioids in the treatment of patients for chronic noncancer pain.

The Washington state medical quality assurance commission (commission) recognizes that principles of quality medical practice dictate that the people of the state of Washington 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 rule, 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 commission 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 rule has been developed to clarify the commission'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 a physician's lack of knowledge about pain management. Fears of investigation or sanction by federal, state, and local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating physician's responsibility. As such, the commission 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 commission 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 noncancer origins. The commission 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 nonpharmacologic 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 commission is obligated under the laws of the state of Washington to protect the public health and safety. The commission 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 commission 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 commission for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The commission 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.

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(+) *CRITERION 2:*
Pain management is part of healthcare 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 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: Identifies the potential impact of important barriers on the provision of effective pain care.

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

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WASHINGTON

REGULATIONS

Medical Board Regulations

(+) ***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.

(CONTINUED)

The commission 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.

These rules are designed to assist practitioners in providing appropriate medical care for patients. They are not inflexible rules or rigid practice requirements and are not intended, nor should they be used, to establish a legal standard of care outside the context of the medical quality assurance committee's jurisdiction.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner based on all the circumstances presented. Thus, an approach that differs from the rules, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the rules when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of these rules. However, a practitioner who employs an approach substantially different from these rules is advised to document in the patient record information sufficient to justify the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment.

Therefore, it should be recognized that adherence to these rules will not assure an accurate diagnosis or a successful outcome. The sole purpose of these rules is to assist practitioners in following a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care.

WAC 246-919-851. Exclusions.

The rules adopted under *WAC 246-919-850* through *246-919-863* do not apply:

(1) To the provision of palliative, hospice, or other end-of-life care; or

(2) To the management of acute pain caused by an injury or surgical procedure.

WAC 246-919-852. Definitions.

The definitions in *WAC 246-919-850* through *246-919-863* apply unless the context clearly requires otherwise.

(1) "Acute pain" means 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, often less than three months in duration, and usually less than six months.

(2) "Addiction" means a primary, chronic, neurobiologic disease with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include:

(a) Impaired control over drug use;
(b) Craving;
(c) Compulsive use; or
(d) Continued use despite harm.

(3) "Chronic noncancer pain" means a state in which noncancer 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.

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(+) ***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 include improvements in patient functioning and quality of life.

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(4) "Comorbidity" means a preexisting or coexisting physical or psychiatric disease or condition.

(5) "Episodic care" means medical care provided by a practitioner other than the designated primary care practitioner in the acute care setting, for example, urgent care or emergency department.

(6) "Hospice" means a model of care that focuses on relieving symptoms and supporting patients with a life expectancy of six months or less. Hospice involves an interdisciplinary approach to provide health care, pain management, and emotional and spiritual support. The emphasis is on comfort, quality of life and patient and family support. Hospice can be provided in the patient's home as well as freestanding hospice facilities, hospitals, nursing homes, or other long-term care facilities.

(7) "Morphine equivalent dose" means a conversion of various opioids to a morphine equivalent dose by the use of accepted conversion tables.

(8) "Multidisciplinary pain clinic" means a clinic or office that provides comprehensive pain management and includes care provided by multiple available disciplines or treatment modalities, for example, medical care through physicians, physician assistants, osteopathic physicians, osteopathic physician assistants, advanced registered nurse practitioners, and physical therapy, occupational therapy, or other complementary therapies.

(9) "Palliative" means care that improves the quality of life of patients and their families facing life-threatening illness. With palliative care particular attention is given to the prevention, assessment, and treatment of pain and other symptoms, and to the provision of psychological, spiritual, and emotional support.

WAC 246-919-853. Patient evaluation.

The physician shall obtain, evaluate, and document the patient's health history and physical examination in the health record prior to treating for chronic noncancer pain.

(1) The patient's health history shall include:

(a) Current and past treatments for pain;
(b) Comorbidities; and
(c) Any substance abuse.

(2) The patient's health history should include:

(a) A review of any available prescription monitoring program or emergency department-based information exchange; and
(b) Any relevant information from a pharmacist provided to a physician.

(3) The initial patient evaluation shall include:

(a) Physical examination;
(b) The nature and intensity of the pain;
(c) The effect of the pain on physical and psychological function;
(d) Medications including indication(s), date, type, dosage, and quantity prescribed;
(e) A risk screening of the patient for potential comorbidities and risk factors using an appropriate screening tool.

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The screening should address:

(i) History of addiction;

(ii) Abuse or aberrant behavior regarding opioid use;

(iii) Psychiatric conditions;

(iv) Regular concomitant use of benzodiazepines, alcohol, or other central nervous system medications;

(v) Poorly controlled depression or anxiety;

(vi) Evidence or risk of significant adverse events, including falls or fractures;

(vii) Receipt of opioids from more than one prescribing practitioner or practitioner group;

(viii) Repeated visits to emergency departments seeking opioids;

(ix) History of sleep apnea or other respiratory risk factors;

(x) Possible or current pregnancy; and

(xi) History of allergies or intolerances.

(4) The initial patient evaluation should include:

(a) Any available diagnostic, therapeutic, and laboratory results; and
(b) Any available consultations.

(5) The health record shall be maintained in an accessible manner, readily available for review, and should include:

(a) The diagnosis, treatment plan, and objectives;
(b) Documentation of the presence of one or more recognized indications for the use of pain medication;
(c) Documentation of any medication prescribed;
(d) Results of periodic reviews;
(e) Any written agreements for treatment between the patient and the physician; and
(f) The physician's instructions to the patient.

WAC 246-919-854. Treatment plan.

(1) The written treatment plan shall state the objectives that will be used to determine treatment success and shall include, at a minimum:

(a) Any change in pain relief;
(b) Any change in physical and psychosocial function; and
(c) Additional diagnostic evaluations or other planned treatments.

(2) After treatment begins the physician should adjust drug therapy to the individual health needs of the patient. The physician shall include indications for medication use on the prescription and require photo identification of the person picking up the prescription in order to fill. The physician shall advise the patient that it is the patient's responsibility to safeguard all medications and keep them in a secure location.

(3) 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.

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

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WAC 246-919-855. Informed consent.

The physician shall discuss the risks and benefits of treatment options with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is without health care decision-making capacity.

WAC 246-919-856. Written agreement for treatment.

Chronic noncancer pain patients should receive all chronic pain management 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, or psychiatric comorbidities, the prescribing physician shall use a written agreement for treatment with the patient outlining patient responsibilities. This written agreement for treatment shall include:

(1) The patient's agreement to provide biological samples for urine/serum medical level screening when requested by the physician;

(2) The patient's agreement to take medications at the dose and frequency prescribed with a specific protocol for lost prescriptions and early refills;

(3) Reasons for which drug therapy may be discontinued (e.g., violation of agreement);

(4) The requirement that all chronic pain management prescriptions are provided by a single prescriber or multidisciplinary pain clinic and dispensed by a single pharmacy or pharmacy system;

(5) The patient's agreement to not abuse alcohol or use other medically unauthorized substances;

(6) A written authorization for:

(a) The physician to release the agreement for treatment to local emergency departments, urgent care facilities, and pharmacies; and
(b) Other practitioners to report violations of the agreement back to the physician;

(7) A written authorization that the physician may notify the proper authorities if he or she has reason to believe the patient has engaged in illegal activity;

(8) Acknowledgment that a violation of the agreement may result in a tapering or discontinuation of the prescription;

(9) Acknowledgment that it is the patient's responsibility to safeguard all medications and keep them in a secure location; and

(10) Acknowledgment that if the patient violates the terms of the agreement, the violation and the physician's response to the violation will be documented, as well as the rationale for changes in the treatment plan.

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WAC 246-919-857. Periodic review.

The physician shall periodically review the course of treatment for chronic noncancer pain, the patient's state of health, and any new information about the etiology of the pain. Generally, periodic reviews shall take place at least every six months. However, for treatment of stable patients with chronic noncancer pain involving nonescalating daily dosages of forty milligrams of a morphine equivalent dose (MED) or less, periodic reviews shall take place at least annually.

(1) During the periodic review, the physician shall determine:

(a) Patient's compliance with any medication treatment plan;

(b) If pain, function, or quality of life have improved or diminished using objective evidence, considering any available information from family members or other caregivers; and

(c) If continuation or modification of medications for pain management treatment is necessary based on the physician's evaluation of progress towards treatment objectives.

(2) The physician shall assess the appropriateness of continued use of the current treatment plan if the patient's progress or compliance with current treatment plan is unsatisfactory. The physician shall consider tapering, changing, or discontinuing treatment when:

(a) Function or pain does not improve after a trial period;

(b) There is evidence of significant adverse effects;

(c) Other treatment modalities are indicated; or

(d) There is evidence of misuse, addiction, or diversion.

(3) The physician should periodically review information from any available prescription monitoring program or emergency department-based information exchange.

(4) The physician should periodically review any relevant information from a pharmacist provided to the physician.

WAC 246-919-858. Long-acting opioids, including methadone.

Long-acting opioids, including methadone, should only be prescribed by a physician who is familiar with its risks and use, and who is prepared to conduct the necessary careful monitoring. Special attention should be given to patients who are initiating such treatment. The physician prescribing long-acting opioids or methadone should have a one-time (lifetime) completion of at least four hours of continuing education relating to this topic.

WAC 246-919-859. Episodic care.

(1) When evaluating patients for episodic care, such as emergency or urgent care, the physician should review any available prescription monitoring program, emergency department-based information exchange, or other tracking system.

(2) Episodic care practitioners should avoid providing opioids for chronic pain management. However, if opioids are provided, the practitioner should limit the use of opioids for a chronic noncancer pain patient to the minimum amount necessary to control the pain until the patient can receive care from a primary care practitioner.

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(3) Prescriptions for opioids written by an episodic care practitioner shall include indications for use or the International Classification of Diseases (ICD) code and shall be written to require photo identification of the person picking up the prescription in order to fill.

(4) If a patient has signed a written agreement for treatment and has provided a written authorization to release the agreement under *WAC 246-919-856(6)* to episodic care practitioners, then the episodic care practitioner should report known violations of the agreement back to the patient's treatment practitioner who provided the agreement for treatment.

WAC 246-919-860. Consultation -- Recommendations and requirements.

(1) The physician shall consider, and document the consideration, referring the patient for additional evaluation and treatment as needed to achieve treatment objectives. Special attention should be given to those chronic noncancer pain patients who are under eighteen years of age, or who are at risk for medication misuse, abuse, or diversion. The management of pain in patients with a history of substance abuse or with comorbid psychiatric disorders may require extra care, monitoring, documentation, and consultation with, or referral to, an expert in the management of such patients.

(2) The mandatory consultation threshold for adults is one hundred twenty milligrams morphine equivalent dose (MED)(oral). In the event a physician prescribes a dosage amount that meets or exceeds the consultation threshold of one hundred twenty milligrams MED (orally) per day, a consultation with a pain management specialist as described in *WAC 246-919-863* is required, unless the consultation is exempted under *WAC 246-919-861* or *246-919-862*. Great caution should be used when prescribing opioids to children with chronic noncancer pain and appropriate referrals to a specialist is encouraged.

(a) The mandatory consultation shall consist of at least one of the following:

(i) An office visit with the patient and the pain management specialist;

(ii) A telephone consultation between the pain management specialist and the physician;

(iii) An electronic consultation between the pain management specialist and the physician; or

(iv) An audio-visual evaluation conducted by the pain management specialist remotely, where the patient is present with either the physician or a licensed health care practitioner designated by the physician or the pain management specialist.

(b) A physician shall document each mandatory consultation with the pain management specialist. Any written record of the consultation by the pain management specialist shall be maintained as a patient record by the specialist. If the specialist provides a written record of the consultation to the physician, the physician shall maintain it as part of the patient record.

(3) Nothing in this chapter shall limit any person's ability to contractually require a consultation with a pain management specialist at any time. For the purposes of *WAC 246-919-850* through *246-919-863*, "person" means an individual, a trust or estate, a firm, a partnership, a corporation (including associations, joint stock companies, and insurance companies), the state, or a political subdivision or instrumentality of the state, including a municipal corporation or a hospital district.

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

CATEGORY B:
Issues related to patients

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

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WAC 246-919-861. Consultation -- Exemptions for exigent and special circumstances.

A physician is not required to consult with a pain management specialist as described in *WAC 246-919-863* when he or she has documented adherence to all standards of practice as defined in *WAC 246-919-850* through *246-919-863* and when any one or more of the following conditions apply:

(1) The patient is following a tapering schedule;

(2) The patient requires treatment for acute pain which may or may not include hospitalization, requiring a temporary escalation in opioid dosage, with expected return to or below their baseline dosage level; or

(3) The physician documents reasonable attempts to obtain a consultation with a pain management specialist and the circumstances justifying prescribing above one hundred twenty milligrams morphine equivalent dose (MED) per day without first obtaining a consultation; or

(4) The physician documents the patient's pain and function is stable and the patient is on a nonescalating dosage of opioids.

WAC 246-919-862. Consultation -- Exemptions for the physician.

The physician is exempt from the consultation requirement in *WAC 246-919-860* if one or more of the following qualifications are met:

(1) The physician is a pain management specialist under *WAC 246-919-863*; or

(2) The physician has successfully completed, within the last two years, a minimum of twelve (Category I) continuing education hours on chronic pain management with at least two of these hours dedicated to long acting opioids; or

(3) The physician is a pain management practitioner working in a multidisciplinary chronic pain treatment center, or a multidisciplinary academic research facility; or

(4) The physician has a minimum three years of clinical experience in a chronic pain management setting, and at least thirty percent of his or her current practice is the direct provision of pain management care.

WAC 246-919-863. Pain management specialist.

A pain management specialist shall meet one or more of the following qualifications:

(1) If a physician or osteopathic physician:

(a) Board certified or board eligible by an American Board of Medical Specialties-approved board (ABMS) or by the American Osteopathic Association (AOA) in physical medicine and rehabilitation, rehabilitation medicine, neurology, rheumatology, or anesthesiology; or

(b) Has a subspecialty certificate in pain medicine by an ABMS-approved board; or

(c) Has a certification of added qualification in pain management by the AOA; or

(d) A minimum of three years of clinical experience in a chronic pain management care setting; and

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(i) Credentialed in pain management by an entity approved by the Washington state medical quality assurance commission for physicians or the Washington state board of osteopathic medicine and surgery for osteopathic physicians; and

(ii) Successful completion of a minimum of at least eighteen continuing education hours in pain management during the past two years for physicians or three years for osteopathic physicians; and

(iii) At least thirty percent of the physician's or osteopathic physician's current practice is the direct provision of pain management care or is in a multidisciplinary pain clinic.

(2) If a dentist: Board certified or board eligible in oral medicine or orofacial pain by the American Board of Oral Medicine or the American Board of Orofacial Pain.

(3) If an advanced registered nurse practitioner (ARNP):

(a) A minimum of three years of clinical experience in a chronic pain management care setting;

(b) Credentialed in pain management by the Washington state nursing care quality assurance commission-approved national professional association, pain association, or other credentialing entity;

(c) Successful completion of a minimum of at least eighteen continuing education hours in pain management during the past two years; and

(d) At least thirty percent of the ARNP's current practice is the direct provision of pain management care or is in a multidisciplinary pain clinic.

(4) If a podiatric physician:

(a) Board certified or board eligible in a specialty that includes a focus on pain management by the American Board of Podiatric Surgery, the American Board of Podiatric Orthopedics and Primary Podiatric Medicine, or other accredited certifying board as approved by the Washington state podiatric medical board; or

(b) A minimum of three years of clinical experience in a chronic pain management care setting; and

(c) Credentialed in pain management by the Washington state podiatric medical board-approved national professional association, pain association, or other credentialing entity; and

(d) Successful completion of a minimum of at least eighteen hours of continuing education in pain management during the past two years, and at least thirty percent of the podiatric physician's current practice is the direct provision of pain management care.

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WAC 246-853-660. Pain management -- Intent.

These rules govern the use of opioids in the treatment of patients for chronic noncancer pain.

WAC 246-853-661. Exclusions.

The rules adopted under *WAC 246-853-660* through *246-853-673* do not apply to:

(1) The provision of palliative, hospice, or other end-of-life care; or

(2) The management of acute pain caused by an injury or surgical procedure.

WAC 246-853-662. Definitions.

The definitions in this section apply in *WAC 246-853-600* through *246-853-673* unless the context clearly requires otherwise.

(1) "Acute pain" means 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, often less than three months in duration, and usually less than six months.

(2) "Addiction" means a primary, chronic, neurobiologic disease with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include:

(a) Impaired control over drug use;

(b) Craving;

(c) Compulsive use; or

(d) Continued use despite harm.

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

(3) "Chronic noncancer pain" means a state in which noncancer 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.

(4) "Comorbidity" means a preexisting or coexisting physical or psychiatric disease or condition.

(5) "Episodic care" means medical care provided by a provider other than the designated primary provider in the acute care setting, for example, urgent care or emergency department.

(6) "Hospice" means a model of care that focuses on relieving symptoms and supporting patients with a life expectancy of six months or less. Hospice involves an interdisciplinary approach to provide health care, pain management, and emotional and spiritual support. The emphasis is on comfort, quality of life and patient and family support. Hospice can be provided in the patient's home as well as freestanding hospice facilities, hospitals, nursing homes, or other long-term care facilities.

(7) "Morphine equivalent dose" means a conversion of various opioids to a morphine equivalent dose by the use of accepted conversion tables.

(8) "Multidisciplinary pain clinic" means a clinic or office that provides comprehensive pain management and may include care provided by multiple available disciplines or treatment modalities; for example, physicians, physician assistants, osteopathic physicians, osteopathic physician assistants, advanced registered nurse practitioners, physical therapy, occupational therapy, or other complementary therapies.

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(9) "Palliative" means care that improves the quality of life of patients and their families facing life-threatening illness. With palliative care particular attention is given to the prevention, assessment, and treatment of pain and other symptoms, and to the provision of psychological, spiritual, and emotional support.

WAC § 246-853-660 et seq

WAC 246-853-663. Patient evaluation.

The osteopathic physician shall obtain, evaluate, and document the patient's health history and physical examination in the health record prior to treating for chronic noncancer pain.

(1) The patient's health history shall include:

(a) Current and past treatments for pain;

(b) Comorbidities; and

(c) Any substance abuse.

(2) The patient's health history should include:

(a) A review of any available prescription monitoring program or emergency department-based information exchange; and

(b) Any relevant information from a pharmacist provided to the osteopathic physician.

(3) The initial patient evaluation shall include:

(a) Physical examination;

(b) The nature and intensity of the pain;

(c) The effect of the pain on physical and psychological function;

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

(e) A risk screening of the patient for potential comorbidities and risk factors using an appropriate screening tool. The screening should address:

(i) History of addiction;

(ii) Abuse or aberrant behavior regarding opioid use;

(iii) Psychiatric conditions;

(iv) Regular concomitant use of benzodiazepines, alcohol, or other central nervous system medications;

(v) Poorly controlled depression or anxiety;

(vi) Evidence or risk of significant adverse events, including falls or fractures;

(vii) Receipt of opioids from more than one prescribing practitioner or practitioner group;

(viii) Repeated visits to emergency departments seeking opioids;

(ix) History of sleep apnea or other respiratory risk factors;

(x) Possible or current pregnancy; and

(xi) History of allergies or intolerances.

(4) The initial patient evaluation should include:

(a) Any available diagnostic, therapeutic, and laboratory results; and

(b) Any available consultations.

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(5) The health record shall be maintained in an accessible manner, readily available for review, and should include:

(a) The diagnosis, treatment plan, and objectives;

(b) Documentation of the presence of one or more recognized indications for the use of pain medication;

(c) Documentation of any medication prescribed;

(d) Results of periodic reviews;

(e) Any written agreements for treatment between the patient and the osteopathic physician; and

(f) The osteopathic physician's instructions to the patient.

WAC 246-853-664. Treatment plan.

(1) The written treatment plan shall state the objectives that will be used to determine treatment success and shall include, at a minimum:

(a) Any change in pain relief;

(b) Any change in physical and psychosocial function; and

(c) Additional diagnostic evaluations or other planned treatments.

(2) After treatment begins the osteopathic physician should adjust drug therapy to the individual health needs of the patient. The osteopathic physician shall include indications for medication use on the prescription and require photo identification of the person picking up the prescription in order to fill. The osteopathic physician shall advise the patient that it is the patient's responsibility to safeguard all medications and keep them in a secure location.

(3) 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.

WAC 246-853-665. Informed consent.

The osteopathic physician shall discuss the risks and benefits of treatment options with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is without health care decision-making capacity.

WAC 246-853-666. Written agreement for treatment.

Chronic noncancer pain patients should receive all chronic pain management prescriptions from one osteopathic physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse, or has a history of substance abuse, or psychiatric comorbidities, the prescribing osteopathic physician shall use a written agreement for treatment with the patient outlining patient responsibilities. This written agreement for treatment shall include:

(1) The patient's agreement to provide biological samples for urine/serum medical level screening when requested by the osteopathic physician;

(2) The patient's agreement to take medications at the dose and frequency prescribed with a specific protocol for lost prescriptions and early refills;

(3) Reasons for which drug therapy may be discontinued (e.g., violation of agreement);

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

(+) *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 include improvements in patient functioning and quality of life.

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(4) The requirement that all chronic pain management prescriptions are provided by a single prescriber or multidisciplinary pain clinic and dispensed by a single pharmacy or pharmacy system;

(5) The patient's agreement to not abuse alcohol or use other medically unauthorized substances;

(6) A written authorization for:

(a) The osteopathic physician to release the agreement for treatment to local emergency departments, urgent care facilities, and pharmacies; and

(b) Other practitioners to report violations of the agreement back to the osteopathic physician.

(7) A written authorization that the osteopathic physician may notify the proper authorities if he or she has reason to believe the patient has engaged in illegal activity;

(8) Acknowledgment that a violation of the agreement may result in a tapering or discontinuation of the prescription;

(9) Acknowledgment that it is the patient's responsibility to safeguard all medications and keep them in a secure location; and

(10) Acknowledgment that if the patient violates the terms of the agreement, the violation and the osteopathic physician's response to the violation will be documented, as well as the rationale for changes in the treatment plan.

WAC 246-853-667. Periodic review.

The osteopathic physician shall periodically review the course of treatment for chronic noncancer pain, the patient's state of health, and any new information about the etiology of the pain. Generally, periodic reviews shall take place at least every six months. However, for treatment of stable patients with chronic noncancer pain involving nonescalating daily dosages of forty milligrams of a morphine equivalent dose (MED) or less, periodic reviews shall take place at least annually.

(1) During the periodic review, the osteopathic physician shall determine:

(a) Patient's compliance with any medication treatment plan;

(b) If pain, function, or quality of life have improved or diminished using objective evidence, considering any available information from family members or other caregivers; and

(c) If continuation or modification of medications for pain management treatment is necessary based on the osteopathic physician's evaluation of progress towards treatment objectives.

(2) The osteopathic physician shall assess the appropriateness of continued use of the current treatment plan if the patient's progress or compliance with current treatment plan is unsatisfactory. The osteopathic physician shall consider tapering, changing, or discontinuing treatment when:

(a) Function or pain does not improve after a trial period;

(b) There is evidence of significant adverse effects;

(c) Other treatment modalities are indicated; or

(d) There is evidence of misuse, addiction, or diversion.

(3) The osteopathic physician should periodically review information from any available prescription monitoring program or emergency department-based information exchange.

(4) The osteopathic physician should periodically review any relevant information from a pharmacist provided to the osteopathic physician.

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WAC 246-853-668. Long-acting opioids, including methadone.

Long-acting opioids, including methadone, should only be prescribed by an osteopathic physician who is familiar with its risks and use, and who is prepared to conduct the necessary careful monitoring. Special attention should be given to patients who are initiating such treatment. The osteopathic physician prescribing long-acting opioids or methadone should have a one-time (lifetime) completion of at least four hours of continuing education relating to this topic.

WAC 246-853-669. Episodic care.

(1) When evaluating patients for episodic care, such as emergency or urgent care, the osteopathic physician should review any available prescription monitoring program, emergency department-based information exchange, or other tracking system.

(2) Episodic care practitioners should avoid providing opioids for chronic pain management. However, if opioids are provided, the osteopathic physician should limit the use of opioids for a chronic noncancer pain patient to the minimum amount necessary to control the pain until the patient can receive care from a primary care practitioner.

(3) Prescriptions for opioids written by an episodic care practitioner shall include indications for use or the International Classification of Diseases (ICD) code and shall be written to require photo identification of the person picking up the prescription in order to fill.

(4) If a patient has signed a written agreement for treatment and has provided a written authorization to release the agreement under *WAC 246-853-666(6)* to episodic care practitioners, then the episodic care practitioner should report known violations of the agreement back to the patient's treatment practitioner who provided the agreement for treatment.

WAC 246-853-670. Consultation -- Recommendations and requirements.

(1) The osteopathic physician shall consider referring the patient for additional evaluation and treatment as needed to achieve treatment objectives. Special attention should be given to those chronic noncancer pain patients who are under eighteen years of age, or who are at risk for medication misuse, abuse, or diversion. The management of pain in patients with a history of substance abuse or with comorbid psychiatric disorders may require extra care, monitoring, documentation, and consultation with, or referral to, an expert in the management of such patients.

(2) The mandatory consultation threshold for adults is one hundred twenty milligrams morphine equivalent dose (MED) (oral). In the event an osteopathic physician prescribes a dosage amount that meets or exceeds the consultation threshold of one hundred twenty milligrams MED (orally) per day, a consultation with a pain management specialist as described in *WAC 246-853-673* is required, unless the consultation is exempted under *WAC 246-853-671* or *246-853-672*. Great caution should be used when prescribing opioids to children with chronic noncancer pain, and appropriate referral to a specialist is encouraged.

(a) The mandatory consultation shall consist of at least one of the following:

(i) An office visit with the patient and the pain management specialist;

(ii) A telephone consultation between the pain management specialist and the osteopathic physician;

(iii) An electronic consultation between the pain management specialist and the osteopathic physician; or

(iv) An audio-visual evaluation conducted by the pain management specialist remotely, where the patient is present with either the osteopathic physician or a licensed health care practitioner designated by the osteopathic physician or the pain management specialist.

(CONTINUED ON NEXT PAGE)

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

CATEGORY B:
Issues related to patients

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

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Madison, Wisconsin

WASHINGTON

REGULATIONS

Osteopathic Board Regulations

WAC § 246-853-660 et seq

(b) An osteopathic physician shall document each mandatory consultation with the pain management specialist. Any written record of the consultation by the pain management specialist shall be maintained as a patient record by the specialist. If the specialist provides a written record of the consultation to the osteopathic physician, the osteopathic physician shall maintain it as part of the patient record.

(3) Nothing in this chapter shall limit any person's ability to contractually require a consultation with a pain management specialist at any time. For the purposes of *WAC 246-853-660* through *246-853-673*, "person" means an individual, a trust or estate, a firm, a partnership, a corporation (including associations, joint stock companies, and insurance companies), the state, or a political subdivision or instrumentality of the state, including a municipal corporation or a hospital district.

WAC 246-853-671. Consultation -- Exemptions for exigent and special circumstances.

An osteopathic physician is not required to consult with a pain management specialist as described in *WAC 246-853-673* when he or she has documented adherence to all standards of practice as defined in *WAC 246-853-660* through 246-854-673 and when any one or more of the following conditions apply:

(1) The patient is following a tapering schedule; or

(2) The patient requires treatment for acute pain which may or may not include hospitalization, requiring a temporary escalation in opioid dosage, with expected return to or below their baseline dosage level; or

(3) The osteopathic physician documents reasonable attempts to obtain a consultation with a pain management specialist and the circumstances justifying prescribing above one hundred twenty milligrams morphine equivalent dose (MED) per day without first obtaining a consultation; or

(4) The osteopathic physician documents the patient's pain and function is stable and the patient is on a nonescalating dosage of opioids.

WAC 246-853-672. Consultation -- Exemptions for the osteopathic physician.

The osteopathic physician is exempt from the consultation requirement in *WAC 246-853-670* if one or more of the following qualifications are met:

(1) The osteopathic physician is a pain management specialist under *WAC 246-853-673*; or

(2) The osteopathic physician has successfully completed, within the last two years, a minimum of twelve continuing education hours on chronic pain management approved by the profession's continuing education accrediting organization, with at least two of these hours dedicated to long acting opioids, to include methadone, or within the last three years a minimum of eighteen continuing education hours on chronic pain management approved by the profession's continuing education accrediting organization, with at least three of these hours dedicated to long acting opioids, to include methadone; or

(3) The osteopathic physician is a pain management practitioner working in a multidisciplinary chronic pain treatment center, or a multidisciplinary academic research facility; or

(4) The osteopathic physician has a minimum three years of clinical experience in a chronic pain management setting, and at least thirty percent of his or her current practice is the direct provision of pain management care.

(CONTINUED ON NEXT PAGE)

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REGULATIONS

Osteopathic Board Regulations

WAC § 246-853-660 et seq

WAC 246-853-673. Pain management specialist.

A pain management specialist shall meet one or more of the following qualifications:

(1) If a physician or osteopathic physician:

(a) Board certified or board eligible by an American Board of Medical Specialties-approved board (ABMS) or by the American Osteopathic Association (AOA) in physical medicine and rehabilitation, rehabilitation medicine, neurology, rheumatology, or anesthesiology; or

(b) Has a subspecialty certificate in pain medicine by an ABMS-approved board; or

(c) Has a certification of added qualification in pain management by the AOA; or

(d) A minimum of three years of clinical experience in a chronic pain management care setting; and

(i) Credentialed in pain management by an entity approved by the Washington state medical quality assurance commission for physicians or the Washington state board of osteopathic medicine and surgery for osteopathic physicians; and

(ii) Successful completion of a minimum of at least eighteen continuing education hours in pain management during the past two years for a physician or three years for an osteopathic physician; and

(iii) At least thirty percent of the physician's or osteopathic physician's current practice is the direct provision of pain management care or in a multidisciplinary pain clinic.

(2) If a dentist: Board certified or board eligible in oral medicine or orofacial pain by the American Board of Oral Medicine or the American Board of Orofacial Pain.

(3) If an advanced registered nurse practitioner (ARNP):

(a) A minimum of three years of clinical experience in a chronic pain management care setting;

(b) Credentialed in pain management by a Washington state nursing care quality assurance commission-approved national professional association, pain association, or other credentialing entity;

(c) Successful completion of a minimum of at least eighteen continuing education hours in pain management during the past two years; and

(d) At least thirty percent of the ARNP's current practice is the direct provision of pain management care or is in a multidisciplinary pain clinic.

(4) If a podiatric physician:

(a) Board certified or board eligible in a specialty that includes a focus on pain management by the American Board of Podiatric Surgery, the American Board of Podiatric Orthopedics and Primary Podiatric Medicine, or other accredited certifying board as approved by the Washington state podiatric medical board; or

(b) A minimum of three years of clinical experience in a chronic pain management care setting; and

(c) Credentialed in pain management by a Washington state podiatric medical board-approved national professional association, pain association, or other credentialing entity; and

(d) Successful completion of a minimum of at least eighteen hours of continuing education in pain management during the past two years, and at least thirty percent of the podiatric physician's current practice is the direct provision of pain management care.

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WASHINGTON

STATUTES

Professional Practice

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

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (guidelines) for the board to improve pain management.

Rev. Code Wash. (ARCW) § 18.130.340

§ 18.130.340. Opiate therapy guidelines

The secretary of health shall coordinate and assist the regulatory boards and commissions of the health professions with prescriptive authority in the development of uniform guidelines for addressing opiate therapy for acute pain, and chronic pain associated with cancer and other terminal diseases, or other chronic or intractable pain conditions. The purpose of the guidelines is to assure the provision of effective medical treatment in accordance with recognized national standards and consistent with requirements of the public health and safety.

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WASHINGTON

REGULATIONS

Hospice Plan of Care

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

CATEGORY C:
Regulatory or policy issues

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

WAC § 246-335-085

WAC 246-335-085. Hospice plan of care.

(1) Hospice licensees must, except as provided in subsection (2) of this section:

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(c) Assure the hospice plan of care includes:

(i) Current diagnoses and information on health status;

(ii) Goals or outcome measures;

(iii) Symptom and pain management;

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REGULATIONS

Adult Residential Care Service

WAC § 388-110-220

WAC 388-110-220. Enhanced adult residential care service standards.

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(3) In a boarding home with an enhanced adult residential care-specialized dementia care services contract, for residents served under that contract, the contractor must:

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(d) Ensure that each staff who works directly with residents has at least six hours of continuing education per year related to dementia, including Alzheimer's disease. This six hours of continuing education may be part of the ten hours of continuing education required by *WAC 388-112-0205*. Appropriate topics include, but are not limited to:

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(xi) Recognizing and assessing pain in people with dementia.

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (staff training) for adult residential care facilities to ensure that pain management is an essential part of patient care.

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WEST VIRGINIA

STATUTES

- CONTROLLED SUBSTANCES ACT
  Chapter 60A. Uniform Controlled Substances Act

- MEDICAL PRACTICE ACT
  Chapter 30. Professions and Occupations; Article 3. West Virginia Medical Practice Act

- MANAGEMENT OF PAIN ACT (*Part of Medical Practice Act*)
  Chapter 30. Professions and Occupations; Article 3A. Management of Pain Act

- OSTEOPATHIC PRACTICE ACT (*No provisions found*)
  Chapter 30. Professions and Occupations; Article 14. Osteopathic Physicians and Surgeons

- PHARMACY PRACTICE ACT
  Chapter 30. Professions and Occupations; Article 5. Pharmacists, Pharmacy Technician, Pharmacy Interns and Pharmacies

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS *(Part of Pharmacy Board Regulations)* (*No provisions found*)
  Title 15. Legislative Rule; West Virginia Board of Pharmacy;
  Series 2. Rules of the Board of Pharmacy for the Uniform Controlled Substances Act

- MEDICAL BOARD REGULATIONS
  Title 11. Legislative Rule; West Virginia Board of Medicine

- OSTEOPATHIC BOARD REGULATIONS
  Title 24. Legislative Rule; West Virginia Board of Osteopathy

- PHARMACY BOARD REGULATIONS
  Title 15. Legislative Rule; West Virginia Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
  State of West Virginia Board of Medicine. *Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain*. Adopted: September 9, 2013.

- JOINT BOARD POLICY STATEMENT
  West Virginia Examiners for Registered Professional Nurses, Medicine, Osteopathy, and Pharmacy Boards. *Joint Policy Statement on Pain Management at the End of Life*. Adopted: March 12, 2001.

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RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- CHRONIC PAIN CLINIC LICENSING ACT
  Chapter 16. Public Health; Article 5H. Chronic Pain Clinic Licensing Act

- OPIOID TREATMENT PROGRAMS
  Title 69. Legislative Rule Health and Human Resources;
  Series 7. Regulation of Opioid Treatment Programs

WEST VIRGINIA

STATUTES

Controlled Substances Act

W. Va. Code § 60A-1-101

§ 60A-1-101 Definitions

As used in this act:

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(x) "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 professional practice or research in this state.

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W. Va. Code § 60A-9-5

§ 60A-9-5. Confidentiality; limited access to records; period of retention; no civil liability for required reporting.

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(2) Subject to the provisions of subdivision (1) of this subsection, the board shall also review the West Virginia Controlled Substance Monitoring Program database and issue reports that identify abnormal or unusual practices of patients who exceed parameters as determined by the advisory committee established in this section. The board shall communicate with prescribers and dispensers to more effectively manage the medications of their patients in the manner recommended by the advisory committee. All other reports produced by the board shall be kept confidential. The board shall maintain the information required by this article for a period of not less than five years. Notwithstanding any other provisions of this code to the contrary, data obtained under the provisions of this article may be used for compilation of educational, scholarly or statistical purposes, and may be shared with the West Virginia Department of Health and Human Resources for those purposes, as long as the identities of persons or entities and any personally identifiable information, including protected health information, contained therein shall be redacted, scrubbed or otherwise irreversibly destroyed in a manner that will preserve the confidential nature of the information. No individual or entity required to report under section four [§ 60A-9-4] of this article may be subject to a claim for civil damages or other civil relief for the reporting of information to the Board of Pharmacy as required under and in accordance with the provisions of this article

(3) The board shall establish an advisory committee to develop, implement and recommend parameters to be used in identifying abnormal or unusual usage patterns of patients in this state. This advisory committee shall:

(A) Consist of the following members: A physician licensed by the West Virginia Board of Medicine, a dentist licensed by the West Virginia Board of Dental Examiners, a physician licensed by the West Virginia Board of Osteopathy, a licensed physician certified by the American Board of Pain Medicine, a licensed physician board certified in medical oncology recommended by the West Virginia State Medical Association, a licensed physician board certified in palliative care recommended by the West Virginia Center on End of Life Care, a pharmacist licensed by the West Virginia Board of Pharmacy, a licensed physician member of the West Virginia Academy of Family Physicians, an expert in drug diversion and such other members as determined by the board.

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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: Requires an expertise in pain management on an Advisory Committee that provides consultation and recommendations about PMP data on prescribing patterns.

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WEST VIRGINIA

STATUTES

Medical Practice Act

W. Va. Code § 30-3-4

§ 30-3-4. Definitions

As used in this article:

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(3) "Practice of medicine and surgery" means the diagnosis or treatment of, or operation or prescription for, any human disease, pain, injury, deformity or other physical or mental condition.

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W. Va. Code § 30-3-14

§ 30-3-14. Professional discipline of physicians and podiatrists; reporting of information to board pertaining to professional malpractice and professional incompetence required; penalties; grounds for license denial and discipline of physicians and podiatrists; investigations; physical and mental examinations; hearings; sanctions; summary sanctions; reporting by the board; reapplication; civil and criminal immunity; voluntary limitation of license; probable cause determinations

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(c) The board may deny an application for license or other authorization to practice medicine and surgery or podiatry in this state and may discipline a physician or podiatrist licensed or otherwise lawfully practicing in this state who, after a hearing, has been adjudged by the board as unqualified due to any of the following reasons:

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(13) Prescribing, dispensing, administering, mixing or otherwise preparing a prescription drug, including any controlled substance under state or federal law, other than in good faith and in a therapeutic manner in accordance with accepted medical standards and in the course of the physician's or podiatrist's professional practice: Provided, that a physician who discharges his or her professional obligation to relieve the pain and suffering and promote the dignity and autonomy of dying patients in his or her care, and in so doing, exceeds the average dosage of a pain relieving controlled substance, in Schedule II and III of the Uniform Control Substance Act, does not violate this article;

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

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

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WEST VIRGINIA

STATUTES

Management of Pain Act

W. Va. Code § 30-3A-1

§ 30-3A-1. Definitions.

For the purposes of this article, the words or terms defined in this section have the meanings ascribed to them. These definitions are applicable unless a different meaning clearly appears from the context.

(1) An "accepted guideline" is a care or practice guideline for pain management developed by a nationally recognized clinical or professional association or a specialty society or government-sponsored agency that has developed practice or care guidelines based on original research or on review of existing research and expert opinion. An accepted guideline also includes policy or position statements relating to pain management issued by any West Virginia board included in chapter thirty [*§§ 30-1-1 et seq.] of the West Virginia Code* with jurisdiction over various health care practitioners. Guidelines established primarily for purposes of coverage, payment or reimbursement do not qualify as accepted practice or care guidelines when offered to limit treatment options otherwise covered by the provisions of this article.

(2) "Board" or "licensing board" means the West Virginia Board of Medicine, the West Virginia Board of Osteopathy, the West Virginia Board of Registered Nurses or the West Virginia Board of Pharmacy.

(3) "Nurse" means a registered nurse licensed in the State of West Virginia pursuant to the provisions of article seven [*§§ 30-7-1* et seq.] of this chapter.

(4) "Pain" means an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

(5) "Pain-relieving controlled substance" includes, but is not limited to, an opioid or other drug classified as a Schedule II through V controlled substance and recognized as effective for pain relief, and excludes any drug that has no accepted medical use in the United States or lacks accepted safety for use in treatment under medical supervision including, but not limited to, any drug classified as a Schedule I controlled substance.

(6) "Pharmacist" means a registered pharmacist licensed in the State of West Virginia pursuant to the provisions of article five [*§§ 30-5-1* et seq.] of this chapter.

(7) "Physician" means a physician licensed in the State of West Virginia pursuant to the provisions of article three or article fourteen [*§§ 30-14-1* et seq.] of this chapter.

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WEST VIRGINIA

STATUTES

Management of Pain Act

(CONTINUED)

§ 30-3A-2. Limitation on disciplinary sanctions or criminal punishment related to management of pain.

(a) A physician is not subject to disciplinary sanctions by a licensing board or criminal punishment by the state for prescribing, administering or dispensing pain-relieving controlled substances for the purpose of alleviating or controlling pain if:

(1) In the case of a dying patient experiencing pain, the physician practices in accordance with an accepted guideline as defined in section one of this article and discharges his or her professional obligation to relieve the dying patient's pain and promote the dignity and autonomy of the dying patient; or

(2) In the case of a patient who is not dying and is experiencing pain, the physician discharges his or her professional obligation to relieve the patient's pain, if the physician can demonstrate by reference to an accepted guideline that his or her practice substantially complied with that accepted guideline. Evidence of substantial compliance with an accepted guideline may be rebutted only by the testimony of a clinical expert. Evidence of noncompliance with an accepted guideline is not sufficient alone to support disciplinary or criminal action.

(b) A registered nurse is not subject to disciplinary sanctions by a licensing board or criminal punishment by the state for administering pain-relieving controlled substances to alleviate or control pain, if administered in accordance with the orders of a licensed physician.

(c) A registered pharmacist is not subject to disciplinary sanctions by a licensing board or criminal punishment by the state for dispensing a prescription for a pain-relieving controlled substance to alleviate or control pain, if dispensed in accordance with the orders of a licensed physician.

(d) For purposes of this section, the term "disciplinary sanctions" includes both remedial and punitive sanctions imposed on a licensee by a licensing board, arising from either formal or informal proceedings.

(e) The provisions of this section apply to the treatment of all patients for pain, regardless of the patient's prior or current chemical dependency or addiction. The board may develop and issue policies or guidelines establishing standards and procedures for the application of this article to the care and treatment of persons who are chemically dependent or addicted.

(CONTINUED ON NEXT PAGE)

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

CATEGORY C:
Regulatory or policy issues

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

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

CATEGORY B:
Issues related to patients

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

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

2013

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WEST VIRGINIA

STATUTES

Management of Pain Act

(CONTINUED)

§ 30-3A-3. Acts subject to discipline or prosecution

(a) Nothing in this article shall prohibit disciplinary action or criminal prosecution of a physician for:

(1) Failing to maintain complete, accurate, and current records documenting the physical examination and medical history of the patient, the basis for the clinical diagnosis of the patient, and the treatment plan for the patient;

(2) Writing a false or fictitious prescription for a controlled substance scheduled in article two [§ 60A-2-201 et seq.], chapter sixty-a of this code; or

(3) Prescribing, administering, or dispensing a controlled substance 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 chapter sixty-a of this code [§ 60A-1-101 et seq.]; or

(4) Diverting controlled substances prescribed for a patient to the physician's own personal use.

(b) Nothing in this article shall prohibit disciplinary action or criminal prosecution of a nurse or pharmacist for:

(1) Administering or dispensing a controlled substance 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 chapter sixty-a of this code [§ 60A-1-101 et seq.]; or

(2) Diverting controlled substances prescribed for a patient to the nurse's or pharmacist's own personal use.

§ 30-3A-4. Construction of article

This article may not be construed to legalize, condone, authorize or approve mercy killing or assisted suicide.

STATUTES

Pharmacy Practice Act

W. Va. Code § 30-5-1b

§ 30-5-4. Definitions

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

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(59) "Practitioner" means an individual authorized by a jurisdiction of the United States to prescribe drugs in the course of professional practices, as allowed by law.

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

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WEST VIRGINIA

REGULATIONS

Medical Board Regulations

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

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT: Although it is reasonable to expect physicians to avoid contributing to diversion, "excessive or inappropriate" implies there is a known standard, but the standard is not specified. Also, eliminating the critically important intent of the physician in deciding cases appears to add to the uncertainty of how this provision might be interpreted.

W. Va. Admin. Code § 11-1A-12

§ 11-1A-12, 12.1

Causes For Denial, Probation, Limitation, Discipline, Suspension, or Revocation of Licenses of Physicians and Podiatrists.

12.1 The Board may deny an application for a licensee on probation, suspend a license, limit or restrict or revoke any license heretofore or hereafter issued by the Board, upon satisfactory proof that the licensee has:

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v. Exercised influence on the patient or client in such a manner as to exploit the patient or client for the financial gain of the licensee or of a third party, which shall include, but not be limited to, the promoting or selling of services, goods, appliances or drugs and the promoting or advertising on any prescription form of a community pharmacy. For the purposes of this subdivision, it is 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 interests of the patient and is not in the course of the physician's or podiatrist's professional practice, without regard to his or her intent;

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WEST VIRGINIA

REGULATIONS

Osteopathic Board Regulations

W. Va. CSR § 24-1-3

§ 24-1-3. Definitions.

3.1. Affiliate. -- A member of a group of 2 or more fully accredited health care institutions legally united by an agreement of affiliation, conceived to enhance the potential of all participants in the provision of health care and medical education.
3.2. AOA. -- American Osteopathic Association
3.3. Approved program of post-graduate clinical training. -- a program of clinical training approved by, or subject to approval by, the American Osteopathic Association or approved by the Accreditation Council for Graduate Medical Education for the purposes of intern or resident training;
3.4. Board. -- The West Virginia Board of Osteopathic Medicine established in W. *Va. Code §30-14-1.*
3.5. Controlled substances. -- Drugs that are classified by federal or state law in Schedules I, II, III, IV, or V, as defined in W. Va. Code § 60-2-204 through 212.
3.6. Crimes involving moral turpitude. -- Those crimes which have dishonesty as a fundamental and necessary element; including, but not limited to, crimes involving theft, embezzlement, false swearing, perjury, fraud or misrepresentation.
3.7. Drug diversion training and best practice prescribing of controlled substances training -- Training which includes all of the following:
3.7.a. Drug diversion, including West Virginia statistics on prescription drug abuse and resulting deaths.
3.7.b. Epidemiology of chronic pain and misuse of opioids.
3.7.c. Indication for opioids in chronic pain treatment including general characteristics, toxicities and drug interactions.
3.7.d. Examination of patient evaluation and risk assessment and tools to assess risk and monitor benefits.
3.7.e. Initiation and ongoing management of chronic pain patient treated with opioid-based therapies, including treatment objectives; monitoring and periodic review; referrals and consultations; informed consent; prescription of controlled substance agreements, urine screens and pill counts; patient education on safe use, storage and disposal of opioids; discontinuation of opioids for pain due to lack of benefits or increased risks; documentation and medical records.
3.7.f. Case study of a patient with chronic pain.
3.7.g. Identification of diversion and drug-seeking tactics and behaviors.
3.7.h. Best practice methods for working with patients suspected of drug-seeking behavior and diversion.
3.7.i. Compliance with controlled substances laws and rules.
3.7.j. Registration with and use of the West Virginia Controlled Substances Monitoring Program established in West Virginia Code Chapter 60A, Article 9.
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W. Va. CSR § 24-1-18

§ 24-1-18. Causes For Denial, Probation, Limitation, Discipline, Suspension Or Revocation of Licenses of Osteopathic Physicians.

18.1. The Board may deny an application for a license, place a licensee on probation, suspend a license, limit or restrict a license or revoke any license issued by the Board, upon satisfactory proof that the licensee has:
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18.1.v. Exercised influence on the patient or client in such a manner as to exploit the patient or client for the financial gain of the licensee or of a third party, which shall include, but not be limited to, the promoting or selling of services, goods, appliances or drugs and the promoting or advertising on any prescription form of a community pharmacy. For the purposes of this subdivision, it is 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 interests 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 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

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

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT: Although it is reasonable to expect osteopathic physicians to avoid contributing to diversion, "excessive or inappropriate" implies there is a known standard, but the standard is not specified. Also, eliminating the critically important intent of the physician in deciding cases appears to add to the uncertainty of how this provision might be interpreted.

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REGULATIONS

Pharmacy Board Regulations

W. Va. CSR § 15-1-2

§ 15-1-2. Definitions.

2.1. The following words and phrases as used in this Rule have the following meanings:

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2.1.rr. "Practitioner" or "prescribing practitioner" means an individual currently licensed, registered or otherwise authorized by any state, territory or district of the United States to prescribe and administer drugs in the course of professional practices, including allopathic and osteopathic physicians, dentists, physician assistants, optometrists, veterinarians, podiatrists and nurse practitioners as allowed by law.

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

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OTHER GOVERNMENTAL POLICY

Medical Board Guideline

State of West Virginia Board of Medicine
Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain

Section I: Preamble

The Idaho Board of Medicine is obligated under the laws of the State of Idaho to protect the public health and safety. The Idaho Board of Medicine recognizes that principles of high-quality medical practice dictate that the people of the State of Idaho have access to appropriate, safe and effective pain management. The application of up-to-date knowledge and treatment modalities can help to restore function and thus improve the quality of life of patients who suffer from pain, particularly chronic pain [4,8,26].

This policy has been developed to articulate the Board's position on the use of controlled substances for pain, particularly the use of opioid analgesics and with special attention to the management of chronic pain. The policy thus is intended to encourage physicians to be knowledgeable about best clinical practices as regards the prescribing of opioids and be aware of associated risks. For the purposes of this policy, inappropriate treatment of pain includes nontreatment, inadequate treatment, overtreatment, and continued use of ineffective treatments.

The Board recognizes that opioid analgesics are useful and can be essential in the treatment of acute pain that results from trauma or surgery, as well as in the management of certain types of chronic pain, whether due to cancer or non-cancer causes [20,26,28]. The Board will refer to current clinical practice guidelines and expert reviews in approaching allegations of possible mismanagement of pain [8,10,12,14,26-41,80].

Responsibility for Appropriate Pain Management: All physicians and other providers should be knowledgeable about assessing patients' pain and function, and familiar with methods of managing pain [4,16]. Physicians also need to understand and comply with federal and state requirements for prescribing opioid analgesics [3,12,19]. Whenever federal laws and regulations differ from those of a particular state, the more stringent rule is the one that should be followed [42].

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, when current best clinical practices are met.

The Board will consider the use of opioids for pain management to be for a legitimate medical purpose if it is based on sound clinical judgment and current best clinical practices, is appropriately documented, and is of demonstrable benefit to the patient. To be within the usual course of professional practice, a legitimate physician-patient relationship must exist and the prescribing or administration of medications should be appropriate to the identified diagnosis, should be accompanied by careful follow-up monitoring of the patient's response to treatment as well as his or her safe use of the prescribed medication, and should demonstrate that the therapy has been adjusted as needed [7,38,43]. There should be documentation of appropriate referrals as necessary [36-37].

The medical management of pain should reflect current knowledge of evidence-based or best clinical practices for the use of pharmacologic and nonpharmacologic modalities, including the use of opioid analgesics and non-opioid therapies [14,16,27]. Such prescribing must be based on careful assessment of the patient and his or her pain (see the discussion on risk stratification, below) [33].

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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 substandard practices might be.

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

(+) *CRITERION 4:*
Encourages pain management

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

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Pain should be assessed and treated promptly, and the selection of therapeutic modalities (including the quantity and frequency of medication doses) should be adjusted according to the nature of the pain, the patient's response to treatment, and the patient's risk level relative to the use of medications with abuse potential [8,10,12,14,26-38].

Preventing Opioid Diversion and Abuse: The Board also recognizes that individuals' use of opioid analgesics for other than legitimate medical purposes poses a significant threat to the health and safety of the individual as well as to the public health [3]. The Board further recognizes that inappropriate prescribing of controlled substances by physicians may contribute to drug misuse and diversion by individuals who seek opioids for other than legitimate medical purposes [5,19,44]. Accordingly, the Board expects physicians to incorporate safeguards into their practices to minimize the risk of misuse and diversion of opioid analgesics and other controlled substances [19-23,38,45-46].

Allegations of inappropriate pain management will be evaluated on an individual basis. The Board may use a variety of sources to determine the appropriateness of treatment including prescribing information obtained from the State Prescription Drug Monitoring Program. The Board will not take disciplinary action against a physician for deviating from this Model Policy when contemporaneous medical records show reasonable cause for such a deviation.

The Board will judge the validity of the physician's treatment of a patient on the basis of available documentation, rather than solely on the quantity and duration of medication administered. The goal is the management of the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors, and mitigating risk of misuse, abuse, diversion and overdose [4,29].

The Board will consider the unsafe or otherwise inappropriate treatment of pain to be a departure from best clinical practice, taking into account whether the treatment is appropriate to the diagnosis and the patient's level of risk.

Section II: Guidelines

The Board has adopted the following criteria for use in evaluating a physician's management of a patient with pain, including the physician's prescribing of opioid analgesics:

Understanding Pain: The diagnosis and treatment of pain is integral to the practice of medicine [4,34-37]. In order to cautiously prescribe opioids, physicians must understand the relevant pharmacologic and clinical issues in the use of such analgesics, and carefully structure a treatment plan that reflects the particular benefits and risks of opioid use for each individual patient. Such an approach should be employed in the care of every patient who receives chronic opioid therapy [4,8].

Patient Evaluation and Risk Stratification: The medical record should document the presence of one or more recognized medical indications for prescribing an opioid analgesic [7] and reflect an appropriately detailed patient evaluation [38]. Such an evaluation should be completed before a decision is made as to whether to prescribe an opioid analgesic.

The nature and extent of the evaluation depends on the type of pain and the context in which it occurs. For example, meaningful assessment of chronic pain, including pain related to cancer or non-cancer origins, usually demands a more detailed evaluation than an assessment of acute pain. Assessment of the patient's pain typically would include the nature and intensity of the pain, past and current treatments for the pain, any underlying or co-occurring disorders and conditions, and the effect of the pain on the patient's physical and psychological functioning [31].

[CONTINUED ON NEXT PAGE]

(+) *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 goal of pain treatment should include improvements in patient functioning and quality of life.

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

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For every patient, the initial work-up should include a systems review and relevant physical examination, as well as laboratory investigations as indicated [33,36,48-53]. Such investigations help the physician address not only the nature and intensity of the pain, but also its secondary manifestations, such as its effects on the patient's sleep, mood, work, relationships, valued recreational activities, and alcohol and drug use.

Social and vocational assessment is useful in identifying supports and obstacles to treatment and rehabilitation; for example: Does the patient have good social supports, housing, and meaningful work? Is the home environment stressful or nurturing? [14].

Assessment of the patient's personal and family history of alcohol or drug abuse and relative risk for medication misuse or abuse also should be part of the initial valuation [11,14,21-23,45], and ideally should be completed prior to a decision as to whether to prescribe opioid analgesics [56-58]. This can be done through a careful clinical interview, which also should inquire into any history of physical, emotional or sexual abuse, because those are risk factors for substance misuse [31]. Use of a validated screening tool (such as the Screener and Opioid Assessment for Patients with Pain [SOAPP-R; 48] or the Opioid Risk Tool [ORT; 49]), or other validated screening tools, can save time in collecting and evaluating the information and determining the patient's level of risk.

All patients should be screened for depression and other mental health disorders, as part of risk evaluation. Patients with untreated depression and other mental health problems are at increased risk for misuse or abuse of controlled medications, including addiction, as well as overdose.

Patients who have a history of substance use disorder (including alcohol) are at elevated risk for failure of opioid analgesic therapy to achieve the goals of improved comfort and function, and also are at high risk for experiencing harm from this therapy, since exposure to addictive substances often is a powerful trigger of relapse [11,31,45]. Therefore, treatment of a patient who has a history of substance use disorder should, if possible, involve consultation with an addiction specialist before opioid therapy is initiated (and follow-up as needed). Patients who have an active substance use disorder should not receive opioid therapy until they are established in a treatment/recovery program [31] or alternatives are established such as co-management with an addiction professional. Physicians who treat patients with chronic pain should be encouraged to also be knowledgeable about the treatment of addiction, including the role of replacement agonists such as methadone and buprenorphine. For some physicians, there may be advantages to becoming eligible to treat addiction using office-based buprenorphine treatment.

Information provided by the patient is a necessary but insufficient part of the evaluation process. Reports of previous evaluations and treatments should be confirmed by obtaining records from other providers, if possible. Patients have occasionally provided fraudulent records, so if there is any reason to question the truthfulness of a patient's report, it is best to request records directly from the other providers [54-55].

If possible, the patient evaluation should include information from family members and/or significant others [22-23,49-50]. Where available, the state prescription drug monitoring program (PDMP) should be consulted to determine whether the patient is receiving prescriptions from any other physicians, and the results obtained from the PDMP should be documented in the patient record [34].

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

CATEGORY B:
Issues related to patients

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

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

[CONTINUED]

Development of a Treatment Plan and Goals: The goals of pain treatment include reasonably attainable improvement in pain and function; improvement in pain-associated symptoms such as sleep disturbance, depression, and anxiety; and avoidance of unnecessary or excessive use of medications [4,8]. Effective means of achieving these goals vary widely, depending on the type and causes of the patient's pain, other concurrent issues, and the preferences of the physician and the patient.

The treatment plan and goals should be established as early as possible in the treatment process and revisited regularly, so as to provide clear-cut, individualized objectives to guide the choice of therapies [38]. The treatment plan should contain information supporting the selection of therapies, both pharmacologic (including medications other than opioids) and nonpharmacologic. It also should specify the objectives that will be used to evaluate treatment progress, such as relief of pain and improved physical and psychosocial function [14,36,47].

The plan should document any further diagnostic evaluations, consultations or referrals, or additional therapies that have been considered [21-23,45].

Informed Consent and Treatment Agreement: The decision to initiate opioid therapy should be a shared decision between the physician and the patient. The physician should discuss the risks and benefits of the treatment plan (including any proposed use of opioid analgesics) with the patient, with persons designated by the patient, or with the patient's surrogate or guardian if the patient is without medical decision-making capacity [32,35]. If opioids are prescribed, the patient (and possibly family members) should be counseled on safe ways to store and dispose of medications [3,37].

Use of a written informed consent and treatment agreement (sometimes referred to as a "treatment contract") is recommended [21-23,35,38].

Informed consent documents typically address:

- The potential risks and anticipated benefits of chronic opioid therapy.
- Potential side effects (both short- and long-term) of the medication, such as constipation and cognitive impairment.
- The likelihood that tolerance to and physical dependence on the medication will develop.
- The risk of drug interactions and over-sedation.
- The risk of impaired motor skills (affecting driving and other tasks).
- The risk of opioid misuse, dependence, addiction, and overdose.
- The limited evidence as to the benefit of long-term opioid therapy.
- The physician's prescribing policies and expectations, including the number and frequency of prescription refills, as well as the physician's policy on early refills and replacement of lost or stolen medications.
- Specific reasons for which drug therapy may be changed or discontinued (including violation of the policies and agreements spelled out in the treatment agreement).

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Treatment agreements outline the joint responsibilities of physician and patient [35-37] and are indicated for opioid or other abusable medications. They typically discuss:

- The goals of treatment, in terms of pain management, restoration of function, and safety.
- The patient's responsibility for safe medication use (e.g., by not using more medication than prescribed or using the opioid in combination with alcohol or other substances; storing medications in a secure location; and safe disposal of any unused medication).
- The patient's responsibility to obtain his or her prescribed opioids from only one physician or practice.
- The patient's agreement to periodic drug testing (as of blood, urine, hair, or saliva).
- The physician's responsibility to be available or to have a covering physician available to care for unforeseen problems and to prescribe scheduled refills.

Informed consent documents and treatment agreements can be part of one document for the sake of convenience.

Initiating an Opioid Trial: Generally, safer alternative treatments should be considered before initiating opioid therapy for chronic, non-malignant pain. Opioid therapy should be presented to the patient as a therapeutic trial or test for a defined period of time (usually no more than 90 days) and with specified evaluation points. The physician should explain that progress will be carefully monitored for both benefit and harm in terms of the effects of opioids on the patient's level of pain, function, and quality of life, as well as to identify any adverse events or risks to safety [51]. When initiating opioid therapy, the lowest dose possible should be given to an opioid naïve patient and titrate to affect. It is generally suggested to begin opioid therapy with a short acting opioid and rotate to a long acting/extended release if indicated.

A decision to continue opioid therapy beyond the trial period should reflect a careful evaluation of benefits versus adverse events [29] and/or potential risks.

Ongoing Monitoring and Adapting the Treatment Plan: The physician should regularly review the patient's progress, including any new information about the etiology of the pain or the patient's overall health and level of function [35,49-50]. When possible, collateral information about the patient's response to opioid therapy should be obtained from family members or other close contacts, and the state PDMP. The patient should be seen more frequently while the treatment plan is being initiated and the opioid dose adjusted [44-51]. As the patient is stabilized in the treatment regimen, follow-up visits may be scheduled less frequently. (However, if the patient is seen less than monthly and an opioid is prescribed, arrangements must be made for the patient to obtain a refill or new prescription when needed.)

At each visit, the results of chronic opioid therapy should be monitored by assessing what have been called the "5As" of chronic pain management; these involve a determination of whether the patient is experiencing a reduction in pain (**A**nalgesia), has demonstrated an improvement in level of function (**A**ctivity), whether there are significant **A**dverse effects, whether there is evidence of **A**berrant substance-related behaviors, and mood of the individual (**A**ffect) [38,52]. Validated brief assessment tools that measure pain and function, such as the three-question "Pain, Enjoyment and General Activity" (PEG) scale [47] or other validated assessment tools, may be helpful and time effective.

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Continuation, modification or termination of opioid therapy for pain should be contingent on the physician's evaluation of (1) evidence of the patient's progress toward treatment objectives and (2) the absence of substantial risks or adverse events, such as overdose or diversion [21-23,45]. A satisfactory response to treatment would be indicated by a reduced level of pain, increased level of function, and/or improved quality of life [29]. Information from family members or other caregivers should be considered in evaluating the patient's response to treatment [14,35-36]. Use of measurement tools to assess the patient's level of pain, function, and quality of life (such as a visual analog or numerical scale) can be helpful in documenting therapeutic outcomes [14,49].

Periodic Drug Testing: Periodic drug testing may be useful in monitoring adherence to the treatment plan, as well as in detecting the use of non-prescribed drugs [53-54]. Drug testing is an important monitoring tool because self-reports of medication use is not always reliable and behavioral observations may detect some problems but not others [55-59]. Patients being treated for addiction should be tested as frequently as necessary to ensure therapeutic adherence, but for patients being treated for pain, clinical judgment trumps recommendations for frequency of testing.

Urine may be the preferred biologic specimen for testing because of its ease of collection and storage and the cost-effectiveness of such testing [53]. When such testing is conducted as part of pain treatment, forensic standards are generally not necessary and not in place, so collection is not observed and chain-of-custody protocols are not followed. Initial testing may be done using class-specific immunoassay drug panels (point-of-care or laboratory-based), which typically do not identify particular drugs within a class unless the immunoassay is specific for that drug. If necessary, this can be followed up with a more specific technique, such as gas chromotography/mass spectrometry (GC/MS) or other chromatographic tests to confirm the presence or absence of a specific drug or its metabolites [53]. In drug testing in a pain practice, it is important to identify the specific drug not just the class of the drug.

Physicians need to be aware of the limitations of available tests (such as their limited sensitivity for many opioids) and take care to order tests appropriately [54]. For example, when a drug test is ordered, it is important to specify that it include the opioid being prescribed [53]. Because of the complexities involved in interpreting drug test results, it is advisable to confirm significant or unexpected results with the laboratory toxicologist or a clinical pathologist [59-60].

While immunoassay, point of care (POC) testing has its utility in the making of temporary and "on the spot" changes in clinical management, its limitations with regard to accuracy have recently been the subject of study. These limitations are such that the use of point of care testing for the making of more long term and permanent changes in management of people with the disease of addiction and other clinical situations may not be justified until the results of confirmatory testing with more accurate methods such as LC-MS/MS are obtained. A recent study on LC-MS/MS results following immunoassay POC testing in addiction treatment settings and found very high rates of "false negatives and positives" [53,81].

Test results that suggest opioid misuse should be discussed with the patient. It is helpful to approach such a discussion in a positive, supportive fashion, so as to strengthen the physician-patient relationship and encourage healthy behaviors (as well as behavioral change where that is needed). Both the test results and subsequent discussion with the patient should be documented in the medical record [53].

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Periodic pill counting is also a useful strategy to confirm medication adherence and to minimize diversion (e.g., selling, sharing or giving away medications). As noted earlier and where available, consulting the state's PDMP before prescribing opioids for pain and during ongoing use is highly recommended. A PDMP can be useful in monitoring compliance with the treatment agreement as well as identifying individuals obtaining controlled substances from multiple prescribers [21-23,55,62].

If the patient's progress is unsatisfactory, the physician must decide whether to revise or augment the treatment plan, whether other treatment modalities should be added to or substituted for the opioid therapy, or whether a different approach—possibly involving referral to a pain specialist or other health professional—should be employed [35-37,62-63].

Evidence of misuse of prescribed opioids demands prompt intervention by the physician [19,21-23,32,35]. Patient behaviors that require such intervention typically involve recurrent early requests for refills, multiple reports of lost or stolen prescriptions, obtaining controlled medications from multiple sources without the physician's knowledge, intoxication or impairment (either observed or reported), and pressuring or threatening behaviors [23]. The presence of illicit or unprescribed drugs, (drugs not prescribed by a physician) in drug tests similarly requires action on the part of the prescriber. Some aberrant behaviors are more closely associated with medication misuse than others [62-63]. Most worrisome is a pattern of behavior that suggests recurring misuse, such as unsanctioned dose escalations, deteriorating function, and failure to comply with the treatment plan [64].

Documented drug diversion or prescription forgery, obvious impairment, and abusive or assaultive behaviors require a firm, immediate response [22-23,38,46]. Indeed, failure to respond can place the patient and others at significant risk of adverse consequences, including accidental overdose, suicide attempts, arrests and incarceration, or even death [23,65-67]. For this reason, physicians who prescribe chronic opioid therapy should be knowledgeable in the diagnosis of substance use disorders and able to distinguish such disorders from physical dependence—which is expected in chronic therapy with opioids and many sedatives.

Consultation and Referral: The treating physician should seek a consultation with, or refer the patient to, a pain, psychiatry, addiction or mental health specialist as needed [37-38]. For example, a patient who has a history of substance use disorder or a co-occurring mental health disorder may require specialized assessment and treatment, if available [31,66].

Physicians who prescribe chronic opioid therapy should be familiar with treatment options for opioid addiction (including those available in licensed opioid treatment programs [OTPs]) and those offered by an appropriately credentialed and experienced physician through office-based opioid treatment [OBOT]), so as to make appropriate referrals when needed [23,31,37,39].

Discontinuing Opioid Therapy: Throughout the course of opioid therapy, the physician and patient should regularly weigh the potential benefits and risks of continued treatment and determine whether such treatment remains appropriate [46].

If opioid therapy is continued, the treatment plan may need to be adjusted to reflect the patient's changing physical status and needs, as well as to support safe and appropriate medication use [22-23].

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Reasons for discontinuing opioid therapy include resolution of the underlying painful condition, emergence of intolerable side effects, inadequate analgesic effect, failure to improve the patient's quality of life despite reasonable titration, deteriorating function, or significant aberrant medication use [38, 45].

If opioid therapy is discontinued, the patient who has become physically dependent should be provided with a safely structured tapering regimen. Withdrawal can be managed either by the prescribing physician or by referring the patient to an addiction specialist [63]. The termination of opioid therapy should not mark the end of treatment, which should continue with other modalities, either through direct care or referral to other health care specialists, as appropriate [21-23].

Additionally, providers should not continue opioid treatment unless the patient has received a benefit, including demonstrated functional improvement.

Medical Records: Every physician who treats patients for chronic pain must maintain accurate and complete medical records. Information that should appear in the medical record includes the following [22-23,38,43-44]:

- Copies of the signed informed consent and treatment agreement.
- The patient's medical history.
- Results of the physical examination and all laboratory tests.
- Results of the risk assessment, including results of any screening instruments used.
- A description of the treatments provided, including all medications prescribed or administered (including the date, type, dose and quantity).
- Instructions to the patient, including discussions of risks and benefits with the patient and any significant others.
- Results of ongoing monitoring of patient progress (or lack of progress) in terms of pain management and functional improvement.
- Notes on evaluations by and consultations with specialists.
- Any other information used to support the initiation, continuation, revision, or termination of treatment and the steps taken in response to any aberrant medication use behaviors [21-23,30,38,45,68]. These may include actual copies of, or references to, medical records of past hospitalizations or treatments by other providers.
- Authorization for release of information to other treatment providers.

The medical record must include all prescription orders for opioid analgesics and other controlled substances, whether written or telephoned. In addition, written instructions for the use of all medications should be given to the patient and documented in the record [25]. The name, telephone number, and address of the patient's pharmacy also should be recorded to facilitate contact as needed [23]. Records should be up-to-date and maintained in an accessible manner so as to be readily available for review [25].

Good records demonstrate that a service was provided to the patient and establish that the service provided was medically necessary. Even if the outcome is less than optimal, thorough records protect the physician as well as the patient [23,38,45,68].

Compliance with Controlled Substance Laws and Regulations: To prescribe, dispense or administer controlled substances, the physician must be registered with the DEA, licensed by the state in which he or she practices, and comply with applicable federal and state regulations [25].

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 and regulations governing the use of controlled substances. Additional resources are available on the DEA's website (at www.deadiversion.usdoj.gov), as well as from (*any relevant documents issued by the state medical board*).

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

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Section III: Definitions

For the purposes of this Model Policy, the following terms are defined as shown.

Aberrant Substance Use Behaviors: Behaviors that are outside the boundaries of the agreed-upon treatment plan may constitute aberrant substance use behaviors [22-23]. For example, obtaining prescriptions for the same or similar drugs from more than one physician or other health care provider without the treating physician's knowledge is aberrant behavior, as is use of illicit drugs.

Abuse: Abuse has been described as a maladaptive pattern of drug use that results in harm or places the individual at risk of harm [29]. Abuse of a prescription medication involves its use in a manner that deviates from approved medical, legal, and social standards, generally to achieve a euphoric state ("high") or to sustain opioid dependence that is opioid addiction or that is other than the purpose for which the medication was prescribed [28].

Addiction: A longstanding definition of addiction is that it is "a primary, chronic, neurobiologic disease, whose development and manifestations are influenced by genetic, psychosocial, and environmental factors" [28]. Addiction often is said to be characterized by behaviors that include impaired control over drug use, craving, compulsive use, and continued use despite harm [28].

A newer definition, adopted by the American Society of Addiction Medicine in 2011, describes addiction as "a primary, chronic disease of brain reward, motivation, memory and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors. Addiction is characterized by inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one's behaviors and interpersonal relationships, and a dysfunctional emotional response. Like other chronic diseases, addiction often involves cycles of relapse and remission. Without treatment or engagement in recovery activities, addiction is progressive and can result in disability or premature death" [40].

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

(As discussed below, physical dependence and tolerance are expected physiological consequences of extended opioid therapy for pain and in this context do not indicate the presence of addiction.)

Controlled Substance: A controlled substance is a drug that is subject to special requirements under the federal Controlled Substances Act of 1970 (CSA) [25], which is designed to ensure both the availability and control of regulated substances. Under the CSA, availability of regulated drugs for medical purposes is accomplished through a system that establishes quotas for drug production and a distribution system that closely monitors the importation, manufacture, distribution, prescribing, dispensing, administering, and possession of controlled drugs. Civil and criminal sanctions for serious violations of the statute are part of the government's control apparatus. The Code of Federal Regulations (Title 21, Chapter 2) implements the CSA.

The CSA provides that responsibility for scheduling controlled substances is shared between the Food and Drug Administration (FDA) and the DEA. In granting regulatory authority to these agencies, the Congress noted that both public health and public safety needs are important and that neither takes primacy over the other. To accomplish this, the Congress provided guidance in the form of factors that must be considered by the FDA and DEA when assessing public health and safety issues related to a new drug or one that is being considered for rescheduling or removal from control.

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The CSA does ***not*** limit the amount of drug prescribed, the duration for which it is prescribed, or the period for which a prescription is valid (although some states do impose such limits).

Most potent opioid analgesics are classified in ***Schedules II or III*** under the CSA, indicating that they have a significant potential for abuse and a currently accepted medical use in treatment in the U.S. (with certain restrictions), and that abuse of the drug may lead to severe psychological or physical dependence. Although the scheduling system provides a rough guide to abuse potential, it should be recognized that all controlled medications have some potential for abuse.

Dependence: Physical dependence is a state of biologic adaptation that is evidenced by a class-specific withdrawal syndrome when the drug is abruptly discontinued or the dose rapidly reduced, and/or by the administration of an antagonist [28]. It is important to distinguish addiction from the type of physical dependence that can and does occur within the context of good medical care, as when a patient on long-term opioid analgesics for pain becomes physically dependent on the analgesic. This distinction is reflected in the two primary diagnostic classification systems used by health care professionals: the ***International Classification of Mental and Behavioural Disorders, 10th Edition (ICD10)*** of the World Health Organization [70], and the ***Diagnostic and Statistical Manual (DSM)*** of the American Psychiatric Association [71]. In the DSM-IV-TR, a diagnosis of "substance dependence" meant addiction. In the upcoming DSM V, the term ***dependence*** is reestablished in its original meaning of physiological dependence. When symptoms are sufficient to meet criteria for substance misuse or addiction, the term "substance use disorder" is used, accompanied by severity ratings [69].

It may be important to clarify this distinction during the informed consent process, so that the patient (and family) understands that physical dependence and tolerance are likely to occur if opioids are taken regularly over a period of time, but that the risk of addiction is relatively low, although estimates do vary. Discontinuing chronic opioid therapy may be difficult, even in the absence of addiction. According to the World Health Organization, "The development of tolerance and physical dependence denote normal physiologic adaptations of the body to the presence of an opioid" [70]. Consequently, physical dependence alone is neither necessary nor sufficient to diagnose addiction [71,72].

Diversion: Drug diversion is defined as the intentional transfer of a controlled substance from authorized to unauthorized possession or channels of distribution [73-74]. The federal Controlled Substances Act (21 U.S.C. §§ 801 et seq.) establishes a closed system of distribution for drugs that are classified as controlled substances. Records must be kept from the time a drug is manufactured to the time it is dispensed. Health care professionals who are authorized to prescribe, dispense, and otherwise control access to such drugs are required to register with the DEA [25,75].

Pharmaceuticals that make their way outside this closed distribution system are said to have been "diverted" [75], and the individuals responsible for the diversion (including patients) are in violation of federal law.

Experience shows that the degree to which a prescribed medication is misused depends in large part on how easily it is redirected (diverted) from the legitimate distribution system [17,19,74].

Misuse: The term *misuse* (also called ***nonmedical use***) encompasses all uses of a prescription medication other than those that are directed by a physician and used by a patient within the law and the requirements of good medical practice [28].

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OTHER GOVERNMENTAL POLICY

Medical Board Guideline

[CONTINUED]

Opioid: An opioid is any compound that binds to an opioid receptor in the central nervous system (CNS) [4]. The class includes both naturally occurring and synthetic or semi-synthetic opioid drugs or medications, as well as endogenous opioid peptides [35].

Most physicians use the terms "opiate" and "opioid" interchangeably, but toxicologists (who perform and interpret drug tests) make a clear distinction between them. "Opioid" is the broader term because it includes the entire class of agents that act at opioid receptors in the CNS, whereas "opiates" refers to natural compounds derived from the opium plant but not semisynthetic opioid derivatives of opiates or completely synthetic agents. Thus, drug tests that are "positive for opiates" have detected one of these compounds or a metabolite of heroin, 6-monoacetyl morphine (MAM). Drug tests that are "negative for opiates" have found no detectable levels of opiates in the sample, even though other opioids that were not tested for—including the most common currently used and misused prescription opioids—may be present in the sample that was analyzed [53,59-260].

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

Acute pain is the normal, predictable physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. Acute pain generally is time-limited, lasting six weeks or less [4].

Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury (e.g., more than three months). It may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over a period of months or years.

Chronic noncancer related pain is chronic pain that is not associated with active cancer and does not occur at the end of life [4,76].

Opioid-induced hyperalgesia may develop as a result of long-term opioid use in the treatment of chronic pain. *Primary hyperalgesia* is pain sensitivity that occurs directly in the damaged tissues, while *secondary hyperalgesia* occurs in surrounding undamaged tissues. Human and animal studies have demonstrated that primary or secondary hyperalgesia can develop in response to both chronic and acute exposure to opioids. Hyperalgesia can be severe enough to warrant discontinuation of opioid treatment [77].

Prescription Drug Monitoring Program: Almost all states have enacted laws that establish prescription drug monitoring programs (PDMPs) to facilitate the collection, analysis, and reporting of information on the prescribing and dispensing of controlled substances. Most such programs employ electronic data transfer systems, under which prescription information is transmitted from the dispensing pharmacy to a state agency, which collates and analyzes the information [3,24].

After analyzing the efficacy of PDMPs, the GAO concluded that such programs have the potential to help law enforcement and regulatory agencies rapidly identify and investigate activities that may involve illegal prescribing, dispensing or consumption of controlled substances. Where real-time data are available, PDMPs also can help to prevent prescription drug misuse and diversion by allowing physicians to determine whether a patient is receiving prescriptions for controlled substances from other physicians, as well as whether the patient has filled or refilled an order for an opioid the physician has prescribed [24,78-79].

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Medical Board Guideline

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Tolerance: Tolerance is a state of physiologic adaptation in which exposure to a drug induces changes that result in diminution of one or more of the drug's effects over time. Tolerance is common in opioid treatment, has been demonstrated following a single dose of opioids, and is not the same as addiction [28].

Trial Period: A period of time during which the efficacy of an opioid for treatment of an individual's pain is tested to determine whether the treatment goals can be met in terms of reduction of pain and restoration of function. If the goals are not met, the opioid dose may be adjusted, a different opioid substituted, an adjunctive therapy added, or use of opioids discontinued and an alternative approach to pain management selected [36].

Universal Precautions: The concept of *universal precautions* is borrowed from an infectious disease model of the same name to underscore its comparability to practices in other areas of medicine. The concept recognizes that all patients have a level of risk that can only be estimated initially, with the estimate modified over time as more information is obtained. The 10 essential steps of universal precautions can be summarized as follows [38]:

1. Make a diagnosis with an appropriate differential.
2. Conduct a patient assessment, including risk for substance use disorders.
3. Discuss the proposed treatment plan with the patient and obtain informed consent.
4. Have a written treatment agreement that sets forth the expectations and obligations of both the patient and the treating physician.
5. Initiate an appropriate trial of opioid therapy, with or without adjunctive medications.
6. Perform regular assessments of pain and function.
7. Reassess the patient's pain score and level of function.
8. Regularly evaluate the patient in terms of the "5 A's": **A**nalgesia, **A**ctivity, **A**dverse effects, **A**berrant behaviors, and **A**ffect.
9. Periodically review the pain diagnosis and any comorbid conditions, including substance use disorders, and adjust the treatment regimen accordingly.
10. Keep careful and complete records of the initial evaluation and each follow-up visit.

By acknowledging the fact that there are no signs that invariably point to substance use disorder [41], the universal precautions encourage a consistent and respectful approach to the assessment and management of pain patients, thereby minimizing stigma, improving patient care, and reducing overall risk [38].

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WEST VIRGINIA

OTHER GOVERNMENTAL POLICY

Joint Board Policy Statement

WEST VIRGINIA BOARDS OF EXAMINERS FOR REGISTERED NURSES, MEDICINE, OSTEOPATHY, AND PHARMACY
JOINT POLICY STATEMENT ON PAIN MANAGEMENT AT THE END OF LIFE

Rationale

The West Virginia Boards of Examiners for Registered Professional Nurses, Medicine, Osteopathy, and Pharmacy (hereinafter the Boards) recognize that:

- inadequate treatment of pain for patients at end-of-life is a serious health problem affecting thousands of patients every year;
- fear about dying in pain is the number one concern of West Virginians and all Americans facing the end of life; [1]
- principles of quality healthcare practice dictate that the people of the State of West Virginia have access to appropriate and effective pain relief; and
- 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 at the end of life as well as reduce the morbidity associated with untreated or undertreated pain.

Insufficient pain control may result from health care professionals' 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 inadequate treatment of pain. **Therefore, this statement has been developed to clarify the Boards' position on adequate pain control and to address misperceptions health care professionals may have, specifically as related to the use of controlled substances for patients with terminal illness, to alleviate health care professional uncertainty and to ensure better pain management.** This statement is not intended to define complete or best practice, but rather to communicate what the Boards consider to be within the boundaries of professional practice.

It is the position of the Boards that nurses, physicians, and pharmacists (hereinafter healthcare professionals) under their respective jurisdictions shall provide adequate pain control as a part of quality practice for all patients who experience pain as a result of terminal illness. Accordingly, all health care professionals who are engaged in treating terminally ill patients are obligated to become knowledgeable about effective methods of pain assessment and treatment as well as statutory requirements for prescribing, administering, and dispensing controlled substances.

This statement applies explicitly and solely to pain management at the end of life. It creates no presumption regarding appropriate or inappropriate pain management in other circumstances.

Definitions

"Adequate pain control" means pain management that reduces a patient's moderate or severe pain to a level of mild pain or no pain at all, as reported by the patient.

"Terminal illness" means the medical condition of a patient who is dying from an incurable, irreversible disease as diagnosed by a treating physician.

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

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies the potential impact of important barriers on the provision of effective pain care.

(+) *CRITERION 4:*
Encourages pain management

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Joint Board Policy Statement

(+) ***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)

Collaboration Among the Healthcare Team

Communication and collaboration among members of the healthcare team and with the patient and family are essential to achieve adequate pain control in end-of-life care. Within this interdisciplinary framework for end-of-life care, effective pain management should include at a minimum:

thorough documentation of all aspects of the patient's assessment and care;

a working diagnosis and therapeutic treatment plan including pharmacologic and non-pharmacologic interventions;

regular and documented evaluation of response to the interventions and, as appropriate, revisions to the treatment plan;

evidence of communication among care providers;

education of the patient and family; and,

a clear understanding by the patient, the family and healthcare team of the treatment goals.

Management of Pain

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

The Boards are obligated under the laws of the State of West Virginia to protect the public health and safety. The Boards recognize that inappropriate prescribing, administering, and dispensing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Health care professionals should be diligent in preventing the diversion of drugs for illegitimate purposes. While not in any way minimizing the severity of this problem, the Boards recognize that governmental policies to prevent the misuse of controlled substances should not interfere with their appropriate use for the legitimate medical purpose of providing effective relief of pain at the end of life.

Health care professionals should not fear disciplinary action from the Boards for prescribing, administering, or dispensing controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice. All such prescribing must be established with clear documentation of unrelieved pain and in compliance with applicable state or federal law.

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

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

(+) ***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.

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OTHER GOVERNMENTAL POLICY

Joint Board Policy Statement

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Physicians

The West Virginia Boards of Medicine and Osteopathy judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and frequency of prescribing. To facilitate communication between health care professionals, physicians should write on the prescription for a controlled substance for a terminally ill patient the diagnosis "terminal illness." 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 spiritual dimensions. The West Virginia Management of Intractable Pain Act sets forth the conditions under which physicians may prescribe opioids without fear of discipline. This act states "that in a case of intractable pain involving a dying patient, the physician discharges his or her professional obligation to relieve the dying patient's intractable pain and promote the dignity and autonomy of the dying patient, even though the dosage exceeds the average dosage of a pain-relieving controlled substance" (West Virginia Code §30-3A-1 *et seq*). This entire act is attached to this statement. Because, by law, West Virginia physicians have a professional and ethical obligation to control the pain of dying patients, the West Virginia Board of Medicine regards inadequate control of pain as a possible basis for professional discipline.[2] The West Virginia Board of Osteopathy acknowledges and accepts that osteopathic physicians have the professional and ethical obligation to control the pain of dying patients.

Nurses

The nurse is often the healthcare professional most involved in the on-going pain assessment, implementation of the prescribed pain management plan, evaluation of the patient's response to pain medications, and adjustment of the amount of medication administered based on patient status. To accomplish adequate pain control, the physician's prescription must provide dosage ranges and frequency parameters within which the nurse may titrate medication to achieve adequate pain control. Consistent with the scope of professional nursing practice (Title 19, Series 10), which includes prime consideration of comfort and safety for all patients, the registered professional nurse is accountable for implementing the pain management plan utilizing his or her knowledge and documented assessment of the patient's needs. The nurse has the authority to adjust the amount of medication administered within the dosage and frequency ranges stipulated by the treating physician and according to established protocols of the healthcare institution or agency. However, the nurse does not have the authority to change the medical pain management plan. When adequate pain control is not being achieved under the currently prescribed treatment plan, the nurse is responsible for reporting such findings to the treating physician and documenting this communication. The West Virginia Management of Intractable Pain Act sets forth the conditions under which nurses may administer opioids without fear of discipline.

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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 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 goal of pain treatment should include improvements in patient functioning and quality of life.

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Joint Board Policy Statement

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Pharmacists

With regard to pharmacy practice, West Virginia has no quantity restrictions on dispensing controlled substances including those in Schedule II. This fact is significant when utilizing the federal rule and state law that allow the partial filling of Schedule II prescriptions for up to 60 days for patients who are terminally ill or in a long-term care facility. In these situations it would minimize expenses and unnecessary waste of drugs if the physician would note on the prescription that the patient is terminally ill and specify partial filling may be appropriate. The pharmacist may then dispense smaller quantities of the prescription to meet the patient's needs up to the total quantity authorized. Government-approved labeling for dosage level and frequency can be useful as guidance for patient care. Health professionals may, on occasion, determine that higher levels are justified in specific cases. Federal and state rules also allow the facsimile transmittal of an original prescription for Schedule II drugs for hospice patients. As an exception to the general rule that prescriptions for Schedule II drugs must be in writing and signed by the physician, in an emergency, a pharmacist may dispense a Schedule II pain-relieving controlled substance upon an oral prescription, provided that the quantity dispensed is limited to the amount adequate to treat the patient during the emergency, and a written prescription is supplied to the pharmacy within 7 days following the oral prescription. Pharmacy rules also allow the emergency refilling of prescriptions in Schedules III, IV, and V. The West Virginia Management of Intractable Pain Act sets forth the conditions under which pharmacists may dispense opioids without fear of discipline.

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[1] West Virginia Initiative to Improve End-of-Life Care. A Report of the Values of West Virginians and Health Care Professionals' Knowledge and Attitudes. January 2000, p. 3; Steinhauser, et al. Factors considered important at the end of life by patients families, physicians, and other care providers. JAMA 2000;284:2476-2482.

[2] American Medical Association Code of Medical Ethics. Opinions 2.20, 2.21 and 2.211.

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Informs practitioners about acceptable practices under Federal and state policies.

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WEST VIRGINIA

STATUTES

Chronic Pain Clinic Licensing Act

W. Va. Code § 16-5H-2

Section 16-5H-1. Purpose and short title.

This article shall be known as the Chronic Pain Clinic Licensing Act. The purpose of this act is to establish licensing requirements for facilities that treat patients for chronic pain management in order to ensure that patients may be lawfully treated for chronic pain by physicians in facilities that comply with oversight requirements developed by the Department of Health and Human Resources.

Section 16-5H-2. Definitions.

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(f) "Prescriber" means an individual who is authorized by law to prescribe drugs or drug therapy related devices in the course of the individual's professional practice, including only a medical or osteopathic physician authorized to practice medicine or surgery; a physician assistant or osteopathic physician assistant who holds a certificate to prescribe drugs; or an advanced nurse practitioner who holds a certificate to prescribe.

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

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WEST VIRGINIA

REGULATIONS

Opiate Addiction Treatment

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

CATEGORY C:
Regulatory or policy issues

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

W. Va. CSR § 64-7-44

§ 64-7-44. Special Populations.

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44.3. Pain Patients.

44.3.a. Each opioid treatment program shall ensure that physicians practicing at the facility are knowledgeable in the management of opioid dependence in a context of chronic pain and pain management. The program may not prohibit a patient diagnosed with chronic pain from receiving medication for either maintenance or withdrawal in a program setting.

44.3.b. Each opioid treatment program shall ensure continuity of care and communication between programs or physicians regarding patients receiving treatment in both an opioid treatment program and a facility or physician's office for purposes of pain management, with the patient's written permission. If a patient refuses permission for the two entities to communicate and coordinate care, the program shall document refusal and may make clinically appropriate decisions regarding take-home medication privileges and continuation in treatment.

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for OTP staff to refer methadone-maintained patients who have chronic pain for treatment of their pain.

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STATUTES

- CONTROLLED SUBSTANCES ACT
  Controlled Substances; Chapter 961. Uniform Controlled Substances Act

- MEDICAL PRACTICE ACT
  Regulation and Licensing; Chapter 448. Medical Practices

- PHARMACY PRACTICE ACT (*No provisions found*)
  Regulation and Licensing; Chapter 450. Pharmacy Examining Board

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*No provisions found*)
  Controlled Substances Board

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Medical Examining Board

- PHARMACY BOARD REGULATIONS
  Pharmacy Examining Board

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD POLICY STATEMENT
  Medical Examining Board of the State of Wisconsin. *Position Statement on Pain Management*. Adopted: March 14, 2007.

- PHARMACY BOARD POLICY STATEMENT
  Wisconsin Pharmacy Examining Board. *Position Statement on the Treatment of Pain*. Adopted: December 7, 2005.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- RESIDENTIAL CARE FACILITIES
  Department of Health Services; Chapter DHS 83. Community-Based Residential Facilities; Subchapter VII. Resident Care and Services

- HOSPICES
  Department of Health Services; Chapter DHS 131. Hospices

- NURSING HOMES
  Department of Health Services; Chapter DHS 132. Nursing Homes; Subchapter VI. Services

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STATUTES

Controlled Substances Act

Wis. Stat. § 961.001

961.001. Declaration of intent.

The legislature finds that the abuse of controlled substances constitutes a serious problem for society. As a partial solution, these laws regulating controlled substances have been enacted with penalties. The legislature, recognizing a need for differentiation among those who would violate these laws makes this declaration of legislative intent:

(1g) Many of the controlled substances included in this chapter have useful and legitimate medical and scientific purposes and are necessary to maintain the health and general welfare of the people of this state.

. . .

Wis. Stat. § 961.01

961.01. Definitions.

As used in this chapter:

. . .

(19) "Practitioner" means:

(a) A physician, advanced practice nurse, dentist, veterinarian, podiatrist, optometrist, scientific investigator or, subject to s. *448.21 (3)* , a physician assistant, or other person licensed, registered, certified or otherwise permitted 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 in this state.

. . .

Wis. Stat. § 961.38

961.38. Prescriptions.

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

. . .

(+) *CRITERION 1:* ***Controlled substances are necessary for public health***

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

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

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STATUTES

Medical Practice Act

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

Wis. Stat. § 448.01

448.01. Definitions.

In this chapter:

(2) "Disease" means any pain, injury, deformity or physical or mental illness or departure from complete health or the proper condition of the human body or any of its parts.

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(9) "Practice of medicine and surgery" means:

(a) To examine into the fact, condition or cause of human health or disease, or to treat, operate, prescribe or advise for the same, by any means or instrumentality.

(b) To apply principles or techniques of medical sciences in the diagnosis or prevention of any of the conditions described in par. (a) and in sub. (2)

(c) To penetrate, pierce or sever the tissues of a human being.

(d) To offer, undertake, attempt or do or hold oneself out in any manner as able to do any of the acts described in this subsection.

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WISCONSIN

REGULATIONS

Pharmacy Board Regulations

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

Wis. Adm. Code Phar 8.04

Phar 8.04 Purpose of issue of prescription order.

(1) Prescription orders for controlled substances shall be issued for a legitimate medical purpose by individual practitioners acting in the usual course of professional practice. Responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who dispenses the prescription. An order purporting to be a prescription order not issued in the usual course of professional treatment or in legitimate and authorized research is not a prescription order within the meaning and intent of ss. *450.01 (21)* and *961.38, Stats*. The person knowingly dispensing pursuant to such a purported order, as well as the person issuing it, shall be subject to the penalties provided for violation of the provision of law relating to controlled substances.

(2) A prescription order issued by a practitioner to obtain controlled substances for the purpose of general dispensing or administration to patients by the practitioner is not valid.

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OTHER GOVERNMENTAL POLICY

Medical Board Policy Statement

Medical Examining Board of the State of Wisconsin
Position Statement on Pain Management

The mission of The Medical Examining Board is to promote and protect the health and welfare of the citizens of the State of Wisconsin by fostering the provision of safe and competent medical care. The Board recognizes that such care involves the provision of appropriate and effective management of pain.

The under treatment of pain continues to be a significant public health problem in the United States. Inadequate pain control may result from physicians' lack of knowledge about pain assessment and management and/or their misunderstanding of the safety and efficacy of opioid analgesics, drugs that are essential for the management of moderate to severe pain. Physicians may also fear investigation or sanction by federal, state and local agencies which may lead to inappropriate treatment of pain.

The Board encourages physicians to view effective pain assessment and management as part of quality medical care for all patients with pain, whether it is acute or chronic. It is especially important for patients who are experiencing pain at the end of life. All physicians should be knowledgeable about effective methods of pain assessment and treatment as well as the statutory requirements for prescribing controlled substances. The medical management of pain should be guided by current knowledge and acceptable medical practice, which includes the use of both pharmacologic and non-pharmacologic modalities. Pain should be assessed and treated promptly and appropriately with clear documentation.

The Board recognizes that opioid analgesics are subject to abuse by individuals who seek them for mood altering and other psychological effects rather than for legitimate medical purposes. Physicians who use these drugs in the course of treatment should be diligent and incorporate established safeguards into their practices to minimize the potential for their diversion and abuse.

The Board further recognizes that tolerance and physical dependence are normal consequences of the sustained use of opioid analgesics and are not synonymous with psychological dependence (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: impaired control over drug use, craving, compulsive use, and continued use despite harm. Persons with a history of drug abuse have the right to appropriate pain management, even if opioids must be used. Such persons may require specialized care. Tolerance may occur but it is not an inevitable consequence of chronic opioid therapy. Physical dependence is a normal and predictable state of adaptation to a drug, and by itself, does not equate with addiction.

Physicians should not fear disciplinary action from the Board for administering controlled substances, including opioid analgesics, for a legitimate medical purpose in the usual course of professional practice. The Board will initially consider the use of controlled substances for the treatment of pain to be for a legitimate medical purpose based on accepted scientific knowledge of the treatment of pain, patient clinical presentation and sound clinical judgment. Proper written documentation, the patient's medical condition and clinical response to treatment provide strong foundations for verifying optimal patient care, if review of the patient record is necessitated at some future time.

The Medical Examining Board of the State of Wisconsin is adopting and disseminating this position statement to support and encourage safe, competent, and high quality medical care for persons with pain. By so doing, the Board clearly communicates to physicians that it:

1) encourages safe and effective pain management practices
2) recognizes that pain management, which may involve the use of opioid analgesics, is a critical part of medical practice
3) will not sanction physicians solely for providing opioid analgesics provided the physician administers the medication in a safe and effective manner in compliance with state and federal law.

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

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Identifies the potential impact of important barriers on the provision of effective pain care.

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

CATEGORY B:
Issues related to patients

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

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

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OTHER GOVERNMENTAL POLICY

Pharmacy Board Policy Statement

The Wisconsin Pharmacy Examining Board Examining Board encourages patient pain control by optimizing the Patient - Pharmacy – Medical care management triad.

BACKGROUND

The Wisconsin Pharmacy Examining Board has been approached by June L. Dahl, PhD, Director of the Wisconsin Pain Initiative and Matt Bromley, Communications and Policy Director for the American Alliance of Cancer Pain Initiatives, to expand its position statement of *Pain & Policy Studies Group on Wisconsin Pharmacists and Schedule II Medications* as published in the Board's Wisconsin Regulatory Digest article *Volume 13, No. 2 October, 2001* http://drl.wi.gov/boards/phm/digest/20011000.pdf

A survey of Wisconsin pharmacists' knowledge and attitudes about dispensing opioid analgesics for chronic cancer and non-cancer pain was published in the March/April 2001 issue of the Journal of the American Pharmaceutical Association. http://www.medsch.wisc.edu/painpolicy/publicat/01japhak/01japhak.htm The study found that not all pharmacists knew what constituted legitimate dispensing practices for controlled substances under federal or state policy in emergencies or for patients with terminal illness. Also many pharmacists were unaware of the distinction between addiction, physical dependence, and tolerance. The Board encourages pharmacists to re-educate themselves with current literature on pain management. Appropriate pain control can improve or at least maintain a patient's quality of life. It is the pharmacist's duty to provide medications along with proper counseling to ensure pain control. The PEB considers refusal to fill a Schedule II prescription based on speculation or ignorance unacceptable.

Specifically, this expanded Position Board Statement clearly articulates to pharmacists that the Board;
1) encourages pain management;
2) recognizes that pain management, and the use of opioids for pain management, are a part of medical / pharmacy practice; and,
3) recognizes confusion exists around the terms addiction, physical dependence and tolerance.

While developing this statement, the Board surveyed multiple other state's Position Statements for completeness and consistency. The Board acknowledges utilization of the position statements of The Iowa and Texas Boards of Pharmacy.

As with all professional and practice questions, should they require clarification, the Board encourages Pharmacist contact. Written correspondence is preferred either via the Department of Regulation and Licensing URLs or by US Postal Service.

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WISCONSIN

OTHER GOVERNMENTAL POLICY

Pharmacy Board Policy Statement

(CONTINUED)

The Wisconsin Pharmacy Examining Board
Position Statement on the Treatment of Pain

The mission of The Wisconsin Pharmacy Examining Board is to promote, preserve and protect the public health, safety and welfare by fostering provision of quality pharmaceutical care to all Wisconsinites. The Board recognizes quality care dictates the citizens of the State of Wisconsin have access to appropriate and effective pain relief. The appropriate application of current knowledge, practice standards and treatment modalities can serve to improve the quality of life for those patients who suffer from pain. This in turn will reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages pharmacists to view effective pain management as a part of quality care for ALL patients with pain, acute or chronic. 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 dispensing controlled substances.

Inadequate pain control may result from physicians' and pharmacists' lack of knowledge about pain management or an inadequate understanding of addiction. The Board recognizes controlled substances, including opioid analgesics, may be essential in the treatment of pain, whether acute due to trauma or surgery or chronic due to cancer or non-cancer origins.

The Board recognizes controlled substances are subject to abuse by individuals who seek them for mood altering and other psychological effects rather than their legitimate medical uses. When dispensing controlled substances, the pharmacist should be diligent in preventing them from being diverted from legitimate to illegitimate use.

Tolerance and physical dependence are normal consequences of sustained use of these drugs and are NOT synonymous with psychological dependency (addiction). Psychological dependency is characterized by the compulsion to take a drug despite its harmful and destructive effect on the individual. Tolerance represents a secondary medical condition requiring pharmacy and medical assistance to resolve and continue patient pain control. Psychological dependency requires social (regulatory), plus pharmacy and medical assistance to maximize patient care while controlling the harmful and destructive patient behavior.

As with all medication therapies, the Board affirms the pharmacist's duty to provide medications along with proper counseling to ensure pain control. Failure to:

a) counsel, monitor and assist the patient in receiving optimal care of any condition or,
b) knowingly facilitating care, continuing care or providing medications known to be inappropriate to the patient is unprofessional practice with the possibility of discipline under various Board rules plus Wisconsin and Federal Regulations. IE, controlled substances shall only be dispensed for legitimate medical purposes.

By participating as a member of the health care team, Pharmacists should NOT fear disciplinary action from the Board for dispensing controlled substances, including opioid analgesics, for a legitimate medical purpose in the usual course of professional practice. The Board will initially consider dispensing controlled substances for pain to be for a legitimate medical purpose based on accepted scientific knowledge of the treatment of pain, patient clinical presentation and sound clinical judgment. All such dispensing must be based on clear documentation in the patient's pharmacy records of the patient's medical condition plus pertinent discussions with the prescribing practitioner. Using proper written documentation, the patient's medical condition and clinical response to treatment provide a strong foundation for verifying optimal patient care, if review of the patient record is necessitated at some future time.

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

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

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

(+) *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: Identifies the potential impact of important barriers on the provision of effective pain care.

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

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Madison, Wisconsin

WISCONSIN

REGULATIONS

Residential Care Facilities

Wis. Adm. Code DHS 83.35

DHS 83.35 Assessment, individual service plan and evaluations

(1) ASSESSMENT. (a) *Scope*. The CBRF shall assess each resident's needs, abilities, and physical and mental condition before admitting the person to the CBRF, when there is a change in needs, abilities or condition, and at least annually. The assessment shall include all areas listed under par. (c). This requirement includes individuals receiving respite care in the CBRF. For emergency admissions the CBRF shall conduct the assessment within 5 days after admission.

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(c) *Areas of assessment*. The assessment, at a minimum, shall include all of the following areas applicable to the resident:

1. Physical health, including identification of chronic, short-term and recurring illnesses, oral health, physical disabilities, mobility status and the need for any restorative or rehabilitative care.

2. Medications the resident takes and the resident's ability to control and self-administer medications.

3. Presence and intensity of pain.

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

CATEGORY C:
Regulatory or policy issues

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

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Madison, Wisconsin

WISCONSIN

REGULATIONS

Hospices

Wis. Adm. Code DHS 131.19

DHS 131.19 Patient rights

(1) GENERAL INFORMATION. A hospice shall provide each patient and patient's representative, if any, with a written statement of the rights of patients before services are provided, and shall fully inform each patient and patient's representative, if any, of all of the following:

(a) Those patient rights and all hospice rules and regulations governing patient responsibilities, which shall be evidenced by written acknowledgement provided by the patient, if possible, or the patient's representative, if any, prior to receipt of services.

(b) The right to prepare an advance directive.

(c) The right to be informed of any significant change in the patient's needs or status.

(d) The hospice's criteria for discharging the individual from the program.

(2) RIGHTS OF PATIENTS. In addition to rights to the information under sub. (1), each patient shall have all of the following rights:

(a) To receive effective pain management and symptom control from the hospice for conditions related to the terminal illness.

. . .

Wis. Adm. Code DHS 131.20

DHS 131.20 Assessment

(1) INITIAL ASSESSMENT. (a) If the hospice determines that it has the general capability to meet the prospective patient's described needs, then before services are provided, a registered nurse shall perform an initial assessment of the person's condition and needs and shall describe in writing the person's current status, including physical condition, present pain status, emotional status, pertinent psychosocial and spiritual concerns and coping ability of the prospective patient and family support system, and shall determine the appropriateness or inappropriateness of admission to the hospice based on the assessment.

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Wis. Adm. Code DHS 131.21

DHS 131.21 Plan of care

. . .

(3) PLAN OF CARE. (a) *Integrated plan of care.* The hospice core team shall develop an integrated plan of care for the new patient within 5 days after the admission. The core team shall use the initial plan of care as a basis for team decision-making and shall update intervention strategies as a result of core team assessment and planning collaboration.

(b) *Content of the plan of care.* The hospice shall develop an individualized written plan of care for each patient. The plan of care shall reflect patient and family goals and interventions based on the problems identified in the initial, comprehensive, and updated comprehensive assessments. The plan of care shall include all services necessary for the palliation and management of the terminal illness and related conditions, including all of the following:

1. Interventions to manage pain and symptoms.

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

CATEGORY C:
Regulatory or policy issues

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

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

CATEGORY C:
Regulatory or policy issues

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

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

CATEGORY C:
Regulatory or policy issues

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

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WISCONSIN

REGULATIONS

Nursing Homes

Wis. Adm. Code DHS 132.60

DHS 132.60 Resident care.

(1) INDIVIDUAL CARE. Unless it is in conflict with the plan of care, each resident shall receive care based upon individual needs.

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(c) Basic nursing care. 1. Nursing care initiated in the hospital shall be continued immediately upon admission to the nursing home unless ordered otherwise by the admitting physician.

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5. The nursing home shall provide appropriate assessment and treatment of pain for each resident suspected of or experiencing pain based on accepted standards of practice that includes all of the following:

a. An initial assessment of pain intensity that shall include: the resident's self-report of pain, unless the resident is unable to communicate; quality and characteristics of the pain, including the onset, duration and location of pain; what measures increase or decrease the pain; the resident's pain relief goal; and the effect of the pain on the resident's daily life and functioning.

b. Regular and periodic reassessment of the pain after the initial assessment, including quarterly reviews, whenever the resident's medical condition changes, and at any time pain is suspected, including prompt reassessment when a change in pain is self-reported, suspected or observed.

c. The delivery and evaluation of pain treatment interventions to assist the resident to be as free of pain as possible.

d. Consideration and implementation, as appropriate, of non-pharmacological interventions to control pain.

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

CATEGORY C:
Regulatory or policy issues

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

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WYOMING

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 35. Public Health and Safety; Chapter 7. Food and Drugs; Article 10. Controlled Substances

- MEDICAL PRACTICE ACT
  Title 33. Professions and Occupations; Chapter 26. Physicians and Surgeons

- PHARMACY PRACTICE ACT (*No provisions found*)
  Title 33. Professions and Occupations; Chapter 24. Pharmacy

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Agency 024. Department of Administration and Information; Sub-Agency 060. Commissioner of Drugs and Substances Control; Chapters 001-008. Rules and Regulations

- MEDICAL BOARD REGULATIONS
  Agency 024. Department of Administration and Information; Sub-Agency 052. Board of Medicine; Chapters 001-003. Rules and Regulations

- PHARMACY BOARD REGULATIONS
  Agency 024. Department of Administration and Information; Sub-Agency 059. Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- JOINT BOARD POLICY STATEMENT
  Wyoming Boards of Medicine, Nursing, Dental Examiners, Pharmacy, Podiatry, Optometry, and Veterinary Medicine. *Uniform Policy for the Use of Controlled Substances in the Treatment of Pain*. Adopted: February 13, 2009.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- CANCER CONTROL PLAN AND PROGRAM
  Title 35. Public Health and Safety; Chapter 25. Public Programs; Article 2. Wyoming Cancer Control Act

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Madison, Wisconsin

WYOMING

STATUTES

Controlled Substances Act

Wyo. Stat. § 35-7-1002

§ 35-7-1002 Definitions

(a) As used in this act:

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(xx) "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 administer a controlled substance in the course of professional practice or research in this state;

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Wyo. Stat. § 35-7-1060

§ 35-7-1060 Controlled substances prescription tracking program

(a) In addition to other duties and responsibilities as provided by this act, the board shall maintain a computerized program to track prescriptions for controlled substances for the purposes of assisting patients, practitioners and pharmacists to avoid inappropriate use of controlled substances and of assisting with the identification of illegal activity related to the dispensing of controlled substances. The tracking program and any data created thereby shall be administered by the board, and the board may charge reasonable fees to help defray the costs of operating the program. Any fee shall be included with and in addition to other registration fees established by the board as authorized in W.S. 35-7-1023.

(b) All prescriptions for schedule II, III and IV controlled substances dispensed by any retail pharmacy licensed by the board shall be filed with the board electronically or by other means required by the board. The board may require the filing of other prescriptions and may specify the manner in which the prescriptions are filed.

(c) The tracking program shall not be used to infringe on the legal use of a controlled substance. Information obtained through the controlled substance prescription tracking program is confidential and may not be released and is not admissible in any judicial or administrative proceeding, except as follows:

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

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Recognizes that a prescription monitoring program should not interfere with the legitimate medical use of controlled substances.

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Madison, Wisconsin

WYOMING

STATUTES

Medical Practice Act

Wyo. Stat. § 33-26-102

§ 33-26-102 Definitions

(a) As used in this chapter:

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(xi) "Practicing medicine" means any person who in any manner:

(A) Advertises, holds out, or represents to the public that he is authorized to practice medicine in this state; or

(B) Offers or undertakes to prevent, diagnose, correct or treat, in any manner, by any means, method or device, any human disease, illness, pain, wound, fracture, infirmity, defect or abnormal physical or mental condition, injury, deformity or ailment, including the management of pregnancy and parturition;

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Wyo. Stat. § 33-26-402

§ 33-26-402 Grounds for suspension; revocation; restriction; imposition of conditions; refusal to renew or other disciplinary action

(a) The board may refuse to renew, and may revoke, suspend or restrict a license or take other disciplinary action, including the imposition of conditions or restrictions upon a license on one (1) or more of the following grounds:

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(xi) Except as permitted by law, repeatedly prescribing or administering, selling or supplying any drug legally classified as a narcotic, addicting or scheduled drug to a known abuser;

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

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

CATEGORY A:
Restrictions based on patient characteristics

COMMENT: Wyoming law does not seem to create an exemption for patients with pain and a history of addiction.

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WYOMING

REGULATIONS

Controlled Substances Regulations

WCWR 024-060-001

Section 1.01. Definitions.

As used herein, the following terms shall have the meanings specified:

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(f) The term "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 continuous 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"*

REGULATIONS

Medical Board Regulations

WCWR 024-052-001

Chapter 1 LICENSE ELIGIBILITY, APPLICATION AND INTERVIEWS

Section 3. Definitions.

The definitions contained in W.S. 33-26-102 and those contained in the APA are incorporated herein by this reference. In addition, the following definitions apply to this chapter:

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(k) "Practicing medicine" means any person who in any manner:

(i) Advertises, holds out or represents to the public that he is authorized to practice medicine in this state; or

(ii) Offers or undertakes to prevent, diagnose, correct or treat, in any manner, by any means, method or device any human disease, illness, pain, wound, fracture, infirmity, defect or abnormal physical or mental condition, injury, deformity or ailment, including the management of pregnancy and parturition;

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

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Madison, Wisconsin

WYOMING

REGULATIONS

Pharmacy Board Regulations

WCWR 024-059-002

CHAPTER 002. GENERAL PRACTICE OF PHARMACY REGULATIONS

Section 4. Definitions.

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(II) "Practitioner" means an individual currently licensed, registered or otherwise authorized by the jurisdiction in which he/she practices to prescribe drugs in the course of professional practice.

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

Pain & Policy Studies Group
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Madison, Wisconsin

WYOMING

OTHER GOVERNMENTAL POLICY

Joint Board Policy Statement

Wyoming Health Care Licensing Boards'
Uniform Policy for the Use of Controlled Substances
in the Treatment of Pain

Section I: Preamble

The Wyoming state boards of Medicine, Nursing, Dental Examiners, Pharmacy, Podiatry, Optometry, and Veterinary Medicine1 ("the Boards"), recognize that principles of quality health care practice dictate that the people of the State of Wyoming 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 provision of health care. The Boards encourage all prescribers to view pain management as a part of quality 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 prescribers 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 policy has been developed to clarify the Boards' position on pain control, particularly as related to the use of controlled substances, to alleviate prescriber uncertainty, and to encourage better pain management.

Inappropriate pain treatment may result from prescribers' 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 prescriber's responsibility. As such, the Boards 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 Boards recognize that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The Boards will refer to current clinical practice guidelines appropriate to the prescriber's profession and practice, as well as expert review, in approaching cases involving management of pain. The 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 prescriber. 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. Prescribers should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

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[1] This Policy is specifically applicable to the treatment of pain in human patients. Because of the very real possibility of diversion of pain medications properly prescribed for use in animals to improper use by humans, however, the Wyoming Board of Veterinary Medicine has adopted this Policy to provide guidance to veterinarians in their practice.

(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 4:*
Encourages pain management

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

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies the potential impact of important barriers on the provision of effective pain care.

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

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Madison, Wisconsin

WYOMING

OTHER GOVERNMENTAL POLICY

Joint Board Policy Statement

(CONTINUED)

The Boards are obligated under the laws of the State of Wyoming to protect the public health and safety. The Boards recognize that the use of opioid analgesics for other than legitimate 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 use. Accordingly, the Boards expect that prescribers will incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

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

Prescribers should not fear disciplinary action from the Boards for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate purpose and in the course of professional practice. The Boards will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate 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 prescriber-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 Boards will judge the validity of the prescriber'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, but not limited to, physical, psychological, social and work-related factors. This reliance upon the record to support the use of pain medications makes it critical for prescribers to thoroughly document the patient's care and treatment.

(+) *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 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.

Allegations of inappropriate pain management will be evaluated on an individual basis. The Boards will not take disciplinary action against prescribers for deviating from this policy when contemporaneous medical records document reasonable cause for deviation. A prescriber'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 Boards have adopted the following criteria when evaluating prescribers' treatment of pain, including the use of controlled substances:

1. Evaluation of the Patient—A patient 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 prescriber should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

(CONTINUED ON NEXT PAGE)

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WYOMING

OTHER GOVERNMENTAL POLICY

Joint Board Policy Statement

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

(CONTINUED)

3. Informed Consent and Agreement for Treatment—The prescriber 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 decision-making capacity. The patient should receive prescriptions from one prescriber and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the prescriber should strongly consider the use of a written agreement between prescriber and patient outlining patient responsibilities including, where appropriate:

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 (e.g., violation of agreement).

4. Periodic Review—The prescriber 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 prescriber'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 prescriber should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

5. Consultation—The prescriber 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.

6. Medical Records—The prescriber should keep accurate and complete records to include

a. the patient's history and physical examination,
b. diagnostic, therapeutic and laboratory results,
c. evaluations and consultations,
d. treatment objectives,
e. discussion of risks and benefits,
f. informed consent,
g. treatments,
h. medications (including date, type, dosage and quantity prescribed),
i. instructions and agreements, and
j. 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 prescriber must be licensed in Wyoming and comply with applicable federal and state laws and regulations. Prescribers are referred to the *Physicians Manual of the U.S. Drug Enforcement Administration* (and any relevant documents issued by the Boards) for specific rules governing controlled substances as well as applicable state regulations.

(CONTINUED ON NEXT PAGE)

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

CATEGORY B:
Issues related to patients

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

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

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

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University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

WYOMING

OTHER GOVERNMENTAL POLICY

Joint Board Policy Statement

(CONTINUED)

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.

Medical Records—Patient-specific records maintained by a prescriber in the course of his or her practice.

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.

Prescriber—A person properly licensed or approved by one or more of the Boards to prescribe controlled substances.

Prescriber/Patient Relationship—An established, documented professional treatment relationship established between a patient and a prescriber.

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.

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University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

WYOMING

STATUTES

Cancer Control Plan and Program

Wyo. Stat. § 35-25-203

§ 35-25-203. Cancer control plan and program.

(a) The department shall develop a comprehensive cancer control plan.

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(iv) Palliative care including pain management and other steps to improve the quality of life of probably terminal cancer patients;

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Wyo. Stat. § 35-25-206

§ 35-25-206. Pain management.

(a) The department may establish an acute and chronic pain management advisory committee consisting of the following members:

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (pain management advisory committee) 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 mechanism (cancer control plan and program) to ensure that pain management is an essential part of patient care.

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SECTION X: RESULTS – PROFILES OF STATE PAIN POLICIES GOVERNING NURSING PRACTICE

Alabama
Alaska
Arizona
Arkansas
California
Colorado
Connecticut
Delaware
District of Columbia
Florida
Georgia
Hawaii
Idaho
Illinois
Indiana
Iowa
Kansas
Kentucky
Louisiana
Maine
Maryland
Massachusetts
Michigan
Minnesota
Mississippi
Missouri
Montana
Nebraska
Nevada
New Hampshire
New Jersey
New Mexico
New York
North Carolina
North Dakota
Ohio
Oklahoma
Oregon
Pennsylvania
Rhode Island
South Carolina
South Dakota
Tennessee
Texas
Utah
Vermont
Virginia
Washington
West Virginia
Wisconsin
Wyoming

SECTION X: RESULTS – PROFILES OF STATE PAIN POLICIES GOVERNING NURSING PRACTICE

On May 18, 2007, the National Council of State Boards of Nursing (NCSBN) adopted a brief policy statement, entitled "National Council of State Boards of Nursing Statement on the Regulatory Implications of Pain Management" (National Council of State Boards of Nursing, 2007), to help facilitate the development of policies and guidelines regarding the regulatory issues raised in the statement. A year later, the NCSBN finalized a document, entitled "Report of Disciplinary Resources Committee" (the Report) (National Council of State Boards of Nursing, 2008), which is considered their official guideline and policy statement regarding expectations about pain management issues (personal communication with Maryann Alexander, Chief Officer, Nursing Regulation, NCSBN, June 2009). The Report was made available to all nursing boards to serve as a template for the creation of state nursing regulatory policy, much like what the Federation of State Medical Boards has accomplished for medical regulators with its "Model Guideline for the Use of Controlled Substances for the Treatment of Pain" (Federation of State Medical Boards of the United States Inc., 1998), "Model Policy for the Use of Controlled Substances for the Treatment of Pain" (Federation of State Medical Boards of the United States Inc., 2004), and "Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain" (Federation of State Medical Boards of the United States Inc., 2013). With the creation of this policy resource, the NCSBN became an authoritative source to guide policy development for nursing practice regarding pain relief. As a result, nurse practitioners have been formally recognized as an essential component of patients' pain relief, treating pain is considered an accepted part of patient care, and the expectation is establishd that policies from individual state nursing boards should address pain issues.

Of course, the availability of NCSBN guidelines provides the requisite authoritative source to justify the broad recognition of prescribing for pain treatment as an acceptable part of the practice of Advanced Practice Nurses (APNs), which established the conceptual foundation for this evaluation of nursing policy. Existing statutes and regulations governing nursing practice from all states and the District of Columbia have been fully reviewed and analyzed for their relevance to the current evaluation methodology. Examining the entire population of nursing statutes, regulations, and administrative guidelines/policy statements now allows a thorough illustration of the nuances of nurse prescribing requirements regarding pain management issues, including the prescribing of opioid analgesics. This was especially important because not all states permit APNs to prescribe, or else place some restrictions on, the Schedule II controlled medications which are indicated for the treatment of moderate to severe pain. In addition, the evaluation also analyzed the content of nursing board guidelines or policy states, or for joint, multi-board, policy statements for which nurisng regulators were involved; although such policies do not have the force of law, they are a traditional mechanism to provide guidance to licensees about current expectations and standards of regulatory boards.

Since 2000, the PPSG has periodically published a systematic criteria-based evaluation of state statutes, regulations, and regulatory guidelines or policy statements addressing healthcare practice relevant to pain management, including the use of Schedule II controlled substances. Healthcare regulatory policies related to medical practice had always been part of this evaluation because the national regulatory organization for this health discipline had provided declaratory statements that explicitly recognized pain management and the prescribing of controlled substances as part of legitimate professional practice. This policy research now represents a comprehensive evaluation of policies governing physician, pharmacist, and nursing practice as it relates to the treatment of pain, it can help achieve a better balance between drug control and appropriate use to treat pain for a greater variety of healthcare professionals – when such practices relate to the clinical use of controlled medications. The broader methodology also better acknowledges the contributions of individual members of the healthcare team in achieving improved pain care.

Section X: Results – Profiles of State Pain Policies Governing Nursing Practice

A recent report from the National Governors Association (NGA) focused on the function of nurses in meeting current demands for primary care services (National Governors Association, 2012). There seems to be consensus that APNs generally have substantial professional autonomy (Newhouse et al., 2012). However, the report's author recognized that "states tend to place greater restrictions on [Nurse Practitioners'] NPs' prescriptive authority than on NPs' other practice authority and the restrictions may differ depending on the type of drugs and devices prescribed" (National Governors Association, 2012)(p. 9). Although the NGA provided a broad review of NPs' scope of practice, the evaluation used here sought to specifically characterize the scope of practice governing pain management and APN prescribing privaleges for Schedule II controlled medications.

Like our evaluations of other types of policies, this effort was limited to the "black letter" content of state policies and, therefore, does not account for practices or non-policy standards that also can guide APN pain care activities (see Section IV). Four categories, derived from application of the evaluation criteria presented in Section VIII, represent current levels of APNs' prescriptive authority for Schedule II controlled substances in each state:

(1) Independent prescribing authority (20 states)
Alaska, Arizona, Colorado, District of Columbia, Hawaii, Idaho, Iowa, Maine, Maryland, Montana, Nevada, New Hampshire, New Mexico, North Dakota, Oregon, Rhode Island, Vermont, Virginia, Washington, and Wyoming

(2) Requires formal physician involvement (15 states)
California, Connecticut,Delaware, Indiana, Kansas, Massachusetts, Minnesota, Mississippi, Nebraska, New Jersey, New York, Tennessee, Texas, Utah, and Wisconsin

(3) Requires formal physician involvement with additional prescribing limitations (8 states)
Illinois, Kentucky, Louisiana, Michigan, North Carolina, Ohio, Pennsylvania, and South Dakota

(4) No prescribing authority (8 states)
Alabama, Arkansas, Florida, Georgia, Missouri, Oklahoma, South Carolina, and West Virginia

Results from this research can be used to inform the discussion about the need for healthcare legal and regulatory policy that effectively promotes appropriate patient care, as well as the medical use of controlled substances to treat pain, and about the need to communicate the messages from such policies to better guide practice. Ideas for policy changes stemming from this current evaluation have the potential to enhance appropriate availability and access to pain management for people with cancer or other chronic conditions who experience pain throughout the course of their disease or illness.

This section contains a comprehensive criteria-based evaluation of every states' laws and regulatory policies governing nurses' prescriptive authority and pain management practices. It is important to note, however, that results from this analsyis were not part of the methodology to grade states based on policy content (reported in the *Progress Report Card 2013*). Modifying the grading method so substantially, by incorporating a new population of policies representing nursing practice, would have disrupted the trend lines and prohibited a clear interpretion of grade changes within a state. As a result, grades from the *Progress Report Card 2013* (like those from all prior report cards) relate only to medical, osteopathic, and pharamcy practice.

ALABAMA

STATUTES

- Controlled Substances Act
  Title 20. Food, Drugs, and Cosmetics; Chapter 2. Controlled Substances;
  Article 11. Prescribing of Certain Schedules of Controlled Substances by Certified Registered Nurse Practitioners and Certified Nurse Midwives

REGULATIONS

- Nursing Board Regulations
  Alabama Board of Nursing; Chapter 610-X

OTHER GOVERNMENTAL POLICIES

No policies found

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ALABAMA

STATUTES

Controlled Substances Act

Code of Ala. § 20-2-250

§ 20-2-250. Definitions.

As used in this article, the following words shall have the following meanings:

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(4) Certified registered nurse practitioner or CRNP. An advanced practice nurse who is subject to a collaborative practice agreement with a collaborating physician pursuant to Title 34, Chapter 21, Article 5, and who has advanced knowledge and skills in the delivery of nursing services within a health care system that provides for consultation, collaborative management, or referral as indicated by the health status of the patient.

(5) Collaborating physician. A doctor of medicine or doctor of osteopathy licensed to practice medicine in Alabama who agrees in writing to practice in collaboration with one or more certified registered nurse practitioners or certified nurse midwives in accordance with Title 34, Chapter 21, Article 5, and the rules and regulations adopted by the Board of Medical Examiners and the Board of Nursing.

(6) Prescribe or prescribing. The act of issuing a prescription for a controlled substance.

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Code of Ala. § 20-2-253

§ 20-2-253. Certified nurse/midwife may prescribe, administer, authorize for administration, or dispense controlled substances.

(a) Upon receipt of a Qualified Alabama Controlled Substances Registration Certificate (QACSC) and a valid registration number issued by the United States Drug Enforcement Administration, a certified registered nurse practitioner (CRNP) or certified nurse midwife (CNM) may prescribe, administer, authorize for administration, or dispense only those controlled substances listed in Schedules III, IV, and V of Article 2, Chapter 2, of this title in accordance with rules adopted by the Board of Medical Examiners and any protocols, formularies, and medical regimens established by the board for regulation of a QACSC.

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Code of Ala. § 20-2-260

§ 20-2-260. Limited Purpose Schedule II Permit (LPSP) for assistants to physicians and certified nurse practitioners/midwives.

(a) The Board of Medical Examiners may at any future date it chooses create a Limited Purpose Schedule II Permit (LPSP), and assess fees associated with the permit, that, along with any other necessary registration, may permit assistants to physicians, certified registered nurse practitioners, or certified nurse midwives to lawfully prescribe, administer, authorize for administration, or dispense only those controlled substances listed in Schedule II substances of Article 2 of Chapter 2 of this title in accordance, as specified and limited by the permit, with rules adopted by the board and any protocols, formularies, and medical regimens established by the board for regulation of a LPSP. Any protocols, formularies, and medical regimens shall not be considered administrative rules under the Alabama Administrative Procedure Act.

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

***CATEGORY D*:**
Undue prescription limitations

COMMENT: Requires formal collaborative practice and protocols with a physician.

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

COMMENT: Establishes a mechanism (LPSP) for eventual prescriptive authority for Schedule II controlled substances.

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

***CATEGORY A*:**
Arbitrary standards for legitimate prescribing

COMMENT: No prescriptive authority for controlled substances is specified.

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ALABAMA

REGULATIONS

Nursing Board Regulations

Ala. Admin. Code r. 610-X-2-.05

610-X-2-.05 Advanced Practice Nursing - Collaborative Practice (CRNP, CNM).

(8) Legend Drug: Any drug, medicine, chemical or poison bearing on the label the words, "Caution, federal law prohibits dispensing without prescription" or similar words indicating that such drug, medicine, chemical, or poison may be sold or dispensed only upon the prescription of a licensed practitioner, except that the term legend drug will not include any drug, substance, or compound which is listed in Schedules I through V of the Alabama Uniform Controlled Substances Act.

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Ala. Admin. Code r. 610-X-2-.05

610-X-5-.11 Prescriptions And Medication Orders By Certified Registered Nurse Practitioners.

(1) Certified registered nurse practitioners engaged in collaborative practice with physicians may be granted prescriptive authority upon submission of evidence of completion of an academic course in pharmacology or evidence of integration of pharmacology theory and clinical application in the certified registered nurse practitioner curriculum.

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

***CATEGORY D*:**
Undue prescription limitations

COMMENT: Requires formal collaborative practice and protocols with a physician.

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

***CATEGORY A*:**
Arbitrary standards for legitimate prescribing

COMMENT: No prescriptive authority for controlled substances is specified.

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ALASKA

STATUTES

- Nurse Practice Act
  Title 8. Business and Professions; Chapter 68. Nursing

REGULATIONS

- Nursing Board Regulations
  Title 12. Professional Regulations; Part 1. Boards and Commissions Subject to Centralized Licensing; Chapter 44. Board of Nursing

OTHER GOVERNMENTAL POLICIES

Alaska Board of Nursing. *Advisory Opinion – Regulatory Implications: The Advanced Practice Registered Nurse in a Pain Management Primary Care Role*. Adopted: January 20, 2009.

ALASKA

STATUTES

Nurse Practice Act

Alaska Stat. § 08.68.410

Sec. 08.68.850. Definitions

In this chapter,

(1) "advanced nurse practitioner" means a registered nurse authorized to practice in the state who, because of specialized education and experience, is certified to perform acts of medical diagnosis and the prescription and dispensing of medical, therapeutic, or corrective measures under regulations adopted by the board;

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

COMMENT*:* Prescriptive authority for Schedule II controlled substances is specified in regulations.

REGULATIONS

Nursing Board Regulations

12 Alaska Admin. Code 44.445

12 AAC 44.445. Controlled substance prescriptive and dispensing authority

(a) In addition to legend drug prescriptive and dispensing authority under *12 AAC 44.440*, the board will, in its discretion, authorize an advanced nurse practitioner or "ANP" to prescribe and dispense schedule 2-5 controlled substances in accordance with applicable state and federal laws if an applicant

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

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ALASKA

OTHER GOVERNMENTAL POLICY

Nursing Board Advisory Opinion

Alaska Board of Nursing
Advisory Opinion
Adopted January 20, 2009

Regulatory Implications: the Advanced Practice Registered Nurse in a Pain Management Primary Care Role

The scope of practice of the APRN is unique in the nursing profession. The APRN practices as an independent primary care provider in a majority of states, with nearly all states conferring controlled substances prescribing authority upon APRNs, in conjunction with the DEA. In the role of primary care provider or licensed independent provider (LIP), the APRN is held to a high standard of education and practice in patient care.

In providing treatment for pain, the APRN is charged with the responsibility to diagnose the causes of pain, intervene with a variety of therapies, and evaluate the effectiveness of pain treatment being prescribed. The APRN is responsible for appropriate, accurate and complete documentation of assessment, treatment plan, informed consent and ongoing review of efficacy.

Introduction to Specific Regulatory Aspects
The Federation of State Medical Boards stated in *Model Policy for the Use of Controlled Substances for the Treatment of Pain,* that the following circumstances contribute to the prevalence of under-treated pain:

Lack of knowledge of medical standards, current research, and clinical guidelines for appropriate pain treatment;

The perception that prescribing [or administering] adequate amounts of controlled substances will result in unnecessary scrutiny by regulatory authorities;

Misunderstanding of addiction and dependence; and

Lack of understanding of regulatory policies and processes. (FSMB, 2004)

Several boards of nursing have addressed expectations regarding pain management. The Arizona and Alaska Boards of Nursing have published Advisory Opinions regarding the use of controlled substances for the treatment of chronic pain by APRNs, providing guidance regarding assessing and treating pain with controlled substances, including clear expectations regarding how the APRN is expected to comply with laws and regulations. (AZ BON, 2004; AK BON, 2006). The California Board of Registered Nursing adopted a standard of care for California RNs of assessing pain and evaluating response to pain interventions using a standard pain management scale, using patient self-report and documentation of pain assessment each time that vital signs are recorded for each patient. (CA BORN, 1999) The Oregon Board of Nursing developed a pain management position statement in 2004, addressing the distinct roles of both the RN and APRN in assessment of pain and administration of relief measures, as well as the APRN role in prescribing opioid analgesics and other interventions (see Appendices).

APRNs need to be knowledgeable about the regulation of advanced practice nursing and the significant variations in APRN scope of practice from state to state.

Professional Standards and Practice Expectations
Promoting pain relief, while at the same time preventing abuse of pain medications, becomes a balancing act. Preventing drug abuse is an important societal goal, but there is consensus by law enforcement agencies, health care practitioners, and patient advocates alike, that it should not hinder patients' ability to receive the care they need and deserve. (Joint Statement of the DEA et al., 2001)

The APRN, like all primary care providers, must work collaboratively with the patient for the best outcome. It is important for the patient to be fully informed concerning side effects as well as realistic expectations for pain relief. There are settings and situations where standards of pain management are unique, i.e. end-of-life care or disaster management.

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

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies the potential impact of important barriers on the provision of effective pain care.

(+) *CRITERION 4:*
Encourages 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.

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OTHER GOVERNMENTAL POLICY

Nursing Board Advisory Opinion

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

(CONTINUED)

The APRN treating acute or chronic pain is responsible for understanding the physiology of pain; treatment options, including surgical, physical therapy, pharmacologic and nonpharmacologic interventions; the pharmacokinetics, adverse effects and interactions of the medications selected for treating pain; and the appropriate documentation of treatment choices. While the use of opioid analgesics to treat pain is a legitimate medical use, there is additional responsibility for understanding the complex pharmacokinetics of these medications. Optimal pain management encompasses the correct medication, available in the correct dose, via the correct route of administration, at the correct time, with minimal and manageable side effects.

The field of pain management is rapidly evolving, with improved interventions and greater knowledge of the pharmacokinetics and molecular biology of medications. The APRN must be aware of pain treatment options, which may include aspirin, morphine, antidepressants or anticonvulsants and others, reversible interventions (such as local anesthetics, steroids, nerve blocks, trigger point injections), and irreversible interventions (such as surgery, nerve destruction). Many alternative interventions may be used in conjunction with other therapies, including acupuncture, nerve stimulation, physical therapy, and psychology. Implantable nerve stimulators and infusion pumps may be used for chronic, intractable pain. New technologies are continually being developed, which requires the APRN to be knowledgeable about the appropriate combinations of pharmacologic and non-pharmacologic treatments.

Acute Pain
Acute pain, resulting from injury or surgical intervention, typically lasts less than three months. The principles of pain relief include the importance of titrating medication to the desired effect of pain relief, taking into account the time needed for the medication to take effect, as well as factors affecting length of effect. Co-morbidities can prolong or shorten pain relief onset and/or duration.

Chronic Pain
Chronic pain is generally defined as lasting longer than three months. Medications, opioid and nonopioid, are frequently used to treat chronic pain. Ineffective pain management may be the outcome when concerns regarding potential addiction impact decisions on the use of opioids.

Opioids are not always the first line of treatment for chronic pain. Some chronic pain syndromes do not respond to opioid medications. APRNs treating chronic pain require knowledge of a variety of categories of medications that can relieve pain. For example, neuropathic pain may respond better to antidepressants, anticonvulsants, or alpha-2 adrenergic agonists. Non-pharmacologic interventions may be helpful. Notwithstanding, the best efforts on the part of clinicians; not all patients will experience optimal relief from chronic pain, despite the appropriate use of analgesic interventions.

Some Guidelines for Documentation of Assessment and Care
There is no objective measurement of pain (MGH Handbook of Pain Management).

However, appropriate assessment of history and physical findings, coupled with an understanding of pain pathophysiology guides rational, appropriate treatment.

Documentation of assessment, treatment outcomes and ongoing follow-up is important for patient safety and communication with other health care providers.

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OTHER GOVERNMENTAL POLICY

Nursing Board Advisory Opinion

(CONTINUED)

Consistent with accepted standards (FSMB), accurate, legible and complete records include:

Pain history that includes:

- The onset and character of the pain, such as description, quality, intensity, duration, and impact of the pain on function;
- Treatment history;
- Relevant psychological history (including screening for anxiety, depression, somatoform disorder, coping style, and personality traits);
- Vocational and medical legal issues;
- General medical history;
- Patient's perception about the cause of the pain; and
- Patient's goals and expectations.

Physical examination that includes an appropriate examination for the symptoms. This may be a more thorough examination in the case of acute pain or initial evaluation for chronic pain. A directed examination in ongoing chronic pain management would include:

- Musculoskeletal;
- Neurological;
- Skin; and
- Psychological.

Psychological evaluation should be included in initial evaluation, with regular reassessment, addressing:

- Screening for depression, anxiety, substance abuse;
- Prior psychological evaluation and treatment review; and
- History of alcohol or other drug addiction, including treatment by addiction specialists.

Functional status – self-reported and/or objective evaluation.

Laboratory testing and imaging as appropriate.

Diagnosis, including contributing medical and psychiatric co-morbidities.

Treatment plan, including:

- Specific, measurable, realistic goals;
- Rationale for interventions;
- Documented discussion with the patient of risks, benefits, and alternatives;
- Medications selected, with dose and quantity prescribed;
- Patient education;
- Patient agreements or contracts;
- Plan for consultation, when needed; and
- Plan for re-evaluation.

Outcomes, including:

- Pain reduction; Physical function changes;
- Psychosocial function changes;
- Work status;
- Medication use; and
- Ability to self-manage pain with non-pharmacologic interventions.

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(+) *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 include improvements in patient functioning and quality of life.

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OTHER GOVERNMENTAL POLICY

Nursing Board Advisory Opinion

(CONTINUED)

In the management of chronic, nonmalignant or malignant pain,9 a written agreement between the APRN and the patient may be helpful when opioid analgesics are prescribed.

Typical elements of a medication management agreement are:

- Regular office visits at a prescribed interval;
- Informed consent, outlining the potential risks, benefits and alternatives of the medications being prescribed;
- Limit prescription to one prescriber only;
- Limit refills to only a specified number and frequency, with no early refills;
- Use one pharmacy only, giving the name of that pharmacy;
- Random drug screens, urine or serum, when requested;
- Pill counts, when requested;
- Permission to speak with family members about the effects of the medications being prescribed;
- Psychological counseling as deemed necessary by the APRN; and
- Potential of discontinuation of controlled substance prescriptions.

A written agreement may not be necessary in the management of acute pain, anticipated to last less than three months. This is appropriately determined on a case-by-case basis, taking into account the individual's physical and psychological history.

Periodic review of the effectiveness of the treatment plan is critical. The APRN should reassess the appropriateness of the current plan, altering it as necessary. The treatment of chronic pain is complex and often consultations and referrals are needed for additional evaluation and treatment.

Specialized Knowledge and Skills of the APRN

The treatment of malignant and non-malignant chronic pain, as well as acute pain, is complex, requiring increased awareness and specialized education by the treating APRN. Education must include how to solicit pain level from patient, the phenomena of addiction, pseudo-addiction, tolerance, and dependence, the variety of treatment options, which include non-pharmacologic therapies, and the safe use of controlled substances and other medications.

Specialized education in pain management is the responsibility of the individual practitioner to pursue, appropriate to their practice. Graduate education and preceptors/mentors can work together to assure that graduate students, novice, and experienced APRNs are exposed to current standards and expectations regarding pain management, the latest research and clinical guidelines, the whole range of therapeutic interventions available to manage pain, and the distinctions between drug dependence and drug addiction.

Education is needed to equip APRNs to understand regulatory policies and processes and their implications for day-to-day practice. In addition to expertise in the pain management modalities, APRNs must develop competence in the expected standards of pain management. The state of Oregon has implemented statute requiring a one-time pain management continuing education course for all healthcare providers in the state.

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

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ALASKA

OTHER GOVERNMENTAL POLICY

Nursing Board Advisory Opinion

(CONTINUED)

The Role of the Board of Nursing

Many health care practitioners, including APRNs, fear being investigated for overadministering or over-prescribing controlled substances for pain. This fear can pose a barrier to effective pain management. Regulatory boards must consider the balance of promoting appropriate pain management against deterring inappropriate use of pain medications. Under-treatment of pain decreases patient functional status, safety, and quality of life.

The APRN may feel pulled in different directions by expectations of the employer, licensing board, legal requirements of the Drug Enforcement Agency (DEA), expectations of other health care team members, and the optimal care for the patient.

APRNs who effectively manage pain contribute to improved quality of life for individuals, while those who fail to provide adequate pain interventions may be subject to disciplinary action for failing to meet professional standards.

Boards need to be aware that patients, family members, and other members of the lay community may not understand the need for pain management, which adds to the complexity of effective treatment. Patients may fear addiction or being thought of as an addict. They may fear that pain, especially the need for opioid medications, means that their condition is worse. Patients may think that reporting pain will distract from the treatment of the underlying disease, so they may try to be a "good patient" who does not complain. They may be reluctant to take medications, expecting serious side effects.

Sometimes those with chronic pain think that using the medication now will limit its effectiveness in the future, "when really needed." As a result, patients may still be in pain. Caregivers are afraid of causing harm and may be conflicted between wanting to ease the patient's pain but also being worried about addiction and side effects.

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

There have been situations when a prosecutor becomes alarmed because of high and increasing doses of controlled substances for a group of patients, not understanding that this is a pattern that might be expected in a hospice or palliative care setting and in some patients with persistent pain. Boards of nursing can be effective educators related to the implementation of pain management by APRNs, while upholding standards of care and quality.

If a board has identified that an APRN has failed to meet the expectations of pain management standards, the board must determine the appropriate course of action.

Boards of nursing are charged with public protection and recognize that this protection includes access to effective patient care and assurance of the competency and accountability of nurses, including APRNs.

Boards of nursing need to have knowledge about the complexity of pain management, understanding that:

- Under-treatment of pain is a critical public health problem;
- Standards of practice for pain management have been articulated;
- An array of therapies and tools are available for use in pain management;
- APRNs and other health care practitioners may fear scrutiny by regulators; and
- APRNs and other health care practitioners may fear disciplinary action for administering too much or too little pain medication.

Boards of nursing have an opportunity to collaborate with graduate program educators and preceptors to support pain management practice through education about the:

- Standards of pain management; and
- APRN authority to prescribe, including:
    - Prescribing controlled substances.

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OTHER GOVERNMENTAL POLICY

Nursing Board Advisory Opinion

(CONTINUED)

Guarding against misuse of prescription forms:

- Balance between promoting pain relief and preventing drug abuse; and
- Regulatory process and disciplinary implications when an APRN fails to meet expectations for managing patients pain effectively.

Boards of nursing expect APRNs to:

- Maintain their knowledge of the complexities and challenges of pain management;
- Implement pain management treatment standards, including pain assessment, intervention, documentation, and evaluation;
- Appropriately consult with specialists;
- Comply with state and federal Controlled Substances Law and Regulations;
- Advocate for patient needs; and
- Collaborate and cooperate with other health team members in addressing patient pain.

Conclusion

As independent primary care providers, APRNs are responsible for providing compassionate, evidence-based healthcare. When statutes and regulations permit, APRNs may accept the additional responsibility for prescribing controlled substances for pain management. To assure competence, APRNs are accountable for acquiring and maintaining the knowledge and clinical expertise to provide this type of healthcare.

Boards of nursing are charged to protect the public through the regulation of safe nursing practice. It is vital that boards of nursing understand the complexities of pain management and controlled substance prescribing. The ideal result is implementation of nursing regulation that function as a support, not a barrier, to the implementation of pain management by APRNs, while upholding standards of care and quality. When these conditions coexist, the public optimally benefits from the unique skills and knowledge of APRNs.

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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.

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ARIZONA

STATUTES

- Nurse Practice Act
  Title 32. Professions and Occupations; Chapter 15. Nursing

REGULATIONS

- Nursing Board Regulations
  Title 4. Professions and Occupations; Chapter 19. Board of Nursing

OTHER GOVERNMENTAL POLICIES

Arizona State Board of Nursing. *Advisory Opinion – The Use of Controlled Substances for the Treatment of Chronic Pain*. Adopted: July 19, 2012.

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ARIZONA

STATUTES

Nurse Practice Act

A.R.S. § 32-1601

§ 32-1601. Definitions

In this chapter, unless the context otherwise requires:

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19. "Registered nurse practitioner" means a registered nurse who:

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(d) Has an expanded scope of practice within a specialty area that includes:

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(v) Diagnosing, performing diagnostic and therapeutic procedures, and prescribing, administering and dispensing therapeutic measures, including legend drugs, medical devices and controlled substances within the scope of registered nurse practitioner practice on meeting the requirements established by the board.

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

COMMENT: Prescriptive authority for Schedule II controlled substances is specified in regulations.

REGULATIONS

Nursing Board Regulations

A.A.C. § R4-19-512

R4-19-512. Prescribing Drugs and Devices

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C. An RNP with a DEA registration number may prescribe:

1. A Class II controlled substance as defined in the federal Uniform Controlled Substances Act, *21 U.S.C. § 801* et seq., or Arizona's Uniform Controlled Substances Act, A.R.S. Title 36, Chapter 27, but shall not prescribe refills of the prescription;

2. A Class III or IV controlled substance, as defined in the federal Uniform Controlled Substances Act or Arizona's Uniform Controlled Substances Act, and may prescribe a maximum of five refills in six months; and

3. A Class V controlled substance, as defined in the federal Uniform Controlled Substances Act or Arizona's Uniform Controlled Substances Act, and may prescribe refills for a maximum of one year.

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

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Madison, Wisconsin

ARIZONA

OTHER GOVERNMENTAL POLICY

Board of Nursing Advisory Opinion

ADVISORY OPINION
THE USE OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF CHRONIC PAIN

STATEMENT OF SCOPE
A Registered Nurse Practitioner (RNP) may prescribe controlled substances for the treatment of chronic pain within the nurse practitioner's scope of practice for their specialty area of NP certification.

RATIONALE
These guidelines are intended to assist the RNP in the responsible use of controlled substances in the treatment of patients with chronic pain. RNPs who prescribe controlled substances for treatment of patients with chronic pain should use sound clinical judgment, utilizing the following outlined guidelines of responsible professional practice:

I. GUIDELINES FOR THE USE OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF CHRONIC PAIN

The Arizona State Board of Nursing ("Board") urges RNPs 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 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 medication and nonmedication treatment modalities, often in combination. RNPs shall have sufficient knowledge or seek consultation to make such judgments for their patients. Medications, in particular controlled substances, are considered the cornerstone of treatment for acute and chronic pain. RNPs are referred to available clinical practice guidelines for the management of these types of pain.

For the purposes of these guidelines, chronic pain is defined as:

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. When efforts to remove the cause of pain or to treat it with appropriate referrals and/or other modalities have been unsuccessful, the prescribing of controlled substances for patients with chronic non-cancer pain may be beneficial.

II. GUIDELINES FOR PATIENT CARE WHEN PRESCRIBING CONTROLLED SUBSTANCES FOR CHRONIC PAIN

A. Evaluation of the Patient
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. The evaluation should include:

1. A medical history and physical examination should be conducted and documented in the medical record. The evaluation should include 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 evaluation should also document the presence of one or more recognized indications for the use of a controlled substance. The patient's health history should be corroborated by reviewing the patient's health care records and/or speaking with the patient's former health care providers.
2. Psycho-social assessment, which may include but is not limited to:
   a. The patient's understanding of the 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.

[CONTINUED ON NEXT PAGE]

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

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

(+) *CRITERION 4:*
Encourages pain management

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ARIZONA

OTHER GOVERNMENTAL POLICY

Board of Nursing Advisory Opinion

[CONTINUED]

3. Periodic urine drug screen testing to detect the presence of the prescribed medications and presence of illegal or illicit substances.
4. Diagnostic evaluations such as blood test, radiologic exams, neurophysiologic exams, and psychological evaluations as indicated;
5. Exclusion criteria for controlled substance management, including a history of chemical dependency, major psychiatric disorder, unstable social situation, or a planned pregnancy; and
6. Assessment and reassessment of the patient's, and/or the family's ability/willingness to maintain control and safety of controlled drugs in the home situation prior to issuing them.

B. Treatment Plan
A treatment plan should be developed for the management of chronic pain with measurable outcomes to evaluate therapeutic success including:
1. Improvement in physical function and/or psychosocial function, e.g., ability to work, sleep, need of health care resources, activities of daily living, improvement in pain perception, and quality of social life;
2. Exploration of other multimodal interventions and/or rehabilitation programs as indicted.
3. Ongoing assessment, and if necessary modification and/or discontinuation of the use of controlled substances is expected.

C. Informed Consent
The RNP shall discuss the risks and benefits of the use of controlled substances, as well as alternatives, with the patient, persons designated by the patient, or with the patient's designated surrogate or guardian. The patient shall be counseled on the importance of regular visits, taking medications as prescribed, and the impact of recreational drug use, and avoiding the use of multiple pharmacies and providers for prescriptions. The RNP and the patient shall enter into a written pain treatment agreement that specifically states the patient's responsibilities for the treatment plan and the consequences of breaching the agreement.

D. Consultation
The RNP may refer the patient as necessary for additional evaluation to achieve treatment objectives. 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.

E. Documentation
The RNP shall document the following, as applicable:
1. The health history and physical examination;
2. Diagnostic, therapeutic, and laboratory results;
3. Diagnosis
4. Evaluations and consultations;
5. Treatment objectives; including functional goals
6. Discussion of risks and benefits;
7. Treatments;
8. Medications (including date, type, dosage, and quantity prescribed);
9. Instructions and agreements;
10. Recurrent assessment and re-assessment of the pain and pain treatments for efficacy of pain control with rationale for any dosage changes, patient function, and patient compliance; and
11. Whether or not the patient is a candidate for controlled substance medications, based on the provider's safety and control assessment, including review of Controlled Substance Prescription Monitoring Program.

The RNP shall maintain current and accessible patient records readily available for review.

[CONTINUED ON NEXT PAGE]

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

CATEGORY C:
Conflicting or inconsistent policies or provisions

COMMENT: This provision may create confusion, and even be in conflict, when considered in conjunction with the Consultation section below, which seems to recognize the potential need for pain management services for people with a history of substance abuse.

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

CATEGORY B:
Issues related to patients

COMMENT:
Acknowledges that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate 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 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: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

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OTHER GOVERNMENTAL POLICY

Board of Nursing Advisory Opinion

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

[CONTINUED]

F. Counting and Destroying Medication
The RNP may desire to see and count a patient's medication to determine if the patient is taking the medication as prescribed. The patient should display and count the medication in front of the RNP. Under no circumstance should the RNP touch a patient's controlled substances. If the medication must be destroyed, it should be destroyed in accordance with federal guidelines. The RNP should document this fact in the patient record.

G. Post-Dated Prescriptions
Post-dated prescriptions are illegal in the State of Arizona. Therefore, RNPs may not issue post-dated prescriptions. Multiple prescriptions can be provided to the patient complying with the DEA regulations.

H. Referral of Patients with Active Substance Abuse Problems
Patients discovered to have an active substance abuse problem should be referred to either a detoxification and rehabilitation program or to an appropriate maintenance program for substance abusers.

III. COMPLIANCE WITH LAWS AND REGULATIONS

A. Prescribing Controlled Substances
To prescribe controlled substances, RNPs must comply with all applicable laws, including the following:
1. Possess a valid current RN license and certification as an RNP with prescribing and dispensing authority in the State of Arizona;
2. Possess a valid and current controlled substances Drug Enforcement Administration registration for the schedules being prescribed; and
3. Comply with A.A.C. R4-19-511 and R4-19-512.

B. Dispensing Controlled Substances
To dispense controlled substances, RNPs must comply with all applicable laws, including the following:
1. Possess a valid current RN license and certification as an RNP with prescribing and dispensing authority in the State of Arizona;
2. Possess a valid and current controlled substances Drug Enforcement Administration registration for the schedules being dispensed;
3. Comply with A.A.C. R4-19-511, R4-19-512 and R4-19-513; and
4. Comply with 22 CFR 1306.07(a) if controlled substances are dispensed for detoxification.

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Board of Nursing Advisory Opinion

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ARKANSAS

STATUTES

- Nurse Practice Act
  Title 17. Professions, Occupations, and Businesses; Subtitle 3. Medical Professions; Chapter 87. Nurses

REGULATIONS

- Nursing Board Regulations *(No provisions found)*
  067 Board of Nursing

OTHER GOVERNMENTAL POLICIES

No policies found

ARKANSAS

STATUTES

Nurse Practice Act

A.C.A. § 17-87-310

17-87-310. Prescriptive authority.

(a) The Arkansas State Board of Nursing may grant a certificate of prescriptive authority to an advanced practice registered nurse who:

(1) Submits proof of successful completion of a board-approved advanced pharmacology course that shall include preceptorial experience in the prescription of drugs, medicines, and therapeutic devices; and

(2) Has a collaborative practice agreement with a physician who is licensed under the Arkansas Medical Practices Act, §§ 17-95-201 -- 17-95-207, 17-95-301 -- 17-95-305, and 17-95-401 -- 17-95-411, and who has a practice comparable in scope, specialty, or expertise to that of the advanced practice registered nurse on file with the board.

(b) (1) An advanced practice registered nurse with a certificate of prescriptive authority may receive and prescribe drugs, medicines, or therapeutic devices appropriate to the advanced practice nurse's area of practice in accordance with rules established by the board.

(2) An advanced practice registered nurse's prescriptive authority shall only extend to drugs listed in Schedules III -- V.

(c) A collaborative practice agreement shall include, but not be limited to, provisions addressing:

(1) The availability of the collaborating physician for consultation or referral, or both;

(2) Methods of management of the collaborative practice, which shall include protocols for prescriptive authority;

(3) Coverage of the health care needs of a patient in the emergency absence of the advanced practice registered nurse or physician; and

(4) Quality assurance.

(d) If a collaborative practice results in complaints of violations of the Arkansas Medical Practices Act, §§ 17-95-201 -- 17-95-207, 17-95-301 -- 17-95-305, and 17-95-401 -- 17-95-411, the Arkansas State Medical Board may review the role of the physician in the collaborative practice to determine if the physician is unable to manage his or her responsibilities under the agreement without an adverse affect on the quality of care of the patient.

(e) If a collaborative practice results in complaints of violations of this chapter, the Arkansas State Board of Nursing may review the role of the advanced practice registered nurse in the collaborative practice to determine if the nurse is unable to manage his or her responsibilities under the agreement without an adverse affect on the quality of care of the patient.

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

***CATEGORY A*:**
Arbitrary standards for legitimate prescribing

COMMENT: No prescriptive authority for controlled substances is specified.

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

***CATEGORY D*:**
Undue prescription limitations

COMMENT: Requires use of a collaborative agreement and protocols with a physician.

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Madison, Wisconsin

CALIFORNIA

STATUTES

- Nurse Practice Act
  Business & Professions Code; Division 2. Healing Arts; Chapter 6. Nursing

REGULATIONS

- Nursing Board Regulations
  Title 16. Professional and Vocational Regulations; Division 14. Board of Registered Nursing

OTHER GOVERNMENTAL POLICIES

California Board of Registered Nursing. *Pain Assessment: The Fifth Vital Sign*. Adopted: February, 2000.

CALIFORNIA

STATUTES

Nurse Practice Act

Cal Bus & Prof Code § 2836.1

§ 2836.1. Furnishing or ordering of drugs or devices by nurse practitioners

Neither this chapter nor any other provision of law shall be construed to prohibit a nurse practitioner from furnishing or ordering drugs or devices when all of the following apply:

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(c)

(1) The standardized procedure or protocol covering the furnishing of drugs or devices shall specify which nurse practitioners may furnish or order drugs or devices, which drugs or devices may be furnished or ordered, under what circumstances, the extent of physician and surgeon supervision, the method of periodic review of the nurse practitioner's competence, including peer review, and review of the provisions of the standardized procedure.

(2) In addition to the requirements in paragraph (1), for Schedule II controlled substance protocols, the provision for furnishing Schedule II controlled substances shall address the diagnosis of the illness, injury, or condition for which the Schedule II controlled substance is to be furnished.

(d) The furnishing or ordering of drugs or devices by a nurse practitioner occurs under physician and surgeon supervision. Physician and surgeon supervision shall not be construed to require the physical presence of the physician, but does include (1) collaboration on the development of the standardized procedure, (2) approval of the standardized procedure, and (3) availability by telephonic contact at the time of patient examination by the nurse practitioner.

(e) For purposes of this section, no physician and surgeon shall supervise more than four nurse practitioners at one time.

(f)

(1) Drugs or devices furnished or ordered by a nurse practitioner may include Schedule II through Schedule V controlled substances under the California Uniform Controlled Substances Act (Division 10 (commencing with *Section 11000) of the Health and Safety Code*) and shall be further limited to those drugs agreed upon by the nurse practitioner and physician and surgeon and specified in the standardized procedure.

(2) When Schedule II or III controlled substances, as defined in Sections 11055 and 11056, respectively, of the Health and Safety Code, are furnished or ordered by a nurse practitioner, the controlled substances shall be furnished or ordered in accordance with a patient-specific protocol approved by the treating or supervising physician. A copy of the section of the nurse practitioner's standardized procedure relating to controlled substances shall be provided, upon request, to any licensed pharmacist who dispenses drugs or devices, when there is uncertainty about the nurse practitioner furnishing the order.

(g)

(1) The board has certified in accordance with Section 2836.3 that the nurse practitioner has satisfactorily completed a course in pharmacology covering the drugs or devices to be furnished or ordered under this section.

(2) a course in pharmacology covering the drugs or devices to be furnished or ordered under this section.

(3) Nurse practitioners who are certified by the board and hold an active furnishing number, who are authorized through standardized procedures or protocols to furnish Schedule II controlled substances, and who are registered with the United States Drug Enforcement Administration, shall complete, as part of their continuing education requirements, a course including Schedule II controlled substances based on the standards developed by the board. The board shall establish the requirements for satisfactory completion of this subdivision.

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

(+) *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 with information/education about issues affecting pain management.

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

CATEGORY D:
Undue prescription limitations

COMMENT: Requires formal collaborative practice and procedures with a physician.

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CALIFORNIA

REGULATIONS

Nursing Board Regulations

16 CCR 1485

§ 1485. Scope of Practice

Nothing in this article shall be construed to limit the current scope of practice of the registered nurse authorized pursuant to the Business and Professions Code, Division 2, Chapter 6. The nurse practitioner shall function within the scope of practice as specified in the Nursing Practice Act and as it applies to all registered nurses.

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

COMMENT: Prescriptive authority for Schedule II controlled substances is specified in statute.

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

***CATEGORY D*:**
Undue prescription limitations

COMMENT: Requires formal collaborative practice and procedures with a physician (based on statute).

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CALIFORNIA

OTHER GOVERNMENTAL POLICY

Nursing Board Policy Statement

PAIN ASSESSMENT: THE FIFTH VITAL SIGN

Assembly Bill 791 (Thomson) was signed into law by Governor Gray Davis on September 15, 1999, and is effective January 1, 2000. Section 1254.7 was added to the Health and Safety Code (HSC) as part of this bill. HSC 1254.7 reads:

(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 insure 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 2:*
Pain management is part of healthcare practice

This legislative mandate is consistent with state and federal concerns regarding appropriate pain management for all persons. The Veterans Administration has adopted similar policies, referring to pain as the fifth vital sign.

In 1994, the BRN adopted a pain management policy for RN practice and pain management curriculum guidelines for nursing programs. Both of these documents include a standard of care for California RNs of *assessing pain and evaluating response to pain management interventions using a standard pain management scale based on patient self-report*. This new law places a similar requirement on licensed health care facilities. Nursing programs need to integrate pain as the fifth vital sign into their curriculum and health facilities need to educate staff regarding pain management.

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

It is now required that all health care staff record pain assessment each time that vital signs are recorded for each patient. If the institution is using the zero to ten pain assessment scale, a recording of *pain 2/10,* fulfills the requirements of this law. The Board reminds RNs that pain assessment is based on patient self-report and that patient's can be asleep and still experience significant pain; appropriate charting would be to write "asleep" for the pain rating. Registered nurses will continue to be required to monitor all five vital signs and take appropriate action based on deviations from normal. In other words, a competent registered nurse intervenes when the patient's pain is not being managed according to the agreed upon comfort level.

RNs should remember that *prn* means in the nurse's judgment. In regards to pain medications that are ordered *prn,* registered nurses can choose to give the medication routinely, around-the-clock. In many acute pain situations, such as post-operative or post-trauma, medications ordered *q4h prn* (every four hours as needed), for example, should be given (or at least offered) q4h (every four hours) routinely for the first 24-48 hours to keep ahead of the patient's pain. Research shows that when patient's acute pain is managed around the clock and the pain level is kept from becoming severe, the total amount of opioid needed is reduced.

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COLORADO

STATUTES

- Nurse Practice Act

Title 12. Professions and Occupations; Health Care; Article 38. Nurses

REGULATIONS

- Nursing Board Regulations

Department of Regulatory Agencies; Board of Nursing

OTHER GOVERNMENTAL POLICIES

No policies found

COLORADO

STATUTES

Nurse Practice Act

C.R.S. 12-38-103

12-38-103. Definitions

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(10) (a) "Practice of professional nursing" means the performance of both independent nursing functions and delegated medical functions in accordance with accepted practice standards. Such functions include the initiation and performance of nursing care through health promotion, supportive or restorative care, disease prevention, diagnosis and treatment of human disease, ailment, pain, injury, deformity, and physical or mental condition using specialized knowledge, judgment, and skill involving the application of biological, physical, social, and behavioral science principles required for licensure as a professional nurse pursuant to *section 12-38-111*.

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C.R.S. 12-38-111.6

12-38-111.6. Prescriptive authority - advanced practice nurses - rules

(1) The board may authorize an advanced practice nurse who is listed on the advanced practice registry, has a license in good standing without disciplinary sanctions issued pursuant to *section 12-38-111*, and has fulfilled requirements established by the board pursuant to this section to prescribe controlled substances or prescription drugs as defined in part 1 of article 42.5 of this title.

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

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

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Madison, Wisconsin

COLORADO

REGULATIONS

Nursing Board Regulations

3 CCR 716-1

3 CCR 716-1. NURSING

CHAPTER XV
Rules and regulations regarding prescriptive authority for advanced practice nurses

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1. Definitions

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1.10 Full Prescriptive Authority: The authority granted to the RXN to prescribe medications upon completion of the required Mentorship and development of an Articulated Plan in accordance with the Role/Specialty and Population Focus of the RXN. Prescribing with Full Prescriptive Authority will be in accordance with the RXN's Articulated Plan.

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

COMMENT: Prescribing authority for Schedule II controlled substances is specified in statute.

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CONNECTICUT

STATUTES

- Nurse Practice Act
  Title 20. Professional and Occupational Licensing, Certification, Title Protection and Registration; Examining Boards; Chapter 378. Nursing

REGULATIONS

- Nursing Board Regulations *(No provisions found)*
  Title 20. Professional Licenses; Department of Public Health and Addiction Services; Registered Nursing Education

OTHER GOVERNMENTAL POLICIES

Connecticut Board of Examiners for Nursing. *Statement of the Connecticut Board of Examiners for Nursing on the Use of Controlled Substances for the Treatment of Pain*. Adopted: December 20, 2006.

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CONNECTICUT

STATUTES

Nurse Practice Act

Conn. Gen. Stat. § 20-87a

Sec. 20-87a. Definitions. Scope of practice.

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(b) Advanced nursing practice is defined as the performance of advanced level nursing practice activities that, by virtue of postbasic specialized education and experience, are appropriate to and may be performed by an advanced practice registered nurse. The advanced practice registered nurse performs acts of diagnosis and treatment of alterations in health status, as described in subsection (a) of this section, and shall collaborate with a physician licensed to practice medicine in this state. In all settings, the advanced practice registered nurse may, in collaboration with a physician licensed to practice medicine in this state, prescribe, dispense and administer medical therapeutics and corrective measures and may request, sign for, receive and dispense drugs in the form of professional samples in accordance with *sections 20-14c to 20-14e*, inclusive, except that an advanced practice registered nurse licensed pursuant to *section 20-94a* and maintaining current certification from the American Association of Nurse Anesthetists who is prescribing and administrating medical therapeutics during surgery may only do so if the physician who is medically directing the prescriptive activity is physically present in the institution, clinic or other setting where the surgery is being performed. For purposes of this subsection, "collaboration" means a mutually agreed upon relationship between an advanced practice registered nurse and a physician who is educated, trained or has relevant experience that is related to the work of such advanced practice registered nurse. The collaboration shall address a reasonable and appropriate level of consultation and referral, coverage for the patient in the absence of the advanced practice registered nurse, a method to review patient outcomes and a method of disclosure of the relationship to the patient. Relative to the exercise of prescriptive authority, the collaboration between an advanced practice registered nurse and a physician shall be in writing and shall address the level of schedule II and III controlled substances that the advanced practice registered nurse may prescribe and provide a method to review patient outcomes, including, but not limited to, the review of medical therapeutics, corrective measures, laboratory tests and other diagnostic procedures that the advanced practice registered nurse may prescribe, dispense and administer. An advanced practice registered nurse licensed under the provisions of this chapter may make the determination and pronouncement of death of a patient, provided the advanced practice registered nurse attests to such pronouncement on the certificate of death and signs the certificate of death no later than twenty-four hours after the pronouncement.

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

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

***CATEGORY D*:**
Undue prescription limitations

COMMENT: Requires formal collaborative practice with a physician.

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Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

CONNECTICUT

OTHER GOVERNMENTAL POLICY

Nursing Board Guideline

STATEMENT OF THE CONNECTICUT BOARD OF EXAMINERS FOR NURSING
ON THE USE OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN

Section I: Preamble

The Connecticut Board of Examiners for Nursing (Board) recognizes that principles of quality nursing 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 assessment and treatment of pain is integral to the practice of nursing. Therefore, the Board encourages nurses to view pain management as a part of quality nursing 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 nurses and health care professionals should become knowledgeable about assessing patients' pain and effective methods of pain treatment. In addition, advanced practice registered nurses (APRNs) should know all state and federal statutory and regulatory requirements for prescribing controlled substances. Accordingly this Statement has been developed to encourage nurses 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 APRNs 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 nursing 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.

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.

(CONTINUED ON NEXT PAGE)

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

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

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

(+) *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 4:*
Encourages pain management

(+) *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 include improvements in patient functioning and quality of life.

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Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

CONNECTICUT

OTHER GOVERNMENTAL POLICY

Nursing Board Guideline

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

(CONTINUED)

However, APRNs may face serious questions as to the legitimate medical purpose of a prescription where no provider-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. This statement is directed toward registered nurses. Although licensed practical nurses participate in the provision of pain management, they may only do so under the direction of a registered nurse.

Section II: Nursing Principles of Pain Management

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

- A nursing assessment includes a comprehensive description of pain, objective data, and the need for physical, psychosocial/spiritual support, and identification of patients who may require specialized assessment, care and treatment.
- Nurses and other clinicians pursue the most effective modes of treatment to their maximal benefit.
- Nurses provide pain management even when the person is unresponsive.
- Nurses may utilize sedation as an acceptable means for controlling pain and discomfort.
- Nurses are responsible for maintaining the knowledge and skills necessary to coordinate optimal pain management, including but not limited to:
    - Ensuring that persons or their legal representative actively participate in the treatment plan and understand the options available for pain relief and potential side effects.
    - Educating persons and their families in a culturally competent manner regarding pain management.
    - Educating staff members about pain assessment, treatment and the common barriers to adequate pain management.
    - Using a standardized scale to periodically assess and document a person's pain in accordance with institutional or agency policies and procedures.
    - Developing and implementing a plan of care that prevents and alleviates pain as much as possible.
    - Administering medications and treatments as prescribed using knowledge to maintain both safety and pain relief.
    - Adjusting medication levels within the dosage and frequency ranges stipulated by the prescriber and according to the institution's/agency's established protocols.
    - Initiating non-pharmacological nursing interventions as indicated. Serving as an advocate to assure effective pain management.
    - Communicating side effects or any reports of unrelieved pain to the prescriber and to appropriate team members.
    - Documenting pain assessment, intervention, evaluation and changes to the plan of care in a clear and concise manner.

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OTHER GOVERNMENTAL POLICY

Nursing Board Guideline

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

(CONTINUED)

1. **Assessment**
   A complete health history and physical examination must be conducted and documented in the health record.

2. **Treatment Plan**
   The plan should state objectives to be used to determine treatment, such as pain relief and improved physical and psychosocial function. The drug therapy plan should be adjusted to meet the individual needs of the patient and needs must be addressed and reassessed on a continuing basis. Other treatments modalities may be necessary based on the etiology of the person's pain.

3. **Informed Consent**
   The APRN should discuss risks and benefits of the use of controlled substances with patient and/or significant others depending on the health status of the patient.

4. **Agreement for treatment of High Risk Patients**
   If a patient is determined to be at high risk for medication abuse or with a history of substance abuse, the APRN should consider the use of a written agreement 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).

5. **Periodic Review**
   The course of treatment and/or new information on the etiology of pain must be evaluated at reasonable intervals. APRNs involved with the management of pain should evaluate progress toward meeting goals in light of improvement in patients' pain intensity and improved physical or psychosocial function. If treatment goals are not being achieved despite medication adjustment, the health care provider should reevaluate and alter the treatment plan.

6. **Consultation**
   The APRN should be willing to refer the patient for additional evaluation and treatment as needed in order to achieve treatment goals.

7. **Medical records**
   The APRN should keep accurate and complete records to include:
   - Medical history and physical examination, including;
     - Nature and intensity of the pain, including treatment for any underlying or conditions coexisting; and
     - Presence of one or more recognized medical indications for the use of a controlled substance;
   - Diagnostic, therapeutic and laboratory results;
   - Evaluations and consultations;
   - Treatment goals;
   - Discussion of risk and benefits, including treatment contract, if one has been established;
   - Treatments;
   - Medications including date, type, dosage, and quantity prescribed.;
   - Instructions and agreements; and
   - Periodic reviews.

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OTHER GOVERNMENTAL POLICY

Nursing Board Guideline

(CONTINUED)

Section III. Definitions

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

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.

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

- 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.
- 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.

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.

Adopted by the Connecticut Board of Examiners for Nursing on December 20, 2006.

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

DELAWARE

STATUTES

- Nurse Practice Act
  Title 24. Professions and Occupations; Chapter 19. Nursing

REGULATIONS

- Nursing Board Regulations
  Agency 24. Regulated Professions and Occupations; Sub-Agency. Department of State; Division of Professional Regulation; Chapter 1900. Board of Nursing; Rules and Regulations

OTHER GOVERNMENTAL POLICIES

No policies found

DELAWARE

STATUTES

Nurse Practice Act

24 Del. C. § 1902

§ 1902. Definitions

(a) "Administration of medications" means a process whereby a single dose of a prescribed drug or biological is given to a patient by an authorized licensed person by 1 of several routes, oral, inhalation, topical, or parenteral. The person verifies the properly prescribed drug order, removes the individual dose from a previously dispensed, properly labeled container (including a unit dose container), assesses the patient's status to assure that the drug is given as prescribed to the patient for whom it is prescribed and that there are no known contraindications to the use of the drug or the dosage that has been prescribed, gives the individual dose to the proper patient, records the time and dose given and assesses the patient following the administration of medication for possible untoward side effects.

(b) (1) "Advanced practice nurse" means an individual whose education and certification meet criteria established by the Board of Nursing who is currently licensed as a registered nurse and has a master's degree or a postbasic program certificate in a clinical nursing specialty with national certification. When no national certification at the advanced level exists, a master's degree in a clinical nursing specialty will qualify an individual for advanced practice nurse licensure. "Advanced practice nurse" shall include, but not be limited to, nurse practitioners, certified registered nurse anesthetists, certified nurse midwives or clinical nurse specialists. Advanced practice nursing is the application of nursing principles, including those described in subsection (n) of this section, at an advanced level and includes:

a. For those advanced practice nurses who do not perform independent acts of diagnosis or prescription, the authority as granted within the scope of practice rules and regulations promulgated by the Board of Nursing; and

b. For those advanced practice nurses performing independent acts of diagnosis and/or prescription with the collaboration of a licensed physician, dentist, podiatrist or licensed Delaware health care delivery system without written guidelines or protocols and within the scope of practice as defined in the rules and regulations promulgated by the Joint Practice Committee and approved by the Board of Medical Practice.

Nothing in this act is to be construed to limit the practice of nursing by advanced practice nurses as is currently being done or allowed including nursing diagnosis as pursuant to subsection (n)(2) of this section.

Advanced practice nurses shall operate in collaboration with a licensed physician, dentist, podiatrist, or licensed Delaware health care delivery system to cooperate, coordinate, and consult with each other as appropriate pursuant to a collaborative agreement defined in the rules and regulations promulgated by the Board of Nursing, in the provision of health care to their patients. Advanced practice nurses desiring to practice independently or to prescribe independently must do so pursuant to § 1906(20) of Title 24.

(2) Those individuals who wish to engage in independent practice without written guidelines or protocols and/or wish to have independent prescriptive authority shall apply for such privilege or privileges to the Joint Practice Committee and do so only in collaboration with a licensed physician, dentist, podiatrist or licensed Delaware health care delivery system. This does not include those individuals who have protocols and/or waivers approved by the Board of Medical Licensure and Discipline.

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

COMMENT: Prescriptive authority for Schedule II controlled substances is specified in regulations.

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

***CATEGORY D*:**
Undue prescription limitations

COMMENT: Requires formal collaborative practice with a physician.

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DELAWARE

REGULATIONS

Nursing Board Regulations

CDR 24-1900

CHAPTER 1900. Board of Nursing; Rules and Regulations

8.4 Definitions

"Advanced Practice Nurse" as defined in 24 Del.C. § 1902(d)(1). Such a nurse will be given the title Advanced Practice Nurse by state licensure, and may use the title Advanced Practice Nurse within his/her specific specialty area.

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"Collaborative Agreement" Written verification of health care facility approved clinical privileges; or health care facility approved job description; or a written document that outlines the process for consultation and referral between an Advanced Practice Nurse and a licensed physician, dentist, podiatrist, or licensed Delaware health care delivery system.

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8.18 Prescriptive Authority

8.18.1 APNs may prescribe, administer, and dispense legend medications including Schedule II - V controlled substances, (as defined in the Controlled Substance Act and labeled in compliance with 24 Del.C. § 2536(C), parenteral medications, medical therapeutics, devices and diagnostics.

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

***CATEGORY D*:**
Undue prescription limitations

COMMENT: Requires use of a collaborative agreement with a physician.

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

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DISTRICT OF COLUMBIA

STATUTES

- Health Occupations Boards Act
  Division I. Government of District; Title 3. District of Columbia Boards and Commissions; Subtitle I. General; Chapter 12. Health Occupations Boards

REGULATIONS

- Nursing Board Regulations
  Title 17. Business, Occupations and Professions;
  Chapter 54. Registered Nursing
  Chapter 59. Nurse Practitioners

OTHER GOVERNMENTAL POLICIES

No policies found

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Madison, Wisconsin

DISTRICT OF COLUMBIA

STATUTES

Health Occupations Boards Act

D.C. Code § 3-1206.04

§ 3-1206.04. Authorized acts

An advanced practice registered nurse may:

(1) Initiate, monitor, and alter drug therapies;

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

COMMENT: Prescriptive authority for Schedule II controlled substances is specified in regulations.

REGULATIONS

Nursing Board Regulations

CDCR 17-5910

17-5910. PRESCRIBING CONTROLLED SUBSTANCES

5910.1 A nurse-practitioner shall have authority to prescribe those drugs on Schedules II through V established pursuant to the District of Columbia Uniform Controlled Substances Act of 1981, D.C. Law 4-29, D.C. Code §§ 33-501 et seq., that are authorized by the protocol under which the nurse-practitioner is practicing.

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

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FLORIDA

STATUTES

- Professional Practice Act
  Title 32. Regulation of Professions and Occupations; Chapter 456. Health Professions and Occupations; General Provisions

- Nurse Practice Act *(No provisions found)*
  Title 32. Regulation of Professions and Occupations; Chapter 464. Nursing; Part I. Nurse Practice Act

REGULATIONS

- Nursing Board Regulations
  Title 64. Department of Health; Division 64B9. Board of Nursing

OTHER GOVERNMENTAL POLICIES

See Joint Policy from the Florida profile in Section IX

FLORIDA

STATUTES

Professional Practice Act

Fla. Stat. § 456.0392

§ 456.0392. Prescription labeling

(1) A prescription written by a practitioner who is authorized under the laws of this state to write prescriptions for drugs that are not listed as controlled substances in chapter 893 but who is not eligible for a federal Drug Enforcement Administration number shall include that practitioner's name and professional license number. The pharmacist or dispensing practitioner must include the practitioner's name on the container of the drug that is dispensed. A pharmacist shall be permitted, upon verification by the prescriber, to document any information required by this section.

(2) A prescription for a drug that is not listed as a controlled substance in chapter 893 which is written by an advanced registered nurse practitioner certified under s. 464.012 is presumed, subject to rebuttal, to be valid and within the parameters of the prescriptive authority delegated by a practitioner licensed under chapter 458, chapter 459, or chapter 466.

(3) A prescription for a drug that is not listed as a controlled substance in chapter 893 which is written by a physician assistant licensed under chapter 458 or chapter 459 is presumed, subject to rebuttal, to be valid and within the parameters of the prescriptive authority delegated by the physician assistant's supervising physician.

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

***CATEGORY A*:**
Arbitrary standards for legitimate prescribing

COMMENT: No prescriptive authority for controlled substances is specified.

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

***CATEGORY D*:**
Undue prescription limitations

COMMENT: Requires use of a collaborative agreement with a physician as specified in regulation.

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Madison, Wisconsin

FLORIDA

REGULATIONS

Nursing Board Regulations

64B9-4.010, F.A.C.

64B9-4.010 Standards for Protocols.

(1) An Advanced Registered Nurse Practitioner shall only perform medical acts of diagnosis, treatment, and operation pursuant to a protocol between the ARNP and a Florida-licensed medical doctor, osteopathic physician, or dentist. The degree and method of supervision, determined by the ARNP and the physician or dentist, shall be specifically identified in the written protocol and shall be appropriate for prudent health care providers under similar circumstances. General supervision by the physician or dentist is required unless these rules set a different level of supervision for a particular act. The number of persons to be supervised shall be limited to insure that an acceptable standard of medical care is rendered in consideration of the following factors:

(a) Risk to patient;

(b) Educational preparation, specialty, and experience of the parties to the protocol;

(c) Complexity and risk of the procedures;

(d) Practice setting; and

(e) Availability of the physician or dentist.

(2) A written protocol signed by all parties, representing the mutual agreement of the physician or dentist and the ARNP, shall include the following, at a minimum:

(a) General Data.

1. Signatures of individual parties to the protocol;

a. Name, address, ARNP certificate number;

b. Name, address, license number, and DEA number of the physician or dentist;

2. Nature of practice, practice location, including primary and satellite sites; and

3. Date developed and dates amended with signatures of all parties.

(b) Collaborative Practice Agreement.

1. A description of the duties of the ARNP.

2. A description of the duties of the physician or dentist (which shall include consultant and supervisory arrangements in case the physician or dentist is unavailable).

3. The management areas for which the ARNP is responsible, including

a. The conditions for which therapies may be initiated,

b. The treatments that may be initiated by the ARNP, depending on patient condition and judgment of the ARNP,

c. The drug therapies that the ARNP may prescribe, initiate, monitor, alter, or order.

4. A provision for annual review by the parties.

5. Specific conditions and a procedure for identifying conditions that require direct evaluation or specific consultation by the physician or dentist. The parties to the protocol, to insure an acceptable standard of supervision and medical care, will decide the detail and scope needed in the description of conditions and treatments, and in doing so will consider the factors listed in subparagraphs (1)(a) through (e) above.

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

***CATEGORY D*:**
Undue prescription limitations

COMMENT: Requires use of a collaborative agreement with a physician.

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

***CATEGORY A*:**
Arbitrary standards for legitimate prescribing

COMMENT: No prescriptive authority for controlled substances is specified.

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GEORGIA

STATUTES

- Medical Practice Act
  Title 43. Professions and Businesses; Chapter 34. Physicians, Acupuncture, Physician Assistants, Cancer and Glaucoma Treatment, Respiratory Care, Clinical Perfusionists, and Orthotics and Prosthetics Practice

- Nurse Practice Act *(No provisions found)*
  Title 43. Professions and Businesses; Chapter 26. Nurses

REGULATIONS

- Nursing Board Regulations
  Title 410. Georgia Board of Nursing

OTHER GOVERNMENTAL POLICIES

No policies found

GEORGIA

STATUTES

Medical Practice Act

O.C.G.A. § 43-34-25

§ 43-34-25. Delegation of certain medical acts to advanced practice registered nurse; construction and limitations of such delegation; definitions; conditions of nurse protocol; issuance of prescription drug orders

(a) As used in this Code section, the term:

(1) "Advanced practice registered nurse" shall have the same meaning as provided in paragraph (1.1) of Code Section 43-26-3.

(2) "Birthing center" means a facility or building where human births occur on a regular or ongoing basis and which is classified by the Department of Community Health as a birthing center.

(3) "Controlled substance" means any controlled substance as defined in Code Section 16-13-21 but shall not include any Schedule I controlled substance included in Code Section 16-13-25 or any Schedule II controlled substance included in Code Section 16-13-26.

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

***CATEGORY A*:**
Arbitrary standards for legitimate prescribing

COMMENT: No prescriptive authority for controlled substances is specified.

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

***CATEGORY D*:**
Undue prescription limitations

COMMENT: Requires formal collaborative practice and protocols with a physician as specified in regulation.

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GEORGIA

REGULATIONS

Nursing Board Regulations

Ga. Comp. R. & Regs. r. 410-13-.02

410-13-.02 Regulation of Protocol Use By Advanced Practice Registered Nurses as Authorized by O.C.G.A. § 43 -34-26.3.

(1) An advanced practice registered nurse ("APRN") who uses a protocol authorized by *O.C.G.A. § 43-34-26.3* shall:

(a) hold a current license to practice as a registered professional nurse in Georgia;

(b) hold a current authorization to practice as an advanced practice registered nurse in Georgia;

(c) adhere to a written nurse protocol agreement that is dated and signed by the APRN, the delegating physician, and any other designated physician(s); the APRN's area of practice shall be in the same or comparable specialty as that of the delegating physician; the protocol shall specify the medical acts delegated to the APRN as provided by *O.C.G.A. § 43-34-26.3* and shall provide for immediate consultation with the delegating physician or a designated physician if the delegating physician is not available; and

(d) document preparation and performance specific to each medical act authorized by the written nurse protocol agreement including ordering drugs, medical treatments or diagnostic studies, medical devices, or, in life threatening situations, radiographic imaging tests.

(2) An APRN may practice under a nurse protocol agreement authorized by O.C.G.A. § 43-34-26.3 if the nurse protocol agreement adheres to the following criteria:

(a) shall bear a current review date; be available upon request; and specify parameters under which delegated medical acts may be performed to include kinds of diagnostic studies which may be ordered, the extent to which radio logic image tests may be ordered, provisions for the reading and interpretation of such tests by a physician who is trained in the reading and interpretation of the tests, circumstances under which prescription drugs orders may be executed, number of refills which may be ordered, include a frequency of follow up review of the patient by the physician, including patients who are on controlled substances;

(b) shall include a schedule for periodic review of patient records by the delegating physician, which records review may be achieved with a sampling of such records as determined by the delegating physician;

(c) shall be reviewed, revised or updated annually by the APRN, the delegating physician, and any designated physician;

(d) shall include a provision for immediate consultation with the delegating physician or a physician designated in the absence of the delegating physician; and

(e) shall comply with the provisions of O.C.G.A. § 43-34-26.3 regarding prescription drug orders placed by an APRN for a drug or medical device including, but not limited to, the following:

1. no prescription drug orders submitted by an APRN for Schedule I or II controlled substances;

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

***CATEGORY D*:**
Undue prescription limitations

COMMENT: Requires formal collaborative practice and protocols with a physician.

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

***CATEGORY A*:**
Arbitrary standards for legitimate prescribing

COMMENT: No prescriptive authority for controlled substances is specified.

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Madison, Wisconsin

HAWAII

STATUTES

- Nurse Practice Act
  Division 2. Business; Title 25. Professions and Occupations; Chapter 457. Nurses

REGULATIONS

- Nursing Board Regulations
  Title 16. Department of Commerce and Consumer Affairs; Chapter 89. Nurses

OTHER GOVERNMENTAL POLICIES

No policies found

HAWAII

STATUTES

Nurse Practice Act

HRS § 457-8.6

§ 457-8.6. Prescriptive authority for advanced practice registered nurses.

(a) The board shall grant prescriptive authority to qualified advanced practice registered nurses and shall designate the requirements for advanced nursing practice related to prescriptive authority. The board shall determine the exclusionary formulary for qualified advanced practice registered nurses who are granted prescriptive authority.

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The joint formulary advisory committee shall recommend the applicable formulary for persons recognized under this section. The board shall consider the recommendations of the joint formulary advisory committee in adopting the formulary.

(c) The board shall establish requirements for advanced practice registered nurses' education, experience, and national certification pursuant to rules adopted in accordance with chapter 91.

(d) Advanced practice registered nurses shall be considered qualified if they have met the requirements of section 457-8.5(a), and have met the advanced pharmacology requirements for initial prescriptive authority pursuant to rules adopted by the board. Only qualified advanced practice registered nurses authorized to diagnose, prescribe, and institute therapy or referrals of patients to health care agencies, health care providers, and community resources and, only as appropriate to the practice specialty in which the advanced practice nurse is qualified, may:

(1) Prescribe and administer over the counter drugs, legend drugs, and controlled substances pursuant to this chapter and to chapter 329 and request, receive, and dispense manufacturers' prepackaged samples of over the counter and non-controlled legend drugs to patients under their care; provided that an advanced practice registered nurse shall not request, receive, or sign for professional controlled substance samples;

(2) Prescribe, order, and dispense medical devices and equipment; and

(3) Plan and initiate a therapeutic regimen that includes nutritional, diagnostic, and supportive services including home health care, hospice, and physical and occupational therapy.

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

COMMENT: Prescriptive authority for Schedule II controlled substances is specified in regulations.

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

HAWAII

REGULATIONS

Nursing Board Regulations

WCHR 16-89

§ 16-89-119. Prescriptive Authority Eligibility Requirements.

(a) The requirements for prescriptive authority are as follows:

(1) A completed application for prescriptive authority for controlled or non-controlled substances provided by the board and submitted with all appropriate documents (unless currently filed with the board) and required fees;

(2) Proof of a current, unencumbered license as a registered nurse in this State and in all other states in which the nurse has a current and active license;

(3) Proof of a current, unencumbered recognition or license as an advanced practice registered nurse in this State and in all other states in which the nurse has a current and active recognition or license as an advanced practice registered nurse or similar designation;

(4) Proof of a current, unencumbered certification for specialized and advanced nursing practice from a national certifying body recognized by the board;

(5) Proof of successful completion of an accredited graduate-level nursing program with a significant educational and practical concentration on the direct care of patients, recognized by the board, leading to a master's degree as a certified registered nurse anesthetist, a nurse midwife, a clinical nurse specialist, or a nurse practitioner (nursing education and administration do not qualify);

(6) Proof of successful completion of at least thirty contact hours, as part of a master's degree program from an accredited, board-recognized college or university, of advanced pharmacology education, including advanced pharmacotherapeutics that is integrated into the curriculum, within the three-year time period immediately preceding the date of application. If completed more than the three-year time period, then one of the following shall be completed within the three-year time period immediately preceding the date of application for initial prescriptive authority:

(A) At least thirty contact hours of advanced pharmacology, including advanced pharmacotherapeutics, from an accredited, board-recognized college or university; or

(B) At least thirty contact hours of continuing education ("CE") approved by board-recognized national certifying bodies in advanced pharmacology, including advanced pharmacotherapeutics related to the applicant's scope of nursing practice specialty; and

(7) Payment of a non-refundable application fee.

(b) APRN authorized to prescribe non-controlled substances and who subsequently wish to prescribe controlled substances shall submit the appropriate application for prescriptive authority for controlled substances and meet the requirements of this chapter.

(c) Upon satisfying all requirements in chapter 457, HRS, and this chapter, and payment of required fees, the board shall grant prescriptive authority to the APRN.

(d) Nothing in this section shall preclude a registered nurse, a licensed practical nurse, or an APRN from carrying out the prescribed medical orders of a licensed dentist, physician, osteopath, or podiatrist licensed in accordance with chapters 448, 453, or 463E, HRS, or the orders of a recognized APRN granted prescriptive authority in accordance with this chapter.

(e) Nothing in this chapter shall require a certified registered nurse anesthetist to have prescriptive authority under this chapter in order to provide anesthesia care.

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

HAWAII

REGULATIONS

Nursing Board Regulations

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

Exhibit A. Exclusionary Formulary for Advanced Practice Registered Nurses Granted Prescriptive Authority.

On November 3, 2011, the Board of Nursing ("Board") adopted the exclusionary formulary for Advanced Practice Registered Nurses granted prescriptive authority ("APRN-Rx") by the Board. An APRN-Rx may prescribe and administer over-the-counter and legend drugs, and controlled substances within their specialty and for which drugs that are not excluded in this formulary.

The Exclusionary Formulary shall list drugs or categories of drugs designated and published by the Board, based on the recommendations of the Joint Formulary Advisory Committee, that shall not be prescribed by an APRN granted prescriptive authority.

An APRN-Rx may prescribe and administer over the counter drugs, legend drugs and controlled substances pursuant to chapters 457 and 329 Hawaii Revised Statutes, and request, receive, and dispense manufacturer's prepackaged samples of over the counter and non-controlled legend drugs to patients under their care.

The APRN-Rx accepts full responsibility, accountability, and obligation to practice in accordance with APRN standards and functions as defined by the scope of practice/role definition statements for the APRN's category and specialty. The scope and standards shall include the statutes and rules established by the Board, the standards of the national certifying body, recognized by the Board, by which the APRN is currently certified, and generally accepted standards of practice in prescribing Schedules II to V, including that of the U.S. Drug Enforcement Agency; the Department of Public Safety, Narcotics Enforcement Division; and other applicable state and federal laws and regulations and this Exclusionary Formulary.

The Exclusionary Formulary shall consist of:

-- Investigational drugs except as part of an IRB-approved clinical trial;

-- Stimulants and hormones for treatment of obesity;

-- Human Growth hormones, anabolic steroids, or hormones for performance enhancement or decreasing the impact of aging;

-- Methadone for maintenance or detoxification of a narcotic-dependent person as restricted in *HRS 329-121*; and

-- Medical marijuana as restricted in *HRS section 329-121*.

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Madison, Wisconsin

IDAHO

STATUTES

- Nurse Practice Act
  General Laws; Title 54. Professions, Vocations, and Businesses;
  Chapter 14. Nurses

REGULATIONS

- Nursing Board Regulations
  IDAPA 23. Board of Nursing

OTHER GOVERNMENTAL POLICIES

Idaho Board of Nursing. *Pain Management: Guidance for the Licensed Nurse*. Adopted: November, 2011.

IDAHO

STATUTES

Nurse Practice Act

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

COMMENT: Prescriptive authority for Schedule II controlled substances is specified in regulations.

Idaho Code § 54-1402

§ 54-1402. Definitions

As used in this act:

(1) "Advanced practice professional nurse" means a professional nurse licensed in this state who has gained additional specialized knowledge, skills and experience through a nationally accredited program of study as defined herein and is authorized to perform advanced nursing practice, which may include the prescribing, administering and dispensing of therapeutic pharmacologic agents, as defined by board rules. An advanced practice professional nurse shall perform only those acts as provided herein and for which the individual is educationally prepared. Advanced practice professional nurses shall include certified nurse-midwives, clinical nurse specialists, nurse practitioners, and registered nurse anesthetists as defined in this subsection.

(c) "Nurse practitioner" means a licensed professional nurse who has graduated from a nationally accredited nurse practitioner program, passed a qualifying examination recognized by the board, and has current initial certification or current recertification from a national group recognized by the board. Any person authorized by the board to practice nursing as a nurse practitioner in this state as of July 1, 1998, shall be licensed as a nurse practitioner under the provisions of this act and shall be eligible for renewal of such license under the conditions and standards prescribed in this act. Nurse practitioners who meet these qualifying requirements and are licensed by the board may perform comprehensive health assessments, diagnosis, health promotion and the direct management of acute and chronic illness and disease which may include the prescribing of pharmacologic and nonpharmacologic treatments as defined by rules of the board. The nurse practitioner collaborates with other health professionals in providing health care.

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Madison, Wisconsin

IDAHO

REGULATIONS

Nursing Board Regulations

IDAPA 23.01.01.27

271. Definitions Related to Advanced Practice Professional Nursing.

01. Accountability . Means being answerable for one's own actions.

02. Advanced Practice Professional Nurse . Means a professional nurse licensed in this state who has gained additional specialized knowledge, skills and experience through a post-basic program of study as defined herein and is authorized to perform advanced nursing practice, which may include acts of diagnosis and treatment, and the prescribing, administering and dispensing of therapeutic pharmacologic and non-pharmacologic agents, as defined herein. Advanced practice professional nurses shall include certified nurse-midwives, clinical nurse specialists, nurse practitioners, and registered nurse anesthetists. Advanced practice professional nurses, when functioning within the recognized scope of practice, assume primary responsibility for the care of their patients. This practice incorporates the use of professional judgment in the assessment and management of wellness and conditions appropriate to the advanced practice professional nurse's area of specialization. Effective Date (7-1-99)

03. Authorized Advanced Practice Professional Nurse . Means an advanced practice professional nurse authorized by the Board to prescribe and dispense pharmacologic and non-pharmacologic agents pursuant to Section 315 of these rules. Effective Date (7-1-99)

04. Certification . Means recognition of the applicant's advanced knowledge, skills and abilities in a defined area of nursing practice by a national organization recognized by the Board. The certification process measures the theoretical and clinical content denoted in the advanced scope of practice, and is developed in accordance with generally accepted standards of validation and reliability. Effective Date (7-1-99)

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15. Prescriptive and Dispensing Authorization . Means the legal permission to prescribe, deliver, distribute and dispense pharmacologic and non-pharmacologic agents to a client in compliance with Board rules and applicable federal and state laws. Pharmacologic agents include legend and Schedule II through V controlled substances. Effective Date (7-1-99)

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

Pain & Policy Studies Group
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Madison, Wisconsin

IDAHO

OTHER GOVERNMENTAL POLICY

Nursing Board Guideline

PAIN MANAGEMENT:
GUIDANCE FOR THE LICENSED NURSE

It is estimated that over 76 million Americans suffer from some form of pain. The effects of pain may diminish quality of life physically, emotionally, socially, spiritually and economically. Pain constitutes a dynamic and challenging aspect of health care that requires increased awareness and knowledge on the part of nurses. Nurses face issues involving pain and its management on a regular basis. Nurses are expected to address pain consistent with accepted standards. The nurse whose practice constitutes a substantial departure from established and customary standards of care or whose behavior presents danger to the public may risk disciplinary action by the Board of Nursing.

In its role of safeguarding the public health, safety and welfare, the Board has the responsibility to address the nurse's role in pain management and treatment. Toward this end, the Board has identified four unique situations related to pain management for which guidance may be of benefit to the nurse.

The following issues are addressed in statements developed and adopted by the Board and are included in this informational packet:
***1:* The role of the licensed nurse caring for patients experiencing pain; and**
***2:* The advanced practice registered nurse (APRN) prescribing for patients with pain**
***3:* The practicing nurse experiencing and/or being treated for pain**
***4:* The nurse with a chemical use disorder whose pain is managed with prescribed potentially addictive drugs**

ROLE OF THE LICENSED NURSE CARING FOR PATIENTS EXPERIENCING PAIN INCLUDING THE ADVANCED PRACTICE REGISTERED NURSE (APRN) PRESCRIBING FOR PATIENTS WITH PAIN

The Idaho Board of Nursing believes it is essential that patients experience appropriate and effective pain management. Unrelieved pain can result in longer hospital stays, increased rates of rehospitalization, increased outpatient visits and an individual's decreased ability to function. Ineffective treatment of pain, including non treatment, under treatment, overtreatment and the continued use of inappropriate treatments, places patients at risk of harm or unnecessary suffering.

When caring for patients with pain, nurses may be intimidated by the complexity of pain management. They may be concerned about side effects of pain medications or fear that patients may become tolerant, physically dependent or addicted to these drugs through extended use. They may be concerned about how their own experiences with pain may cloud their judgment while caring for others.

The APRN caring for patients with pain may fear a practice environment where clinicians face possible regulatory or legal sanctions for over- or under-treating pain or for their particular prescribing practices. Additionally, APRNs may encounter patients exhibiting drug-seeking behavior that present a real safety threat to themselves, the nurse and others who may be present in the healthcare setting.

In order to effectively address the needs of patients experiencing pain, the licensed nurse, practicing within defined parameters consistent with his/her level of education, demonstrated competence and category of licensure, must:

(CONTINUED ON NEXT PAGE)

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

(+) *CRITERION 4:*
Encourages pain management

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies the potential impact of important barriers on the provision of effective pain care.

(+) *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.

2013

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University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

IDAHO

OTHER GOVERNMENTAL POLICY

Nursing Board Guideline

(+) *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 C:
Regulatory or policy issues

COMMENT: Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

(CONTINUED)

- Be knowledgeable about effective pain management
- Routinely assess all patients for the presence of pain
- Document all aspects of pain assessment and treatment
- Anticipate pain and effectively manage side effects of pain treatment
- Provide appropriate pain treatment and evaluation of the treatment
- Coordinate patient care/collaborate with other providers/care givers
- Teach/inform patients, family members and other care givers about pain management
- Be aware of the potential for patient abuse/misuse of pain medications and take appropriate steps to minimize risk
- Develop policies and protocols that provide for continuity and consistency in managing patients with pain
- Know and comply with state and federal laws regarding prescribing, dispensing and administering pain medications, including controlled substances
- Identify and eliminate barriers that inhibit or prevent appropriate pain treatment.

CONCLUSION

All persons experiencing pain have the right to expect appropriate management of their pain. Nurses must work through the stated issues and practice in accordance with established pain management standards. It is imperative that the licensed nurse works cooperatively and effectively to meet the goal of pain management in order to avoid patient harm and/or personal risk of licensure discipline by the Board.

Adopted by Board of Nursing:
April 29, 2005

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

CATEGORY B:
Issues related to patients

COMMENT: Recognizes the patient's right to appropriate pain management.

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Madison, Wisconsin

ILLINOIS

STATUTES

- Nurse Practice Act
  Chapter 225. Professions and Occupations; Health; Nursing and Advanced Practice Nursing Act

REGULATIONS

- Nursing Board Regulations
  Title 68. Professions and Occupations; Chapter VII. Department of Financial and Professional Regulation; Subchapter b. Professions and Occupations;
  Part 1300. Nurse Practice Act

OTHER GOVERNMENTAL POLICIES

No policies found

ILLINOIS

STATUTES

Nurse Practice Act

225 ILCS 65/65-40

§ 225 ILCS 65/65-40. Written collaborative agreement; prescriptive authority

Sec. 65-40. (a) A collaborating physician or podiatric physician may, but is not required to, delegate prescriptive authority to an advanced practice nurse as part of a written collaborative agreement. This authority may, but is not required to, include prescription of, selection of, orders for, administration of, storage of, acceptance of samples of, and dispensing over the counter medications, legend drugs, medical gases, and controlled substances categorized as any Schedule III through V controlled substances, as defined in Article II of the Illinois Controlled Substances Act [*720 ILCS 570/100* et seq.], and other preparations, including, but not limited to, botanical and herbal remedies. The collaborating physician or podiatric physician must have a valid current Illinois controlled substance license and federal registration to delegate authority to prescribe delegated controlled substances.

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(d) In addition to the requirements of subsections (a), (b), and (c) of this Section, a collaborating physician or podiatric physician may, but is not required to, delegate authority to an advanced practice nurse to prescribe any Schedule II controlled substances, if all of the following conditions apply:

(1) Specific Schedule II controlled substances by oral dosage or topical or transdermal application may be delegated, provided that the delegated Schedule II controlled substances are routinely prescribed by the collaborating physician or podiatric physician. This delegation must identify the specific Schedule II controlled substances by either brand name or generic name. Schedule II controlled substances to be delivered by injection or other route of administration may not be delegated.

(2) Any delegation must be controlled substances that the collaborating physician or podiatric physician prescribes.

(3) Any prescription must be limited to no more than a 30-day supply, with any continuation authorized only after prior approval of the collaborating physician or podiatric physician.

(4) The advanced practice nurse must discuss the condition of any patients for whom a controlled substance is prescribed monthly with the delegating physician.

(5) The advanced practice nurse meets the education requirements of Section 303.05 of the Illinois Controlled Substances Act.

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

***CATEGORY D*:**
Undue prescription limitations

COMMENT: Requires use of a collaborative agreement with a physician.

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

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

***CATEGORY D*:**
Undue prescription limitations

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Madison, Wisconsin

ILLINOIS

REGULATIONS

Nursing Board Regulations

68 Ill. Adm. Code 1300.430

§ 1300.430 Prescriptive Authority

a) A collaborating physician or podiatrist who delegates prescriptive authority to an advanced practice nurse shall include that delegation in the written collaborative agreement. This authority may include prescription of, selection of, orders for, administration of, storage of, acceptance of samples of, and dispensing over the counter medications, legend drugs, medical gases, and controlled substances categorized as Schedule III, III-N, IV or V controlled substances, as defined in Article II of the Illinois Controlled Substances Act, and other preparations, including, but not limited to, botanical and herbal remedies. The collaborating physician or podiatrist must have a valid current Illinois controlled substance license and federal registration to delegate authority to prescribe delegated controlled substances.

b) Pursuant to Section 65-40(d) of the Act, a collaborating physician may, but is not required to, delegate authority to an advanced practice nurse to prescribe Schedule II or II-N controlled substances under the following conditions:

1) No more than 5 Schedule II or II-N controlled substances by oral dosage may be delegated. For the purposes of this Section generic substitution pursuant to Section 25 of the Pharmacy Practice Act shall be allowed under this Section when not prohibited by a prescriber's indication on the prescription that the pharmacist "may not substitute".

2) The collaborating physician can only delegate controlled substances that the collaborating physician prescribes.

3) Any prescription must be limited to no more than a 30-day oral dosage, with any continuation authorized only after prior approval of the collaborating physician.

4) The advanced practice nurse must discuss the condition of any patients for whom a controlled substance is prescribed monthly with the delegating physician.

c) An APN who has been given controlled substances prescriptive authority shall be required to obtain an Illinois mid-level practitioner controlled substances license in accordance with *77 Ill. Adm. Code 3100*. The physician or podiatrist shall file a notice of delegation of prescriptive authority with the Division. The delegation of authority form shall be submitted to the Division prior to the issuance of a controlled substance license.

d) The APN may only prescribe and dispense controlled substances that the collaborating physician or podiatrist prescribes. Licensed dentists may not delegate prescriptive authority.

e) All prescriptions written and signed by an advanced practice nurse shall indicate the name of the collaborating physician or podiatrist. The

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

CATEGORY D:
Undue prescription limitations

COMMENT: Requires use of a collaborative agreement with a physician.

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

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

CATEGORY D:
Undue prescription limitations

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Madison, Wisconsin

INDIANA

STATUTES

- Nurse Practice Act
  Title 25. Professions and Occupations; Article 23. Nurses

REGULATIONS

- Nursing Board Regulations
  Title 848. Indiana State Board of Nursing

OTHER GOVERNMENTAL POLICIES

No policies found

INDIANA

STATUTES

Nurse Practice Act

Burns Ind. Code Ann. § 25-23-1-19.4

25-23-1-19.4. Advanced practice nurse to operate in collaboration with licensed practitioner.

(a) As used in this section, "practitioner" has the meaning set forth in IC 16-42-19-5. However, the term does not include the following:

(1) A veterinarian.

(2) An advanced practice nurse.

(3) A physician assistant.

(b) An advanced practice nurse shall operate in collaboration with a licensed practitioner as evidenced by a practice agreement, or by privileges granted by the governing board of a hospital licensed under IC 16-21 with the advice of the medical staff of the hospital that sets forth the manner in which an advanced practice nurse and a licensed practitioner will cooperate, coordinate, and consult with each other in the provision of health care to their patients.

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Burns Ind. Code Ann. § 25-23-1-19.5

25-23-1-19.5. Establishment of program under which advanced practice nurses may be authorized to prescribe legend drugs -- Requirements.

(a) The board shall establish a program under which advanced practice nurses who meet the requirements established by the board are authorized to prescribe legend drugs, including controlled substances (as defined in IC 35-48-1).

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

(-) CRITERION 12:
Healthcare decisions are restricted

CATEGORY D:
Undue prescription limitations

COMMENT: Requires use of a collaborative agreement with a physician.

REGULATIONS

Nursing Board Regulations

848 IAC 5-1-1

848 IAC 5-1-1 Initial authority to prescribe legend drugs

Sec. 1. (a) An advanced practice nurse may be authorized to prescribe legend drugs, including controlled substances, if the advanced practice nurse does the following:

(7) Submits proof of collaboration with a licensed practitioner in the form of a written practice agreement that sets forth the manner in which the advanced practice nurse and licensed practitioner will cooperate, coordinate, and consult with each other in the provision of health care to patients. Practice agreements shall be in writing and shall also set forth provisions for the type of collaboration between the advanced practice nurse and the licensed practitioner and the reasonable and timely review by the licensed practitioner of the prescribing practices of the advanced practice nurse.

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

(-) CRITERION 12:
Healthcare decisions are restricted

CATEGORY D:
Undue prescription limitations

COMMENT: Requires use of a collaborative agreement with a physician.

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IOWA

STATUTES

- Professional Practice Act
  Title IV. Public Health; Subtitle 3. Health-Related Professions; Chapter 147. General Provisions; Health-Related Professions

- Nurse Practice Act *(No provisions found)*
  Title IV. Public Health; Subtitle 3. Health-Related Professions; Chapter 152. Nursing

REGULATIONS

- Nursing Board Regulations
  Nursing Boards [655]

OTHER GOVERNMENTAL POLICIES

See Joint Policy from the Iowa profile in Section IX

IOWA

STATUTES

Professional Practice Act

Iowa Code § 147.107

147.107 Drug dispensing, supplying, and prescribing -- limitations.

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8. Notwithstanding subsection 1, but subject to the limitations contained in subsections 2 and 3, a registered nurse who is licensed and registered as an advanced registered nurse practitioner and who qualifies for and is registered in a recognized nursing specialty may prescribe substances or devices, including controlled substances or devices, if the nurse is engaged in the practice of a nursing specialty regulated under rules adopted by the board of nursing in consultation with the board of medicine and the board of pharmacy..

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

REGULATIONS

Nursing Board Regulations

655 IAC 7.1(152)

655-7.1(152) Definitions.

The following definitions shall be applicable to the rules of the board of medicine:

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"Prescriptive authority" is the authority granted to an ARNP registered in Iowa in a recognized nursing specialty to prescribe, deliver, distribute, or dispense prescription drugs, devices, and medical gases when the nurse is engaged in the practice of that nursing specialty. Registration as a practitioner with the Federal Drug Enforcement Administration and the Iowa board of pharmacy examiners extends this authority to controlled substances. ARNPs shall access the Iowa board of pharmacy examiners Web site for Iowa pharmacy law and administrative rules and the Iowa Board of Pharmacy Examiners Newsletter.

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

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KANSAS

STATUTES

- Nurse Practice Act
  Chapter 65. Public Health; Article 11. Regulation of Nursing

REGULATIONS

- Nursing Board Regulations
  Agency 60. Kansas State Board of Nursing

OTHER GOVERNMENTAL POLICIES

Kansas State Board of Nursing. *Guideline for Pain Management*. Adopted: July 11, 2001.

See Joint Policy from the Kansas profile in Section IX

KANSAS

STATUTES

Nurse Practice Act

K.S.A. § 65-1130

65-1130. Advanced registered nurse practitioner; standards and requirements for obtaining certificate of qualification; rules and regulations; categories, education, qualifications and role; limitations and restrictions; prescription of drugs authorized.

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(d) An advanced practice registered nurse may prescribe drugs pursuant to a written protocol as authorized by a responsible physician. Each written protocol shall contain a precise and detailed medical plan of care for each classification of disease or injury for which the advanced practice registered nurse is authorized to prescribe and shall specify all drugs which may be prescribed by the advanced practice registered nurse. Any written prescription order shall include the name, address and telephone number of the responsible physician. The advanced practice registered nurse may not dispense drugs, but may request, receive and sign for professional samples and may distribute professional samples to patients pursuant to a written protocol as authorized by a responsible physician. In order to prescribe controlled substances, the advanced practice registered nurse shall (1) register with the federal drug enforcement administration; and (2) notify the board of the name and address of the responsible physician or physicians. In no case shall the scope of authority of the advanced practice registered nurse exceed the normal and customary practice of the responsible physician. An advanced practice registered nurse certified in the role of registered nurse anesthetist while functioning as a registered nurse anesthetist under *K.S.A. 65-1151* to *65-1164*, inclusive, and amendments thereto, shall be subject to the provisions of *K.S.A. 65-1151* to *65-1164*, inclusive, and amendments thereto, with respect to drugs and anesthetic agents and shall not be subject to the provisions of this subsection. For the purposes of this subsection, "responsible physician" means a person licensed to practice medicine and surgery in Kansas who has accepted responsibility for the protocol and the actions of the advanced practice registered nurse when prescribing drugs.

(e) As used in this section, "drug" means those articles and substances defined as drugs in K.S.A. 65-1626 and 65-4101 and amendments thereto.

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

***CATEGORY D*:**
Undue prescription limitations

COMMENT: Requires formal collaborative practice and protocols with a physician.

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

2013

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University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

KANSAS

REGULATIONS

Nursing Board Regulations

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

K.A.R. § 60-11-104a

60-11-104a. Protocol requirements; prescription orders.

(a) Each written protocol that an advanced registered nurse practitioner is to follow when prescribing, administering, or supplying a prescription-only drug shall meet the following requirements:

(1) Specify for each classification of disease or injury the corresponding class of drugs that the advanced registered nurse practitioner is permitted to prescribe;

(2) be maintained in either a loose-leaf notebook or a book of published protocols. The notebook or book of published protocols shall include a cover page containing the following data:

(A) The names, telephone numbers, and signatures of the advanced registered nurse practitioner and a responsible physician who has authorized the protocol; and

(B) the date on which the protocol was adopted or last reviewed; and

(3) be kept at the advanced registered nurse practitioner's principal place of practice.

(b) Each advanced registered nurse practitioner shall ensure that each protocol is reviewed by the advanced registered nurse practitioner and physician at least annually.

(c) Each prescription order in written form shall meet the following requirements:

(1) Include the name, address, and telephone number of the practice location of the advanced registered nurse practitioner;

(2) include the name, address, and telephone number of the responsible physician;

(3) be signed by the advanced registered nurse practitioner with the letters A.R.N.P.;

(4) be from a class of drugs prescribed pursuant to protocol; and

(5) contain any D.E.A. registration number issued to the advanced registered nurse practitioner when a controlled substance, as defined in K.S.A. 65-4101(e) and amendments thereto, is prescribed.

(d) Nothing in this regulation shall be construed to prohibit any registered nurse or licensed practical nurse or advanced registered nurse practitioner from conveying a prescription order orally or administering a drug if acting under the lawful direction of a person licensed to practice either medicine and surgery or dentistry, or certified as an advanced registered nurse practitioner.
(e) When used in this regulation, terms shall be construed to have the meanings set forth in the pharmacy act of the state of Kansas, K.S.A. 65-1626, and amendments thereto.

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

CATEGORY D:
Undue prescription limitations

COMMENT: Requires formal collaborative practice and protocols with a physician.

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KANSAS

OTHER GOVERNMENTAL POLICY

Nursing Board Guideline

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

(+) *CRITERION 4:*
Encourages pain management

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

CATEGORY B:
Issues related to patients

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

Kansas State Board of Nursing
Guideline for Pain Management

Section 1: Purpose

The management of pain must be a major priority for nurses and all others who provide care to persons in pain. Pain is sometimes undertreated due to lack of knowledge or fear of sanctions by regulatory or enforcement agencies. This guideline is intended to:

1) promote the optimal level of nursing practice in pain management;
2) establish a standard of practice that leads to sound clinical judgment in managing acute and chronic, and end-of-life pain; and
3) reassure nurses that by following these guidelines, they will be supported and not disciplined by the Board for appropriate pain management.

Section 2: Nursing Principles of Pain Management

The Kansas State Board of Nursing endorses the "Precepts of Pain Management" set forth by the Living Initiatives for End of Life Care (LIFE) Project and has drawn upon the precepts to formulate nursing principles of pain management. They are:

- All persons who are experiencing pain have the right to have their pain relieved to the greatest extent possible. The nurse's goal is to reduce pain at least to a level specified by the recipient of care, while recognizing that all persons have the right to refuse treatment.
- A person's perception of pain is the optimal standard upon which all pain management interventions are based.
- A comprehensive nursing assessment includes the subjective description of pain, objective data, and the identified need for psychosocial/spiritual support.
- Fear of addiction to opioids and other pain medications need not be a barrier to pain management. Nurses recognize and apply the following concepts:
  - Tolerance and physical dependence are consequences of sustained use of opioid analgesics and are not synonymous with addiction
  - "Pseudoaddiction" is a pattern of drug-seeking behavior of persons with pain who are receiving inadequate pain management and may be mistaken for addiction.
- Persons with a history of substance abuse have the right to adequate pain relief, even if opioids must be used. Such persons require specialized care and treatment.
- Continuity of care within and across health care settings is essential to effective pain management.
- An interdisciplinary approach to pain management is optimal.
- Nurses and other clinicians pursue the most effective modes of treatment to their maximal benefit. Research indicates that most persons experiencing pain can achieve optimal pain relief with simple, cost-effective modes of treatment.
- Pain management continues even if the person becomes unresponsive.
- Sedation is an acceptable means of controlling pain and discomfort when all other reasonable efforts have failed.
- Assisted suicide and euthanasia are illegal in the state of Kansas and are not acceptable alternatives to optimal pain management.

Section 3: Nursing Functions of Pain Management

Nurses are responsible for maintaining the knowledge and skills necessary to coordinate optimal pain management.

The nursing functions of appropriate pain management include:

- Ensuring that the person or their legal representative actively participates in the treatment plan and understands the options available for pain relief and potential side effects.
- Educating persons and their families in a culturally competent manner regarding pain management.

(CONTINUTED ON NEXT PAGE)

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies the potential impact of important barriers on the provision of effective pain care.

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

(+) *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.

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Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

KANSAS

OTHER GOVERNMENTAL POLICY

Nursing Board Guideline

(CONTINUED)

- Educating staff members about pain assessment, treatment and the common barriers to adequate pain management.
- Using a standardized scale, to periodically assess and document a person's pain in accordance with institutional policies and procedures.
- Developing and implementing a plan of care that prevents and alleviates pain as much as possible.
- Administering medications and treatments as prescribed, using knowledge to maintain both safety and pain relief.
- Initiating non-pharmacological nursing interventions as indicated.
- Serving as an advocate to assure effective pain management.
- Communicating side effects or any reports of unrelieved pain to the prescriber and to appropriate team members.
- Documenting pain assessment, intervention, evaluation and changes to the plan of care in a clear and concise manner.

Section 4: Legal Authority
Only the physician or other health professional with authority to prescribe may change the medical pain management plan. When pain is not controlled under the currently prescribed treatment plan, the nurse is responsible for reporting such findings to the prescriber and documenting the communication.

The nurse is often the health professional most involved in on-going pain assessment, implementing the prescribed pain management plan, evaluating the person's response to such interventions and adjusting medication levels based on the person's status. In order to achieve adequate pain management, the prescription must provide dosage ranges and frequency parameters with which the nurse may adjust (titrate) medication in order to achieve adequate pain control. Consistent with the licensee's scope of practice, the RN or LPN is accountable for implementing the pain management plan utilizing his/her knowledge base and documented assessment of the person's needs. The nurse has the authority to adjust medication levels within the dosage and frequency ranges stipulated by the prescriber and according to the agency's established policies and procedures. Nurses should not fear disciplinary action from the Kansas State Board of Nursing for administering medication to control pain for a legitimate medical purpose and in the usual course of professional practice.

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

Section 5: Definitions
For the purposes of these guidelines, the following terms are defined:

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

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

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

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

(CONTINUED ON NEXT PAGE)

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

KANSAS

OTHER GOVERNMENTAL POLICY

Nursing Board Guideline

(CONTINUED)

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

"Pseudoaddiction" is a pattern of drug-seeking behavior of persons with pain who are receiving inadequate pain management that can be mistaken for addiction.

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

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

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Madison, Wisconsin

KENTUCKY

STATUTES

- Nurse Practice Act
  Title XXVI. Occupations and Professions; Chapter 314. Registered Nurses – Practical Nurses

REGULATIONS

- Nursing Board Regulations
  Title 201. General Government Cabinet; Chapter 20. Board of Nursing

OTHER GOVERNMENTAL POLICIES

No policies found

KENTUCKY

STATUTES

Nurse Practice Act

KRS § 314.011

314.011. Definitions for chapter.

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

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(8) "Advanced registered nursing practice" means the performance of additional acts by registered nurses who have gained added knowledge and skills through an organized postbasic program of study and clinical experience and who are certified by the American Nurses' Association or other nationally established organizations or agencies recognized by the board to certify registered nurses for advanced nursing practice. The additional acts shall, subject to approval of the board, include but not be limited to prescribing treatment, drugs, devices, and ordering diagnostic tests. Advanced registered nurse practitioners who engage in these additional acts shall be authorized to issue prescriptions for and dispense nonscheduled legend drugs as defined in KRS 217.905 and to issue prescriptions for but not to dispense Schedules II through V controlled substances as classified in KRS 218A.060, 218A.070, 218A.080, 218A.090, 218A.100, 218A.110, 218A.120, and 218A,130, under the conditions set forth in KRS 314.042 and regulations promulgated by the Kentucky Board of Nursing on or before August 15, 2006.

(a) Prescriptions issued by advanced registered nurse practitioners for Schedule II controlled substances classified under KRS 218A.060 shall be limited to a seventy-two (72) hour supply without any refill. Prescriptions issued under this subsection for psychostimulants may be written for a thirty (30) day supply only by an advanced registered nurse practitioner certified in psychiatric-mental health nursing who is providing services in a health facility as defined in KRS Chapter 216B or in a regional mental health-mental retardation services program as defined in KRS Chapter 210.

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KRS § 314.042

314.042. Registration and designation as an advanced registered nurse practitioner -- Use of "ARNP" -- Prescriptive authority under CAPA-NS and CAPA-CS -- Renewal -- Reinstatement.

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(8) Before an advanced registered nurse practitioner engages in the prescribing or dispensing of nonscheduled legend drugs as authorized by KRS 314.011(8), the advanced registered nurse practitioner shall enter into a written "Collaborative Agreement for the Advanced Registered Nurse Practitioner's Prescriptive Authority for Nonscheduled Legend Drugs" (CAPA-NS) with a physician that defines the scope of the prescriptive authority for nonscheduled legend drugs.

(9) Before an advanced registered nurse practitioner engages in the prescribing of Schedules II through V controlled substances as authorized by KRS 314.011(8), the advanced registered nurse practitioner shall enter into a written "Collaborative Agreement for the Advanced Registered Nurse Practitioner's Prescriptive Authority for Controlled Substances" (CAPA-CS) with a physician that defines the scope of the prescriptive authority for controlled substances.

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

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

CATEGORY D:
Undue prescription limitations

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

CATEGORY D:
Undue prescription limitations

COMMENT: Requires use of a collaborative agreement with a physician.

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University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

KENTUCKY

REGULATIONS

Nursing Board Regulations

201 KAR 20:057

201 KAR 20:057. Scope and standards of practice of advanced practice registered nurses.

Section 1. Definitions. (1) "Collaboration" means the relationship between the advanced practice registered nurse and a physician in the provision of prescription medication, including both autonomous and cooperative decision-making, with the advanced practice registered nurse and the physician contributing their respective expertise.

(2) "Collaborative Agreement for the Advanced Practice Registered Nurse's Prescriptive Authority for Controlled Substances" or CAPA-CS means the written document pursuant to *KRS 314.042(9)*.

(3) "Collaborative Agreement for the Advanced Practice Registered Nurse's Prescriptive Authority for Nonscheduled Legend Drugs (CAPA-NS)" means the written document pursuant to *KRS 314.042(8)*.

Section 2. The practice of the advanced practice registered nurse shall be in accordance with the standards and functions defined in the following scope and standards of practice statements for each specialty area:

(1) Scope and Standards of Psychiatric-Mental Health Nursing Practice;

(2) Nursing: Scope and Standards of Practice;

(3) Scope and Standards for Nurse Anesthesia Practice;

(4) Standards for Office-based Anesthesia Practice;

(5) Standards for the Practice of Midwifery;

(6) The Women's Health Nurse Practitioner: Guidelines for Practice and Education;

(7) Pediatric Nursing: Scope and Standards of Practice;

(8) Standards of Practice for Nurse Practitioners;

(9) Scope of Practice for Nurse Practitioners;

(10) Scope and Standards of Practice for the Acute Care Nurse Practitioner;

(11) Neonatal Nursing: Scope and Standards of Practice;

(12) Scope and Standards for Acute and Critical Care Clinical Nurse Specialist Practice; and

(13) Statement on the Scope and Standards of Advanced Practice Nursing in Oncology.

Section 3. In the performance of advanced practice registered nursing, the advanced practice registered nurse shall seek consultation or referral in those situations outside the advanced practice registered nurse's scope of practice.

Section 4. Advanced practice registered nursing shall include prescribing medications and ordering treatments, devices, and diagnostic tests which are consistent with the scope and standard of practice of the advanced practice registered nurse.

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

***CATEGORY D*:**
Undue prescription limitations

COMMENT: Requires use of a collaborative agreement with a physician.

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

COMMENT: Prescriptive authority for Schedule II controlled substances is specified in statutes.

2013

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

KENTUCKY

REGULATIONS

Nursing Board Regulations

(CONTINUED)

Section 10. Prescribing Standards for Controlled Substances from Schedule II and Schedule III Containing Hydrocodone. (1)(a) This section shall apply to an APRN with a CAPA-CS if prescribing a controlled substance from Schedule II or Schedule III controlled substance containing hydrocodone.

(b) The APRN shall practice according to the applicable scope and standards of practice for the APRN's role and population focus.

(2) This section shall not apply to:

(a) An APRN prescribing or administering a controlled substance immediately prior to, during, or within the fourteen (14) days following an operative or invasive procedure or a delivery if the prescribing or administering is medically related to the operative or invasive procedure or the delivery and the medication usage does not extend beyond the fourteen (14) days;

(b) An APRN prescribing or administering a controlled substance necessary to treat a patient in an emergency situation; or

(c) An APRN prescribing a controlled substance:

1. For administration in a hospital or long-term-care facility with an institutional account, or an APRN in a hospital or facility without an institutional account, if the hospital, long-term-care facility, or licensee queries KASPER for all available data on the patient or resident for the twelve (12) month period immediately preceding the query within twelve (12) hours of the patient's or resident's admission and places a copy of the query in the patient's or resident's medical records during the duration of the patient's stay at the facility;

2. As part of the patient's hospice or end-of-life treatment;

3. For the treatment of pain associated with cancer or with the treatment of cancer;

4. In a single dose to relieve the anxiety, pain, or discomfort experienced by a patient submitting to a diagnostic test or procedure;

5. Within seven (7) days of an initial prescribing pursuant to subsection (1) of this section if the prescribing or dispensing:

a. Is done as a substitute for the initial prescribing;

b. Cancels any refills for the initial prescription; and

c. Requires the patient to dispose of any remaining unconsumed medication;

6. Within ninety (90) days of an initial prescribing pursuant to subsection (1) of this section if the prescribing is done by another licensee in the same practice or in an existing coverage arrangement, if done for the same patient for the same medical condition; or

7. To a research subject enrolled in a research protocol approved by an institutional review board that has an active federal-wide assurance number from the United States Department of Health and Human Services, Office for Human Research Protections if the research involves single, double, or triple blind drug administration or is additionally covered by a certificate of confidentiality from the National Institutes of Health.

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KENTUCKY

REGULATIONS

Nursing Board Regulations

(CONTINUED)

(3) Prior to the initial prescribing of a Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone to a human patient, an APRN shall:

(a) Obtain a medical history and conduct a physical or mental health examination of the patient, as appropriate to the patient's medical complaint, and document the information in the patient's medical record;

(b) Query the electronic monitoring system established in *KRS 218A.202* for all available data on the patient for the twelve (12) month period immediately preceding the patient encounter and appropriately utilize that data in the evaluation and treatment of the patient;

(c) Make a written plan stating the objectives of the treatment and further diagnostic examinations required;

(d) Discuss the risks and benefits of the use of controlled substances with the patient, the patient's parent if the patient is an unemancipated minor child, or the patient's legal guardian or health care surrogate, including the risk of tolerance and drug dependence; and

(e) Obtain written consent for the treatment.

(4)(a) An APRN prescribing an additional amount of a Schedule II controlled substance or Schedule III controlled substance containing hydrocodone for the same medical complaint and related symptoms shall:

1. Review the plan of care at reasonable intervals based on the patient's individual circumstances and course of treatment;

2. Provide to the patient any new information about the treatment; and

3. Modify or terminate the treatment as appropriate.

(b) If the course of treatment extends beyond three (3) months, the licensee shall:

1. Query KASPER no less than once every three (3) months for all available data on the patient for the twelve (12) month period immediately preceding the query; and

2. Review that data before issuing any new prescription or refills for the patient for any Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone.

(5) For each patient for whom an APRN prescribes a Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone, the licensee shall keep accurate, readily accessible, and complete medical records, which include, as appropriate:

(a) Medical history and physical or mental health examination;

(b) Diagnostic, therapeutic, and laboratory results;

(c) Evaluations and consultations;

(d) Treatment objectives;

(e) Discussion of risk, benefits, and limitations of treatments;

(f) Treatments;

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

(h) Instructions and agreements; and

(i) Periodic reviews of the patient's file.

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure the clinical indication of such treatment and that opioids will not be used for non-medical purposes.

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

KENTUCKY

REGULATIONS

Nursing Board Regulations

201 KAR 20:215

201 KAR 20:215. Continuing competency requirements.

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Section 5. (1) Registered nurses and licensed practical nurses shall earn a minimum of two (2) contact hours of HIV/AIDS education:

(a) Approved by the Cabinet for Health and Family Services pursuant to *KRS 214.610*; or

(b) Offered by a provider approved pursuant to *201 KAR 20:220*.

(c) These contact hours shall be earned at least one (1) time every ten (10) years.

(2)(a) Advanced practice registered nurses shall earn a minimum of five (5) contact hours in pharmacology.

(b) Advanced practice registered nurses with a Collaborative Agreement for Advanced Practice Registered Nurse's Prescriptive Authority for Controlled Substances (CAPA-CS) shall earn, as a part of the requirement of paragraph (a) of this subsection, at least one and one-half (1.5) contact hours related to the use of the KASPER system, pain management, or addiction disorders.

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

CATEGORY A:
Issues related to healthcare professionals

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

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

LOUISIANA

STATUTES

- Nurse Practice Act
  Louisiana Revised Statutes; Title 37. Professions and Occupations; Chapter 11. Nurses

REGULATIONS

- Nursing Board Regulations
  Title 46. Professional and Occupational Standards; Part XLVII. Nurses: Practical Nurses and Registered Nurses

OTHER GOVERNMENTAL POLICIES

No policies found

LOUISIANA

STATUTES

Nurse Practice Act

La. R.S. 37:913

§ 37:913. Definitions

As used in this Part:

(1) "Advanced practice registered nurse" or "APRN" means a licensed registered nurse who is certified by a nationally recognized certifying body, such as the American Nurses Credentialing Center, as having an advanced nursing specialty as described in this Part and who meets the criteria for an advanced practice registered nurse as established by the board. In the absence of the availability of a national certification examination in a selected clinical area, the board may establish commensurate requirements. An advanced practice registered nurse shall include, but not be limited to, the following:

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(3) (a) "Advanced practice registered nursing" means nursing by a certified registered nurse anesthetist, certified nurse midwife, clinical nurse specialist, or nurse practitioner which is based on knowledge and skills acquired in a basic nursing education program, licensure as a registered nurse, and a minimum of a master's degree with a concentration in the respective advanced practice nursing specialty which includes both didactic and clinical components, advanced knowledge in nursing theory, physical and psychosocial assessment, nursing interventions, and management of health care. Advanced practice registered nursing includes:

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

(b) Advanced practice registered nursing may include certain acts of medical diagnosis, in accordance with R.S. 37:913(8) and (9), or medical prescriptions of therapeutic or corrective nature, prescribing assessment studies, legend and certain controlled drugs, therapeutic regimens, medical devices and appliances, receiving and distributing a therapeutic regimen of prepackaged drugs prepared and labeled by a licensed pharmacist, and free samples supplied by a drug manufacturer, and distributing drugs for administration to and use by other individuals within the scope of practice as defined by the board and in accordance with this Paragraph.

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(7) "Collaboration" means a cooperative working relationship with licensed physicians, dentists, or other health care providers to jointly contribute to providing patient care and may include but not be limited to discussion of a patient's diagnosis and cooperation in the management and delivery of health care with each provider performing those activities that he is legally authorized to perform.

(8) "Collaborative practice" means the joint management of the health care of a patient by an advanced practice registered nurse performing advanced practice registered nursing and one or more consulting physicians or dentists. Except as otherwise provided in *R.S. 37:930*, acts of medical diagnosis and prescription by an advanced practice registered nurse shall be in accordance with a collaborative practice agreement.

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

***CATEGORY D*:**
Undue prescription limitations

COMMENT: Requires use of a collaborative agreement with a physician.

2013

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University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

LOUISIANA

REGULATIONS

Nursing Board Regulations

LAC 46:XLVII.4513

§ 4513. Authorized Practice

A. Collaboration is a process in which an APRN has a relationship with one or more physicians or dentists to deliver health care services. Such collaboration is to be evidenced by the APRN scope of practice and indicates the relationships that they have with physicians or dentists to deal with issues outside their scope of practice.

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D. Prescriptive and Distributing Authority. An Advanced Practice Registered Nurse (APRN) shall practice in a manner consistent with the definition of advanced practice set forth in R.S. 37:913(3). An APRN may be granted prescriptive authority to prescribe assessment studies, including pharmaceutical diagnostic testing (e.g., dobutamine stress testing) legend and certain controlled drugs, therapeutic regimens, medical devices and appliances, receiving and distributing a therapeutic regimen of prepackaged drugs prepared and labeled by a licensed pharmacist, and free samples supplied by a drug manufacturer, and distributing drugs for administration to and use by other individuals within the scope of practice as defined by the board in R.S. 37.913(3)(b).

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b. Controlled Substances. The board may authorize an APRN with prescriptive authority to prescribe or distribute controlled substances as defined, enumerated or included in federal or state statutes or regulations 21 C.F.R.1308.11-15., R.S 40:964, on an individual practice basis An APRN who is so authorized shall provide their Drug Enforcement Administration registration number on all written prescriptions and be furnished on all oral prescriptions and shall comply with all scheduled drug prescription requirements in accordance with LAC 46:LIII.2511:

i. an APRN granted authority to prescribe or distribute controlled substances shall not utilize such substances in connection with the treatment of:

(a). chronic or intractable pain, as defined in LAC 46:XLV.6515-6923;

(b). obesity, as defined in LAC 46:XLV.6901- 6913; or

(c). oneself, a spouse, child or any other family member;

ii. any APRN authorized to prescribe controlled substances shall provide to the board a copy of his or her Louisiana Controlled Dangerous Substance permit and Drug Enforcement Administration registration number prior to prescribing or distributing controlled substances;

iii. controlled substances which may be prescribed by an APRN shall include Schedule III, IV and V. Schedule II shall be approved by the board on an individual basis. Controlled substances shall be limited to, consistent with, and exclusively within the parameters of the practice specialty of the collaborating physician and in the APRN's licensed category and area of specialization. The APRN must have been approved by the board to prescribe and distribute noncontrolled substances. The applicant must submit a collaborative practice agreement that clearly states that the controlled substances prescribed have been jointly agreed upon with the collaborating physician;

iv. the APRN must submit a collaborative practice agreement which delineates controlled substances utilization, which specifies the circumstances, limitations and extent to which such substances may be prescribed or distributed;

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

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

***CATEGORY D*:**
Undue prescription limitations

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

***CATEGORY D*:**
Undue prescription limitations

COMMENT: Requires use of a collaborative agreement with a physician.

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University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

MAINE

STATUTES

- Nurse Practice Act
  Title 32. Professions and Occupations; Chapter 31. Nurses and Nursing

REGULATIONS

- Nursing Board Regulations
  Agency 02. Department of Professional and Financial Regulation;
  Sub-Agency 380. Board of Nursing

OTHER GOVERNMENTAL POLICIES

No policies found

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

MAINE

STATUTES

Nurse Practice Act

32 M.R.S. § 2102

§ 2102. Definitions

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2-A. ADVANCED PRACTICE REGISTERED NURSING. "Advanced practice registered nursing" means the delivery of expanded professional health care by an advanced practice registered nurse that is:

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A certified nurse practitioner or a certified nurse midwife who qualifies as an advanced practice registered nurse may prescribe and dispense drugs or devices, or both, in accordance with rules adopted by the board.

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

COMMENT: Prescriptive authority for Schedule II controlled substances is specified in regulations.

REGULATIONS

Nursing Board Regulations

CMR 02-380-008

02 380 008. REGULATIONS RELATING TO ADVANCED PRACTICE REGISTERED NURSING

Summary: This chapter identifies the role of a registered professional nurse in advanced practice registered nursing; implements the Board's authority to approve the credentials for practice as a certified nurse practitioner, certified nurse-midwife, certified registered nurse anesthetist, and certified clinical nurse specialist; delineates the scope of practice; and implements the Board's authority to grant prescriptive authority.

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Section 7. Formulary for Certified Nurse Practitioners and Certified Nurse-Midwives with Prescriptive Authority.

1. General regulations relating to the formulary

A. Certified nurse practitioners and certified nurse-midwives are authorized to prescribe the following:

(1) over-the-counter drugs
(2) appliances and devices
(3) drugs related to the specialty area of certification.
(4) drugs prescribed off label according to common and established standards of practice.

B. Regardless of the schedules indicated on the certificate issued by the Drug Enforcement Administration, the certified nurse practitioner and certified nurse-midwife shall prescribe only those controlled drugs from schedules II, III, IIIN, IV, and V. A Drug Enforcement Agency (D.E.A.) number is required to prescribe these Drugs.

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

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Madison, Wisconsin

MARYLAND

STATUTES

- Nurse Practice Act
  Health Occupations; Title 8. Nurses

REGULATIONS

- Nursing Board Regulations
  Title 10. Department of Health and Mental Hygiene; Subtitle 27. Board of Nursing

OTHER GOVERNMENTAL POLICIES

No policies found

MARYLAND

STATUTES

Nurse Practice Act

Md. HEALTH OCCUPATIONS Code Ann. § 8-508

§ 8-508. Preparation and dispensing of drugs by nurse practitioners

(a) Definitions. --

(1) In this section the following words have the meanings indicated.

(2) "Nurse practitioner" means a registered nurse who is:

(i) Certified as a nurse practitioner; and

(ii) Authorized to prescribe drugs under regulations adopted by the State Board of Nursing.

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(4) Except for starter dosages or samples dispensed without charge, provide the patient with a written prescription, maintain prescription files, and maintain a separate file for Schedule II prescriptions for a period of at least 5 years.

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

REGULATIONS

Nursing Board Regulations

COMAR 10.27.07.02

.02 Nurse Practitioner--Scope and Standards of Practice.

A. A nurse practitioner may perform independently the following functions:

(1) A comprehensive physical assessment of patients;

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(6) In accordance with *Health General Article, § 13-704*, Annotated Code of Maryland, conduct education and training to certify individuals for the Insect Sting Emergency Treatment Program;

(7) Establish medical diagnosis for common short-term and chronic stable health problems;

(8) In accordance with *Health General Article, § 4-212*, Annotated Code of Maryland, file a replacement death certificate;

(9) In accordance with *Health General Article, § 5-601*, Annotated Code of Maryland, issue a do not resuscitate order on a Maryland Emergency Medical Services form.

(10) Order, perform, and interpret laboratory and diagnostic tests;

(11) Order and perform diagnostic, therapeutic, and corrective measures;

(12) Prescribe drugs;

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

COMMENT: Prescriptive authority for Schedule II controlled substances is specified in statutes.

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Madison, Wisconsin

MASSACHUSETTS

STATUTES

- Nurse Practice Act
  Part I. Administration of the Government; Title XVI. Public Health; Chapter 112. Registration of Certain Professions and Occupations

REGULATIONS

- Nursing Board Regulations
  Title 244. Board of Registration in Nursing

OTHER GOVERNMENTAL POLICIES

Massachusetts Board of Registration in Nursing. *Advisory Ruling on the Management of Pain*. Adopted: February 11, 2009; Revised: November 10, 2010.

MASSACHUSETTS

STATUTES

Nurse Practice Act

ALM GL ch. 112, § 80E

§ 80E. Nurse Practitioners or Psychiatric Nurse Mental Health Clinical Specialist; Ordering of Therapeutics and Tests; Issuance of Written Prescriptions.

A nurse practitioner or psychiatric nurse mental health clinical specialist may issue written prescriptions and order tests and therapeutics pursuant to guidelines mutually developed and agreed upon by the nurse and the supervising physician in accordance with regulations promulgated jointly by the board and the board of registration in medicine after consultation with the board of registration in pharmacy. A prescription made by a nurse practitioner or psychiatric nurse mental health clinical specialist shall include the name of the physician with whom such nurse has developed and signed mutually agreed upon guidelines approved by said board and said board of registration in medicine pursuant to section eighty B.

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

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

***CATEGORY D*:**
Undue prescription limitations

COMMENT: Requires formal collaborative practice and protocols with a physician.

2013

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

MASSACHUSETTS

REGULATIONS

Nursing Board Regulations

244 CMR 4.22

4.22: Development, Approval, and Review of Guidelines for Nurse Midwives, Nurse Practitioners and Nurse Anesthetists

(1) All nurses practicing in an expanded role (physician's office, institution or private practice) shall practice in accordance with written guidelines developed in collaboration with and mutually acceptable to the nurse and to:

(a) a physician expert by virtue of training or experience in the nurse's area of practice in the case of the nurse in the physician's office and the nurse in private practice; or

(b) the appropriate medical staff and nursing administration staff of the institution employing the nurse.

(2) In all cases the written guidelines shall designate a physician who shall provide medical direction as is customarily accepted in the specialty area. Guidelines may authorize the nurse's performance of any professional activities included within her area of practice. The guidelines shall:

(a) specifically describe the nature and scope of the nurse's practice;

(b) describe the circumstances in which physician consultation or referral is required;

(c) describe the use of established procedures for the treatment of common medical conditions which the nurse may encounter; and

(d) include provisions for managing emergencies.

(3) In addition to the requirements of 244 CMR 4.22(2), the guidelines pertaining to prescriptive practice shall:

(a) include a defined mechanism to monitor prescribing practices, including documentation of review with a supervising physician at least every three months;

(b) include protocols for the initiation of intravenous therapies and Schedule II drugs;

(c) specify the frequency of review of initial prescription of controlled substances; the initial prescription of Schedule II drugs must be reviewed within 96 hours; and

(d) conform to M.G.L. c. 94C, the regulations of the Department of Public Health at 105 CMR 700.000 et seq., and M.G.L. c. 112, §§ 80E or 80G, as applicable.

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

CATEGORY D:
Undue prescription limitations

COMMENT: Requires formal collaborative practice and protocols with a physician.

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

2013

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

MASSACHUSETTS

OTHER GOVERNMENTAL POLICY

Nursing Board Guideline

ADVISORY RULING ON THE MANAGEMENT OF PAIN
Advisory Ruling Number: 0901

Authority: The Massachusetts Board of Registration in Nursing issues this Advisory Ruling pursuant to Massachusetts General Laws (G.L.), chapter 30A, section 8.
Date Issued: February 11, 2009
Date Revised: November 10, 2010
Scope of Practice: Licensed Practical Nurse, Registered Nurse (RN) and Advanced Practice RN.

Purpose: To guide the practice of the Licensed Practical Nurse, Registered Nurse and Advanced Practice Registered Nurse in promoting patient access to the appropriate, therapeutic and effective assessment, diagnosis and management of acute and chronic pain. Such pain assessment and management serves 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 including non-treatment, under-treatment, over-treatment and the continued use of ineffective treatment.

Advisory: A nurse licensed by the Massachusetts Board of Registration in Nursing (Board) is responsible and accountable for engaging in the practice of nursing in accordance with accepted standards of care.

It is the Board's current position that these standards, in the context of appropriate, therapeutic and effective assessment, diagnosis and management of pain, include:

- development and implementation of a patient's pain management plan that is evidence-based and includes a comprehensive and on-going pain assessment, appropriate pharmacological and non-pharmacological modalities, and the substantiation of adequate symptom control;
- complete, accurate and legible entries in all appropriate patient or resident records required by federal and state laws and regulations, and accepted standards of care;
- the use, when appropriate, of controlled substances including opioid analgesics in the management of all pain types;
- interdisciplinary consultation and collaboration;
- recognition that tolerance and physical dependence are normal consequences of sustained use of opioids and are not synonymous with addiction: tolerance is a physiologic state resulting from regular use of a drug in which (a) an increased dosage is needed to produce a specific effect, or (b) a reduced effect is observed with a constant dose over time [i]; and 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 [ii];
- exercising sound professional judgment to recognize that pseudoaddiction may develop as a direct consequence of inadequate pain management and that pseudoaddiction can be distinguished from true addiction in that inappropriate drug seeking behaviors resolve when pain is effectively treated;
- recognition that patients with chemical dependency may require specialized pain management involving controlled substances including opioids [iii];
- recognition that a patient who suffers from extreme pain or disease progression may require increased doses of pain medication and that the appropriate dose is the dose required to effectively manage the patient's pain in that particular circumstance;
- adherence to system safe-guards that are designed to minimize the potential for abuse and diversion when controlled substances are used;
- acceptance of patient self-determination and autonomy;
- culturally sensitive patient, family/significant other, and/or caregiver education.

(CONTINUED ON NEXT PAGE)

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

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

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

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

CATEGORY B:
Issues related to patients

COMMENT:
Acknowledges 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 A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should 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: Recognizes the need for a multidisciplinary approach to pain management.

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for nurses the important distinction between drug-seeking behaviors resulting from poorly treated pain (i.e., pseudoaddiction) and drug-seeking behaviors related to abuse or addiction; this language identifies a potential clinical situation and attempts to lessen its impact on patient treatment.

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University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

MASSACHUSETTS

OTHER GOVERNMENTAL POLICY

Nursing Board Guideline

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

(CONTINUED)

The nurse is also responsible and accountable for acquiring and maintaining the knowledge, skills and abilities necessary to practice in accordance with accepted standards of care for pain management. Such competencies may be acquired through basic, graduate or continuing education programs [iv], as appropriate to the nurse's scope of practice. These competencies include, but are not limited to, knowledge of the current federal and state laws and regulations for the prescription, dispensing, administration and destruction of controlled substances, current evidence-based guidelines developed by nationally recognized professional organizations in the assessment and management of pain, and the use of pharmacological and non-pharmacological modalities (e.g. heat and cold therapies).

The Advanced Practice RN with prescriptive authority, pursuant to M.G.L. Chapter 94C, Section 18(e), must in addition to acquiring and maintaining the knowledge, skills and abilities necessary to practice in accordance with accepted standards of care for pain management, must complete appropriate education [v] in the following concepts prior to initial Board authorization to practice in the advanced role, and subsequently, during each renewal period.

1. Effective pain management,
2. Identification of patients at high risk for substance abuse, and
3. Counseling patients about the side effects and addictive nature of controlled substances, and proper storage and disposal of prescription medications.

[i] Adopted by the Federation of State Medical Boards of the United States from the Definitions Related to the Use of Opioids for the Treatment of Pain: A Consensus Document of the American Academy of Pain Medicine, the American Pain Society and the American Society of Addiction Medicine (2001). Available at http://www.painmed.org/pdf/definition.pdf.

[ii] Adopted by the Federation of State Medical Boards of the United States from the Definitions Related to the Use of Opioids for the Treatment of Pain: A Consensus Document of the American Academy of Pain Medicine, the American Pain Society and the American Society of Addiction Medicine (2001). Available at http://www.painmed.org/pdf/definition.pdf.

[iii] In the event the patient with chemical dependency is a licensee of the Board who is enrolled in the Board's substance abuse rehabilitation program, the specialized pain management plan may be developed in collaboration Board's substance abuse rehabilitation program.

[iv] Continuing education programs developed in accordance with 244 CMR 5.00.

[v] Continuing education programs developed in accordance with 244 CMR 5.00.

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MICHIGAN

STATUTES

- Nurse Practice Act *(No provisions found)*
  Chapter 333. Health; Act 368 of 1978. Public Health Code; Article 15. Occupations; Part 172. Nursing

REGULATIONS

- Medical Board Regulations
  Department of Community Health; Director's Office; Medicine – General Rules

- Nursing Board Regulations
  Department of Consumer and Industry Services; Director's Office; Board of Nursing – General Rules

OTHER GOVERNMENTAL POLICIES

Michigan Board of Nursing. *Guidelines for the Use of Controlled Substances for the Treatment of Pain*. Adopted: na.

MICHIGAN

REGULATIONS

Medical Board Regulations

MICH. ADMIN. CODE R 338.2305

R 338.2305 Delegation of prescribing of controlled substances to nurse practitioners or nurse midwives; limitation.

Rule 5.

(1) A physician may delegate the prescription of controlled substances listed in schedules 3 to 5 to a registered nurse who holds specialty certification under section 17210 of the code, with the exception of a nurse anesthetist, if the delegating physician establishes a written authorization that contains all of the following information:

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(5) A delegating physician may delegate the prescription of schedule 2 controlled substances only if all of the following conditions are met:

(a) The delegating physician and nurse practitioner or nurse midwife are practicing within a health facility as defined in section 20106(d), (g), or (i) of the code; specifically, freestanding surgical outpatient facilities, hospitals, and hospices.

(b) The patient is located within the facility described in subdivision (a) of this subrule.

(c) The delegation is in compliance with this rule.

(6) A delegating physician may not delegate the prescription of schedule 2 controlled substances issued for the discharge of a patient for a quantity for more than a 7-day period.

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

CATEGORY D:
Undue prescription limitations

COMMENT: Requires use of a collaborative agreement with a physician.

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

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

CATEGORY D:
Undue prescription limitations

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MICHIGAN

REGULATIONS

Nursing Board Regulations

MICH. ADMIN. CODE R 338.10601

R 338.10601 License renewals; relicensure; requirements; applicability.

Rule 1.

(1) This part applies to applications for renewal of a nursing license and applications for relicensure pursuant to 333.16201(3) that are filed 2 years or more after the effective date of these rules.

(2) An applicant for license renewal who has been licensed for the 2-year period immediately preceding the expiration date of the license or an applicant for relicensure shall accumulate not less than 25 continuing education contact hours that are approved by the board pursuant to these rules during the 2 years preceding an application for renewal or relicensure.

(a) An applicant for license renewal shall complete at least 1 continuing education contact hour in pain and pain symptom management in each renewal period. Continuing education contact hours in pain and pain symptom management may include, but are not limited to, courses in behavior management, psychology of pain, pharmacology, behavior modification, stress management, clinical applications, and drug interactions. This subrule will take effect with the April 1, 2005 renewal cycle.

(3) Submission of an application for renewal or relicensure shall constitute the applicant's certification of compliance with the requirements of this rule. A nurse shall retain documentation of meeting the requirements of this rule for a period of 4 years from the date of applying for license renewal or relicensure. Failure to comply with this rule is a violation of section 16221(g) of the act.

(+) *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.

Pain & Policy Studies Group
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Madison, Wisconsin

MICHIGAN

OTHER GOVERNMENTAL POLICY

Nursing Board Guideline

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

Section I: Preamble

The Michigan Board of Nursing recognizes that principles of quality nursing practice dictate that the people of the State of Michigan have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages nurses to view effective pain management as a part of quality nursing 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 nurses should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

Inadequate pain control may result from nurses' 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 uncertainty of nurses and to encourage better pain management.

The Board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. Nurses are referred to the U.S. Agency for Health Care and Research Clinical Practice Guidelines for a sound approach to the management of acute[1] and cancer-related pain.[2] The medical management of pain should be based on current knowledge and research and include the use of both pharmacologic and non-pharmacologic modalities. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Nurses should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.

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

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

1. Acute Pain Management Guideline Panel. Acute Pain Management: Operative or Medical Procedures and Trauma. *Clinical Practice Guideline*. AHCPR Publication No. 92-0032. Rockville, Md. Agency for Health Care Policy and Research. U.S. Department of Health and Human Resources, Public Health Service. February 1992.

2. Jacox A, Carr DB, Payne R, et al. Management of Cancer Pain. *Clinical Practice Guideline No. 9*. AHCPR Publication No. 94-0592. Rockville, Md. Agency for Health Care Policy and Research. U.S. Department of Health and Human Resources, Public Health Service. March 1994.

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies the potential impact of important barriers on the provision of effective pain care.

(+) *CRITERION 4:*
Encourages pain management

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

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

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MICHIGAN

OTHER GOVERNMENTAL POLICY

Nursing Board Guideline

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

(+) *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 the need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good health care practices.

(CONTINUED)

Nurses 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 and/or administration must be based on clear documentation of unrelieved pain and in compliance with applicable state or federal law.

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

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

Section II: Advanced Practice Nurse Guidelines

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

There are many effective treatments for pain; opioid analgesics play an important role, especially when pain is moderate to severe. For many patients, opioid analgesics—when used as recommended by established pain management guidelines are the most effective way to treat their pain, and are often the only treatment option that provides significant relief.

The following principles are not intended to define complete or best practice, but rather to communicate what the Michigan Board of Nursing considers to be within the boundaries of professional practice.

Principles
1. Assessment of the Patient:
A complete health history and physical examination must be conducted and documented in the health record.

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 indicate if any further diagnostic evaluation or other treatments are planned. After treatment begins, the drug therapy plan should be adjusted to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

(CONTINUED ON NEXT PAGE)

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

(+) *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 include improvements in patient functioning and quality of life.

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MICHIGAN

OTHER GOVERNMENTAL POLICY

Nursing Board Guideline

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

(CONTINUED)

3. Informed Consent:
The advanced practice nurse should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient, or with the patients surrogate or guardian if the patient is incompetent or a minor.

4. Agreement for Treatment of High-Risk Patients:
If the patient is determined to be at high risk for medication abuse or to have a history of substance abuse, or at the discretion of the prescriber, the advanced practice nurse will obtain a written agreement from the patient outlining patient responsibilities, including:

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

6. Consultation:
The advanced practice nurse should be willing to refer the patient for additional evaluation and treatment as necessary in order to achieve treatment goals.

5. Periodic Review:
At reasonable intervals based on the individual circumstances of the patient, the course of treatment and any new information about the etiology of the pain should be evaluated. The advance practice nurse involved with the management of pain should evaluate progress toward meeting treatment goals in light of improvement in the patients' pain intensity and improved physical or psychosocial function i.e., ability to work, use of health care resources, activities of daily living, quality of life. If treatment goals are not being achieved despite medication adjustments, the health care provider's should reevaluate and alter the treatment plan.

7. Medical Records: The advanced practice nurse should keep accurate and complete records to include:

- The medical history and physical examination including:
  a. The nature and intensity of the pain, including treatment for any underlying or coexisting conditions; and,
  b. Presence of one or more recognized medical indications for the use of a controlled substance.
- Diagnostic, therapeutic, and laboratory results.
- Evaluations and consultations.
- Treatment goals.
- Discussion of risks and benefits, including treatment contract, if one has been established.
- Treatments.
- Medications including date, type, dosage, and quantity prescribed.
- Instructions and agreements.
- Periodic reviews.

(CONTINUED ON NEXT PAGE)

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MICHIGAN

OTHER GOVERNMENTAL POLICY

Nursing Board Guideline

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for nurses the important distinction between drug-seeking behaviors resulting from poorly treated pain (i.e., pseudoaddiction) and drug-seeking behaviors related to abuse or addiction; this language identifies a potential clinical situation and attempts to lessen its impact on patient treatment.

(+) *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)

Section III: Nursing Principles of Pain Management

The Board has adopted the following principles when evaluating the use of controlled substances for pain management:

- All persons who are experiencing pain have the right to have their pain relieved to the greatest extent
- A person's self-report of pain is the optimal standard upon which all pain management interventions are
- A comprehensive nursing assessment includes the subjective description of pain, objective data, and the identified need for psychosocial/spiritual support.
- Fear of addiction to opioids and other pain medications should not be a barrier to pain management. Nurses recognize and apply the following concepts in the provision of care:
- Tolerance and physical dependence are consequences of sustained use of opioid analgesics and are not synonymous with addiction.
- Pseudo-addiction is a pattern of drug-seeking behavior by persons with pain who are fearful of receiving inadequate pain management. These behaviors may be mistaken for addiction.
- Continuity of care within and across health care settings is essential to effective pain management.
- Persons with a history of substance abuse have the right to adequate pain relief, even if opioids must be used. Such persons may require specialized care, treatment and a referral to an appropriate healthcare professional.
- An interdisciplinary approach to pain management is optimal.
- Pain management continues even if the person becomes unresponsive.

Section IV: Nursing Guidelines of Pain Management

Nurses are responsible for maintaining the knowledge and skills necessary to coordinate optimal pain management.

The nursing functions of appropriate pain management include:

- Ensuring the person or their legal representative actively participates in the treatment plan and understands the options available for pain relief and potential side effects.
- Educating persons and their families in a culturally competent manner regarding pain management.
- Using a standardized scale, to periodically assess and document a person's pain in accordance with institutional policies and procedures.
- Developing and implementing a plan of care that prevents and alleviates pain as much as possible.
- Administering medications and treatment as prescribed, using knowledge to maintain both safety and pain relief.
- Initiating non-pharmacological nursing interventions as indicated.
- Serving as an advocate to assure effective pain management.
- Communicating side effects or any reports of unrelieved pain to the prescriber and to appropriate team members.
- Documenting pain assessment, intervention, evaluation and ongoing changes to the plan of care in a clear and concise manner.

Consistent with the licensee's scope of practice, the RN or LPN is accountable for implementing the pain management plan utilizing his/her knowledge base and documented assessment of the person's needs. The nurse has the authority to adjust medication levels within the dosage and frequency ranges stipulated by the prescriber and according to the institutions established procedures. When pain is not controlled under the currently prescribed treatment plan, the nurse is responsible for reporting such findings to the prescriber and documenting the communication.

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

CATEGORY B:
Issues related to patients

COMMENT: Recognizes the patient's right to appropriate pain management.

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

CATEGORY A:
Issues related to healthcare professionals

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

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University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

MICHIGAN

OTHER GOVERNMENTAL POLICY

Nursing Board Guideline

(CONTINUED)

Section V: Definitions

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

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

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

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

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

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

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.

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MINNESOTA

STATUTES

- Nurse Practice Act
  Health; Chapter 148. Public Health Occupations; Nurses

REGULATIONS

- Nursing Board Regulations *(No provisions found)*
  Board of Nursing

OTHER GOVERNMENTAL POLICIES

See Joint Policy from the Minnesota profile in Section IX

Pain & Policy Studies Group
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Madison, Wisconsin

MINNESOTA

STATUTES

Nurse Practice Act

Minn. Stat. § 148.235

148.235 PRESCRIBING DRUGS AND THERAPEUTIC DEVICES

Subdivision 1. Certified nurse-midwives.

A certified nurse-midwife may prescribe and administer drugs and therapeutic devices within practice as a certified nurse-midwife.

Subd. 2. Certified nurse practitioners.

A certified nurse practitioner who has a written agreement with a physician based on standards established by the Minnesota Nurses Association and the Minnesota Medical Association that defines the delegated responsibilities related to the prescription of drugs and therapeutic devices, may prescribe and administer drugs and therapeutic devices within the scope of the written agreement and within practice as a certified nurse practitioner. The written agreement required under this subdivision shall be based on standards established by the Minnesota Nurses Association and the Minnesota Medical Association as of January 1, 1996, unless both associations agree to revisions.

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

***CATEGORY D*:**
Undue prescription limitations

COMMENT: Requires use of a collaborative agreement with a physician.

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

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MISSISSIPPI

STATUTES

- Nurse Practice Act
  Title 73. Professions and Vocations; Chapter 15. Nurses

REGULATIONS

- Nursing Board Regulations
  Agency 50. Regulatory Agencies; Sub-Agency 015. Board of Nursing

OTHER GOVERNMENTAL POLICIES

No policies found

MISSISSIPPI

STATUTES

Nurse Practice Act

§73-15-5.

§73-15-5. Definitions.

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(4) "Advanced nursing practice" means, in addition to the practice of professional nursing, the performance of advanced-level nursing approved by the board which, by virtue of graduate education and experience are appropriately performed by an advanced practice registered nurse. The advanced practice registered nurse may diagnose, treat, and manage medical conditions. This may include prescriptive authority as identified by the board. Advanced practice registered nurses must practice in a collaborative/consultative relationship with a physician or dentist with an unrestricted license to practice in the state of Mississippi and advanced nursing must be performed within the framework of a standing protocol or practice guidelines, as appropriate.

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

CATEGORY D:
Undue prescription limitations

COMMENT: Requires formal collaborative practice with a physician.

§73-15-20

§73-15-20. Advanced Practice Registered Nurses.

(1) Advanced practice registered nurses. Any nurse desiring to be certified as an advanced registered nurse practitioner shall apply to the board and submit proof that he or she holds a current license to practice professional nursing and that he or she meets one or more of the following requirements:

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8) Prescribing controlled substances and medications. Certified nurse midwives and certified nurse practitioners may apply for controlled substance prescriptive authority after completing a board approved educational program. Certified nurse midwives and certified nurse practitioners who have completed the program and received prescription authority from the board may prescribe Schedules II-V. The words "administer," "controlled substances," and "ultimate user," shall have the same meaning as set forth in Section 41-29-105, unless the context otherwise requires. The board shall promulgate rules governing prescribing of controlled substances, including distribution, record keeping, drug maintenance, labeling and distribution requirements and prescription guidelines for controlled substances and all medications. Prescribing any controlled substance in violation of the rules promulgated by the board shall constitute a violation of Section 73-15-29(1) (f), (k) and (l) and shall be grounds for disciplinary action. The prescribing, administering or distributing of any legend drug or other medication in violation of the rules promulgated by the board shall constitute a violation of Section 73-15-29(1)(f), (k) and (l) and shall be grounds for disciplinary action.

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

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Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

MISSISSIPPI

REGULATIONS

Board of Nursing Regulations

CMSR 50-015-001

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Part 2840
Advanced Practice

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Chapter 2. Advanced Practice Registered Nurses (APRNs) include Certified Nurse Midwives, Certified Registered Nurse Anesthetists, Certified Nurse Practitioners.

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Rule 2.3 Practice Requirements.

The APRN shall practice:

A. According to standards and guidelines of the national certification organization for which he/she are certified; and

B. In a collaborative/consultative relationship with a Mississippi licensed physician whose practice is compatible with that of the APRN. The APRN must be able to communicate reliably with a collaborating/consulting physician while practicing. CRNAs may also collaborate/consult with licensed dentists; and

C. According to a board-approved protocol or practice guidelines:

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2) APRNs practicing in other specialty areas must practice according to a board-approved protocol which has been mutually agreed upon by the APRN and a Mississippi licensed physician whose practice or prescriptive authority is not limited as a result of voluntary surrender or legal/regulatory order.

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Rule 2.4 Prescribing. Prescribing Controlled Substances and Medications by certified APRNs:

A. Scope.

These regulations apply to all individuals authorized to practice as a APRN in the State of Mississippi. Pursuant to these regulations, authorized certified APRNs may prescribe Schedules II, III, IV, or V. Application for this privilege requires an additional fee.

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

***CATEGORY D*:**
Undue prescription limitations

COMMENT: Requires formal collaborative practice with a physician.

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

2013

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Madison, Wisconsin

MISSOURI

STATUTES

- Medical Practice Act
  Title 22. Occupations and Professions; Chapter 334. Physician and Surgeons, Therapists, Athletic Trainers, Health Care Providers

- Nurse Practice Act *(No provisions found)*
  Title 22. Occupations and Professions; Chapter 335. Nurses

REGULATIONS

- Nursing Board Regulations
  Title 20. Department of Insurance, Financial Institutions and Professional Registration; Division 2200. State Board of Nursing

OTHER GOVERNMENTAL POLICIES

See Joint Policy from the Missouri profile in Section IX

MISSOURI

STATUTES

Medical Practice Act

§ 334.104 R.S.Mo.

§ 334.104. Collaborative practice arrangements, form, contents, delegation of authority--rules, approval, restrictions--disciplinary actions--notice of collaborative practice or physician assistant agreements to board, when--certain nurses may provide anesthesia services, when--contract limitations

1. A physician may enter into collaborative practice arrangements with registered professional nurses. Collaborative practice arrangements shall be in the form of written agreements, jointly agreed-upon protocols, or standing orders for the delivery of health care services. Collaborative practice arrangements, which shall be in writing, may delegate to a registered professional nurse the authority to administer or dispense drugs and provide treatment as long as the delivery of such health care services is within the scope of practice of the registered professional nurse and is consistent with that nurse's skill, training and competence.

2. Collaborative practice arrangements, which shall be in writing, may delegate to a registered professional nurse the authority to administer, dispense or prescribe drugs and provide treatment if the registered professional nurse is an advanced practice registered nurse as defined in subdivision (2) of section 335.016, RSMo. Collaborative practice arrangements may delegate to an advanced practice registered nurse, as defined in section 335.016, RSMo, the authority to administer, dispense, or prescribe controlled substances listed in Schedules III, IV, and V of section 195.017, RSMo; except that, the collaborative practice arrangement shall not delegate the authority to administer any controlled substances listed in schedules III, IV, and V of section 195.017, RSMo, for the purpose of inducing sedation or general anesthesia for therapeutic, diagnostic, or surgical procedures. Schedule III narcotic controlled substance prescriptions shall be limited to a one hundred twenty-hour supply without refill. Such collaborative practice arrangements shall be in the form of written agreements, jointly agreed-upon protocols or standing orders for the delivery of health care services.

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

***CATEGORY A*:**
Arbitrary standards for legitimate prescribing

COMMENT: No prescriptive authority for controlled substances is specified.

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

***CATEGORY D*:**
Undue prescription limitations

COMMENT: Requires formal collaborative practice with a physician.

REGULATIONS

Nursing Board Regulations

20 CSR 2200-4.100

2200-4.100 Advanced Practice Registered Nurse

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(G) Certificate of controlled substance prescriptive authority--Eligibility granted by the Missouri State Board of Nursing (MSBN) to an APRN to apply with the Missouri Bureau of Narcotics and Dangerous Drugs (BNDD) and the federal Drug Enforcement Agency (DEA) for authority to prescribe controlled substances from Schedules III--V as delegated in a collaborative practice arrangement between a collaborating physician and a collaborating APRN.

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

***CATEGORY A*:**
Arbitrary standards for legitimate prescribing

COMMENT: No prescriptive authority for controlled substances is specified.

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

***CATEGORY D*:**
Undue prescription limitations

COMMENT: Requires formal collaborative practice with a physician.

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Madison, Wisconsin

MONTANA

STATUTES

- Nurse Practice Act
  Title 37. Professions and Occupations; Chapter 8. Nursing

REGULATIONS

- Nursing Board Regulations
  Title 24. Labor and Industry; Chapter 159. Nursing

OTHER GOVERNMENTAL POLICIES

See Joint Policy from the Montana profile in Section IX

MONTANA

STATUTES

Nurse Practice Act

Mont. Code Anno., § 37-8-202

37-8-202 Organization -- meetings -- powers and duties.

(1) The board shall:

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(h) adopt rules regarding authorization for prescriptive authority of advanced practice registered nurses. If considered appropriate for an advanced practice registered nurse who applies to the board for authorization, prescriptive authority must be granted.

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

REGULATIONS

Nursing Board Regulations

MONT. ADMIN. R. 24.159.1461

24.159.1461 PRESCRIPTIVE AUTHORITY FOR ELIGIBLE APRNS

(1) Only an APRN granted prescriptive authority by the board may prescribe, procure, administer, and dispense legend drugs and controlled substances pursuant to applicable state and federal laws within the APRN's role and population focus.

(2) Prescriptive authority permits the APRN to receive, sign for, record, and distribute pharmaceutical samples to patients in accordance with applicable state and federal Drug Enforcement Administration laws, regulations, and guidelines in accordance with 37-2-104, MCA.

(3) All APRNs who hold an unencumbered license and meet the qualifications for prescriptive authority within ARM 24.159.1463 may hold prescriptive authority.

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

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Madison, Wisconsin

NEBRASKA

STATUTES

- Nurse Practice Act
  Title 38. Health Occupations and Professions
  Article 2. Advanced Practice Registered Nurse Practice Act
  Article 23. Nurse Practitioner Practice Act

REGULATIONS

- Nursing Board Regulations
  Title 172. Professional and Occupational Licensure (Department of Health and Human Services)

OTHER GOVERNMENTAL POLICIES

No policies found

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NEBRASKA

STATUTES

Nurse Practice Act

R.R.S. Neb. § 38-2310

§ 38-2310. Integrated practice agreement, defined.

(1) Integrated practice agreement means a written agreement between a nurse practitioner and a collaborating physician in which the nurse practitioner and the collaborating physician provide for the delivery of health care through an integrated practice. The integrated practice agreement shall provide that the nurse practitioner and the collaborating physician will practice collaboratively within the framework of their respective scopes of practice. Each provider shall be responsible for his or her individual decisions in managing the health care of patients. Integrated practice includes consultation, collaboration, and referral.

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R.R.S. Neb. § 38-2315

§ 38-2315. Nurse practitioner; functions; scope.

(1) A nurse practitioner may provide health care services within specialty areas. A nurse practitioner shall function by establishing collaborative, consultative, and referral networks as appropriate with other health care professionals. Patients who require care beyond the scope of practice of a nurse practitioner shall be referred to an appropriate health care provider.

(2) Nurse practitioner practice means health promotion, health supervision, illness prevention and diagnosis, treatment, and management of common health problems and acute and chronic conditions, including:

(a) Assessing patients, ordering diagnostic tests and therapeutic treatments, synthesizing and analyzing data, and applying advanced nursing principles;

(b) Dispensing, incident to practice only, sample medications which are provided by the manufacturer and are provided at no charge to the patient; and

(c) Prescribing therapeutic measures and medications relating to health conditions within the scope of practice. Any limitation on the prescribing authority of the nurse practitioner for controlled substances listed in Schedule II of *section 28-405* shall be recorded in the integrated practice agreement established pursuant to *section 38-2310*.

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

CATEGORY D:
Undue prescription limitations

COMMENT: Requires use of a collaborative agreement with a physician.

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

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NEBRASKA

REGULATIONS

Nursing Board Regulations

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

COMMENT: Prescribing authority for Schedule II controlled substances is granted by the referenced statutes.

Nebraska Admin. Code Title 172, Ch. 100

CHAPTER 100. REGULATIONS GOVERNING THE PRACTICE OF ADVANCED REGISTERED NURSE PRACTITIONERS

100-001 SCOPE AND AUTHORITY. These regulations govern the practice of advanced practice registered nurses in the State of Nebraska. The statutory authority for these regulations is Neb. Rev. Stat. " 71-147 to 71-148, 71-150 to 71-162.05, 71-164.01, 71-172.02, 71-1,132.20, and 71-1704 to 71-1726.02.

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100-005 REQUIREMENTS PRIOR TO COMMENCING PRACTICE

100-005.01 An APRN may not practice in an advanced role until s/he meets the following requirements:

1. Current licensure or temporary permit as an APRN issued by the Department;

2. Liability insurance of $ 200,000 per incident and $ 600,000 aggregate per year;

3. An Integrated Practice Agreement with a collaborating physician;

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

***CATEGORY D*:**
Undue prescription limitations

COMMENT: Requires use of a collaborative agreement with a physician.

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Madison, Wisconsin

NEVADA

STATUTES

- Nurse Practice Act
  Title 54. Professions, Occupations and Businesses; Chapter 632. Nursing

REGULATIONS

- Nursing Board Regulations
  Chapter 632. Nursing

OTHER GOVERNMENTAL POLICIES

No policies found

Pain & Policy Studies Group
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Madison, Wisconsin

NEVADA

STATUTES

Nurse Practice Act

Nev. Rev. Stat. Ann. § 632.237

632.237. Advanced practitioner of nursing: Certificate of recognition; regulations.

1. The board may issue a license to practice as an advanced practice registered nurse to a registered nurse who has completed an educational program designed to prepare a registered nurse to:

(a) Perform designated acts of medical diagnosis;

(b) Prescribe therapeutic or corrective measures; and

(c) Prescribe controlled substances, poisons, dangerous drugs and devices, and who meets the other requirements established by the board for such certification.

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3. An advanced practice registered nurse who is authorized to prescribe controlled substances, poisons, dangerous drugs and devices pursuant to NRS 639.2351 shall not prescribe a controlled substance listed in schedule II unless:

(a) The advanced practice registered nurse has at least 2 years or 2,000 hours of clinical experience; or

(b) The controlled substance is prescribed pursuant to a protocol approved by a collaborating physician.

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

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NEVADA

REGULATIONS

Nursing Board Regulations

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

NAC 632.257

632.257 Authorization to issue written prescriptions for controlled substances, poisons, dangerous drugs and devices. (NRS 632.120, 632.237)

1. An applicant for a certificate of recognition as an advanced practitioner of nursing will be authorized to issue written prescriptions for controlled substances, poisons, dangerous drugs and devices only if the applicant:

(a) Is authorized to do so by the Board;

(b) Submits an application for authority to issue written prescriptions for controlled substances, poisons, dangerous drugs or devices to the Board; and

(c) Has successfully completed:

(1) A program that complies with the requirements set forth in paragraph (a) of subsection 1 of *NAC 632.260* and includes an advanced course in pharmacotherapeutics; or

(2) A program of academic study that:

(I) Is approved by the Board;

(II) Consists of at least 2 semester credits or an equivalent number of quarter credits in advanced pharmacotherapeutics; and

(III) Is completed within the 2 years immediately preceding the date the application is submitted to the Board.

2. In addition to the information contained in the application for a certificate of recognition as an advanced practitioner of nursing, an applicant who completes, before June 1, 2005, a program designed to prepare an advanced practitioner of nursing and who does not hold a master's degree with a major in nursing or a related health field approved by the Board must, in his or her application for authority to write a prescription for controlled substances, poisons, dangerous drugs and devices, include documentation of 1,000 hours of active practice in the immediately preceding 2 years as an advanced practitioner of nursing under a collaborating physician. The documentation must consist of a signed statement from the collaborating physician indicating to the Board that the applicant is competent to prescribe those classes of drugs listed in his or her protocols.

3. Except as otherwise provided in subsection 4, if an advanced practitioner of nursing who is authorized to prescribe certain controlled substances, poisons, dangerous drugs and devices changes his or her medical specialty, he or she must submit an application to the Board for authority to prescribe those controlled substances, poisons, dangerous drugs and devices which are currently within the standard of medical practice in that specialty. In addition to the information contained in an application submitted pursuant to this subsection, an advanced practitioner of nursing who completes, before June 1, 2005, a program designed to prepare an advanced practitioner of nursing and who does not hold a master's degree with a major in nursing or a related health field approved by the Board must include in his or her application documentation of 1,000 hours of active practice in the new medical specialty as an advanced practitioner of nursing under a collaborating physician.

4. An advanced practitioner of nursing who:

(a) Is authorized to prescribe certain controlled substances, poisons, dangerous drugs and devices; and

(b) Changes his or her medical specialty to a medical specialty that is substantially similar to his or her former medical specialty, is not required to submit to the Board the application required pursuant to subsection 3 if the Board has authorized him or her to prescribe controlled substances, poisons, dangerous drugs and devices in the practice of his or her former medical specialty.

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Madison, Wisconsin

NEW HAMPSHIRE

STATUTES

- Nurse Practice Act
  Title XXX. Occupations and Professions; Chapter 326. Nurses

REGULATIONS

- Nursing Board Regulations *(No provisions found)*
  Agency Nur. Board of Nursing

OTHER GOVERNMENTAL POLICIES

No policies found

NEW HAMPSHIRE

STATUTES

Nurse Practice Act

RSA 326-B:11

326-B:11 Scope of Practice and Authority; Advanced Practice Registered Nurse.

I. Advanced practice registered nursing by nurse practitioners shall consist of a combination of knowledge and skills acquired in basic nursing education. The APRN scope of practice, with or without compensation or personal profit, shall be limited to:

(a) Performing acts of advanced assessment, diagnosing, prescribing, selecting, administering, and providing therapeutic measures and treatment regimes;

(b) Obtaining consultation, planning, and implementing collaborative management, referral, or transferring the care of the client as appropriate; and

(c) Providing such functions common to a nurse practitioner for which the APRN is educationally and experientially prepared and which are consistent with standards established by a national credentialing or certification body recognized by the National Council of State Boards of Nursing and approved by the board in the appropriate APRN role and specialty.

II. An APRN shall practice within standards consistent with standards established by a national credentialing or certification body recognized by the National Council of State Boards of Nursing and approved by the board in the appropriate APRN role and specialty. The board shall not approve a new advanced practice specialty category that has not been developed by a national credentialing or certifying body recognized by the National Council of State Board of Nursing without approval of the legislature under *RSA 332-G:6*. Each APRN shall be accountable to clients and the board:

(a) For complying with this chapter and the quality of advanced nursing care rendered;

(b) For recognizing limits of knowledge and experience and planning for the management of situations beyond the APRN's expertise; and

(c) For consulting with or referring clients to other health care providers as appropriate.

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

III. An APRN shall have plenary authority to possess, compound, prescribe, administer, and dispense and distribute to clients controlled and non-controlled drugs within the scope of the APRN's practice as defined by this chapter. Such authority may be denied, suspended, or revoked by the board after notice and the opportunity for hearing, upon proof that the authority has been abused.

IV. Any expansion of the scope of practice shall be adopted by legislation in accordance with *RSA 332-G:6*.

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Madison, Wisconsin

NEW JERSEY

STATUTES

- Nurse Practice Act
  Title 45. Professions and Occupations; Subtitle 1. Professions and Occupations Subject to State Boards of Registration and Examination; Chapter 11. Nurses

REGULATIONS

- Nursing Board Regulations
  Title 13. Law and Public Safety; Chapter 37. New Jersey Board of Nursing

OTHER GOVERNMENTAL POLICIES

No policies found

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NEW JERSEY

STATUTES

Nurse Practice Act

N.J. Stat. § 45:11-49

§ 45:11-49. Permitted duties of advanced practice nurse

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c. An advanced practice nurse may prescribe medications and devices in all other medically appropriate settings, subject to the following conditions:

(1) the collaborating physician and advanced practice nurse shall address in the joint protocols whether prior consultation with the collaborating physician is required to initiate a prescription for a controlled dangerous substance;

(2) the prescription is written in accordance with standing orders or joint protocols developed in agreement between a collaborating physician and the advanced practice nurse, or pursuant to the specific direction of a physician;

(3) the advanced practice nurse writes the prescription on a New Jersey Prescription Blank pursuant to P.L. 2003, c. 280 (*C. 45:14-40* et seq.), signs his name to the prescription and prints his name and certification number;

(4) the prescription is dated and includes the name of the patient and the name, address and telephone number of the collaborating physician;

(5) the physician is present or readily available through electronic communications;

(6) the charts and records of the patients treated by the advanced practice nurse are periodically reviewed by the collaborating physician and the advanced practice nurse;

(7) the joint protocols developed by the collaborating physician and the advanced practice nurse are reviewed, updated and signed at least annually by both parties; and

(8) the advanced practice nurse has completed six contact hours of continuing professional education in pharmacology related to controlled substances, including pharmacologic therapy and addiction prevention and management, in accordance with regulations adopted by the New Jersey Board of Nursing. The six contact hours shall be in addition to New Jersey Board of Nursing pharmacology education requirements for advanced practice nurses related to initial certification and recertification of an advanced practice nurse as set forth in *N.J.A.C. 13:37-7.2* and *13:37-7.5*.

d. The joint protocols employed pursuant to subsections b. and c. of this section shall conform with standards adopted by the Director of the Division of Consumer Affairs pursuant to section 12 of P.L. 1991, c. 377 (*C. 45:11-51*) or section 10 of P.L. 1999, c. 85 (*C. 45:11-49.2*), as applicable.

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

(+) *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.

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

CATEGORY D:
Undue prescription limitations

COMMENT: Requires formal collaborative practice and protocols with a physician.

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Madison, Wisconsin

NEW JERSEY

REGULATIONS

Nursing Board Regulations

N.J.A.C. 13:37-1.8

§ 13:37-1.8 Maintaining accreditation: curriculum organization and content

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(f) The nursing curriculum of all professional nursing education programs shall include:

1. Content in the sciences, social sciences and humanities; and

2. Nursing courses and clinical experiences in a variety of settings that include:

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x. Pain management and end of life issues; and

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(g) The curriculum of a practical nursing education program shall:

1. Include content in the sciences and social sciences;

2. Contain nursing courses and clinical experiences that include:

i. The provision of supportive and restorative care under the direction of a registered professional nurse;

ii. Critical thinking;

iii. The nursing practice act, *N.J.S.A. 45:11-23* et seq., and Board rules, *N.J.A.C. 13:37*;

iv. Legal and ethical issues affecting licensed practical nursing practice and responsibilities;

v. Delegation from a registered professional nurse pursuant to *N.J.A.C. 13:37-6.2*, and delegation from a licensed physician or licensed dentist;

vi. Cultural implications of practice;

vii. Pain management and end of life issues; and

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N.J.A.C. 13:37-7.9

§ 13:37-7.9 Prescriptive practice

(a) An advanced practice nurse may prescribe or order medications and devices and shall do so in conformity with the provisions of this subchapter, *N.J.S.A. 45:11-45* et seq., and written protocols for the prescription of medications and devices jointly developed by the advanced practice nurse and the collaborating physician in accordance with the standards of *N.J.S.A. 45:11-51* and *N.J.A.C. 13:37-6.3*.

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

CATEGORY C:
Regulatory or policy issues

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

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

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

CATEGORY D:
Undue prescription limitations

COMMENT: Requires formal collaborative practice and protocols with a physician.

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Madison, Wisconsin

NEW MEXICO

STATUTES

- Nurse Practice Act
  Chapter 61. Professional and Occupational Licenses; Article 3. Nursing

REGULATIONS

- Nursing Board Regulations
  Title 16. Occupational and Professional Licensing; Chapter 12. Nursing and Health Care Related Providers

OTHER GOVERNMENTAL POLICIES

See Joint Policy from the New Mexico profile in Section IX

NEW MEXICO

STATUTES

Nurse Practice Act

N.M. Stat. Ann. § 61-3-23.2

§ 61-3-23.2. Certified nurse practitioner; qualifications; practice; examination; endorsement

A. The board may license for advanced practice as a certified nurse practitioner an applicant who furnishes evidence satisfactory to the board that the applicant:

(1) is a registered nurse;

(2) has successfully completed a program for the education and preparation of nurse practitioners; provided that if the applicant is initially licensed by the board or a board in another jurisdiction after January 1, 2001, the program shall be at the master's level or higher;

(3) has successfully completed the national certifying examination in the applicant's specialty area; and

(4) is certified by a national nursing organization.

B. Certified nurse practitioners may:

(1) perform an advanced practice that is beyond the scope of practice of professional registered nursing;

(2) practice independently and make decisions regarding health care needs of the individual, family or community and carry out health regimens, including the prescription and distribution of dangerous drugs and controlled substances included in Schedules II through V [*30-31-7 to 30-31-10 NMSA* 1978] of the Controlled Substances Act; and

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

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NEW MEXICO

REGULATIONS

Nursing Board Regulations

16.12.9-13.12.9.9 NMAC (et seq)

§ 16.12.9.6. OBJECTIVE

It is the position of the board that certified nurse practitioners, certified registered nurse anesthetists and clinical nurse specialists with prescriptive authority have an obligation to treat chronic pain and that a wide variety of medicines including controlled substances and other drugs may be prescribed after a thorough evaluation has been completed.

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

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

§ 16.12.9.7. DEFINITIONS

A. "Acute Pain" means the normal, predicted physiological response to a noxious chemical or thermal or mechanical stimulus, typically associated with invasive procedures, trauma or disease and generally time limited.

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

B. "Addiction" is a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects. It is characterized by behaviors that include one or more of the following: impaired control over drug use; compulsive use; continued use despite harm; and craving. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not by themselves be considered addiction.

C. "Chronic pain" means pain that persists after reasonable efforts have been made to relieve the pain or its cause and that continues, either continuously or episodically, for longer than three consecutive months. "Chronic pain" does not, for the purpose of the Pain Relief Act requirements, include pain associated with a terminal condition or with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition.

D. "Clinical expert" means a person who, by reason of specialized education or substantial relevant experience in pain management, has knowledge regarding current standards, practices and guidelines.

E. "Drug abuser" means a person who takes a drug or drugs for other then legitimate medical purposes.

F. "Pain" means an unpleasant sensory and emotional experience associated with inflammation or with actual or potential tissue damage, or described in terms of such inflammation and damage, which could include acute, persistent or chronic pain.

G. "Physical dependence" means a state of adaptation that is manifested by a drug-specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, administration of an antagonist, or a combination of these.

H. "Prescription monitoring program (PMP)" means a centralized system to collect, monitor, and analyze electronically, for controlled substances, prescribing and dispensing data submitted by pharmacies and dispensing practitioners. The data are used to support efforts in education, research, enforcement and abuse prevention.

I. "Therapeutic purpose" means the use of pharmaceutical and non-pharmaceutical treatments and the spectrum of available modalities that conforms substantially to accepted guidelines for pain management.

J. "Tolerance" means a state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drug's effects over time.

(CONTINUED ON NEXT PAGE)

Pain & Policy Studies Group
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Madison, Wisconsin

NEW MEXICO

REGULATIONS

Nursing Board Regulations

(CONTINUED)

§ 16.12.9.8. RULES

The following rules shall be used by the board to determine whether a health care practitioner's prescriptive practices are consistent with the appropriate treatment of pain.

A. The treatment of pain with various medicines or controlled substances is a legitimate nursing practice when accomplished in the usual course of professional practice. It does not preclude treatment of patients with addiction, physical dependence or tolerance who have legitimate pain. However, such patients do require very close monitoring and precise documentation.

B. Pain management for patients with substance use disorders should include a contractual agreement, the use of drug screens prior to treatment with opiates and during the course of treatment to identify actual drugs being consumed and to compare with patients self reports. If concerns about misuse are identified, the patient will be referred for appropriate consultation, and scheduled for re-evaluation at appropriate time intervals.

C. The prescribing, ordering, administering or dispensing of controlled substances to meet the individual needs of the patient for management of chronic pain is appropriate if prescribed, ordered, administered or dispensed in compliance with the following.

(1) A practitioner shall complete a history and physical examination and include an evaluation of the patient's psychological and pain status. The medical history shall include any previous history of significant pain, past history of alternate treatments for pain, potential for substances abuse, coexisting disease or medical conditions, and the presence of a medical indication or contra-indication against the use of controlled substances.

(2) A practitioner shall be familiar with and employ screening tools, as well as the spectrum of available modalities for therapeutic purposes, in the evaluation and management of pain. They shall consider an integrative approach to pain management specialists including but not limited to an acupuncturist, chiropractor, doctor of oriental medicine, exercise physiologist, massage therapist, pharmacist, physical therapist, psychiatrist, psychologist or other advanced practice registered nurse.

(3) A written treatment plan shall be developed and tailored to the individual needs of the patient, taking age, gender, culture, and ethnicity into consideration, with stated objectives by which treatment can be evaluated, e.g. by degree of pain relief, improved physical and psychological function, or other accepted measure. Such a plan should include a statement of the need for further testing, consultation, referral or use of other treatment modalities.

(4) The practitioner shall provide education and discuss the risks and benefits of using controlled substances with the patient or surrogate or guardian, and shall document this in the record.

(5) Complete and accurate records of care provided and drugs prescribed shall be maintained. When controlled substances are prescribed, the name of the drug, quantity, prescribed dosage and number of refills authorized should be recorded. Prescriptions for opioids shall include indications for use. For chronic noncancer pain patients treated with controlled substance analgesic(s), the prescribing practitioner shall use a written agreement for treatment with the patient outlining patient responsibilities. As part of a written agreement, chronic noncancer pain patients shall receive all chronic pain management prescriptions from one practitioner and one pharmacy whenever possible.

(CONTINUED ON NEXT PAGE)

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

CATEGORY A:
Issues related to healthcare professionals

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

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

NEW MEXICO

REGULATIONS

Nursing Board Regulations

(CONTINUED)

(6) The management of patients needing chronic pain control requires monitoring by the attending or the consulting practitioner. The practitioner shall periodically review the course of treatment for chronic noncancer pain, the patient's state of health, and any new information about the etiology of the chronic noncancer pain at least every six months. In addition, a practitioner should consult, when indicated by the patient's condition, with health care professionals who are experienced (by the length and type of their practice) in the area of chronic pain control; such professionals need not be those who specialize in pain control. Consultation should occur early in the course of long-term treatment, and at reasonable intervals during continued long-term treatment for assessment of benefit and need, at least every six months. Drug screening is recommended and should be conducted when other factors suggest an elevated risk of misuse or diversion.

(7) If, in a practitioner's opinion, a patient is seeking pain medication for reasons that are not medically justified, the practitioner is not required to prescribe controlled substances for the patient.

D. The board will evaluate the quality of care on the following basis: appropriate diagnosis and evaluation; appropriate medial indication for the treatment prescribed; documented change or persistence of the recognized medical indication; and, follow-up evaluation with appropriate continuity of care. The board will judge the validity of prescribing based on the practitioner'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.

E. The board will review both over-prescription and under-prescription of pain medications using the same standard of patient protection as a guiding principle.

F. A practitioner who appropriately prescribes controlled substances and who follows this section would be considered to be in compliance with this rule and not be subject to discipline by the board, unless there is some violation of the Nursing Practice Act, board rules and Pain Relief Act (24-2 D, 1 to 24-2 D, 6 NMSA 1978).

§ 16.12.9.9. PRESCRIPTION MONITORING PROGRAM (PMP) REQUIREMENTS

The intent of the NM board of nursing in requiring participation in the PMP is to assist practitioners in balancing the promotion of the safe use of controlled substances for the provision of nursing care and services with the need to impede illegal and harmful activities involving these pharmaceuticals.

A. A health care provider who holds a federal drug enforcement administration registration and licensure to prescribe opioids shall register with the board of pharmacy to become a regular participant in PMP inquiry and reporting.

B. Upon prescribing, ordering, administering or dispensing a controlled substance, the practitioner shall obtain and review a prescription monitoring report covering at least a one year time period or another state's report, where applicable and available. The practitioner shall be aware of a person currently:

(CONTINUED ON NEXT PAGE)

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

2013

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

NEW MEXICO

REGULATIONS

Nursing Board Regulations

(CONTINUED)

(1) receiving opiates from multiple prescribers;

(2) receiving opiates for more than twelve consecutive weeks;

(3) receiving more than one controlled substance analgesic;

(4) receiving a new prescription for any long-acting controlled substance analgesic formulation, including oral dosage forms and transdermal (e.g. fentanyl) or methadone;

(5) exhibiting potential for abuse or misuse of opiates (i.e. over-utilization, early refills, appears overly sedated or intoxicated upon presentation, or an unfamiliar patient requesting an opiate by specific name, street name, color, or identifying marks, or paying cash when the patient has prescription insurance).

C. Upon recognizing any of the above, the practitioner, using professional judgment, shall take appropriate steps to avoid or resolve the potential problem. These steps may include requesting and reviewing additional controlled substance prescription monitoring reports or another state's report if applicable and available, or consulting with a pain management specialist or addiction treatment specialist or counseling the patient, which may include termination of treatment. The practitioner shall document steps taken to resolve the potential problem, which may include termination from treatment.

D. After obtaining an initial prescription monitoring report on a patient, the practitioner shall use professional judgment based on prevailing standards of practice in deciding the frequency of requesting and reviewing further prescription monitoring reports or other state's report on that patient. Prescription monitoring reports shall be requested and reviewed a minimum of once every six months during the continuous use of opioids for each established patient. The practitioner shall document the review of these reports.

§ 16.12.9.10. NON-CANCER PAIN MANAGEMENT CONTINUING EDUCATION

Any health care provider with a DEA registration and licensure that permits prescribing opioids, shall obtain continuing education on the management of non-cancer pain. These practitioners shall be required to obtain five CE of the 15 CE currently required every two years in pharmacology to include a review of these rules (16.12.9 NMAC) for management of non-cancer pain, an understanding of the pharmacology and risks of controlled substances, a basic awareness of the problems of abuse, addiction and diversion, and awareness of state and federal regulations for the prescription of controlled substances.

§ 16.12.9.11. NOTIFICATION

The board shall notify the following persons of the Pain Relief Act and Part 9 of the New Mexico nursing board rule: 16.12.9 NMAC. The board shall notify the following persons of the Pain Relief Act and rules:

(1) health care providers under its jurisdiction; and

(2) a health care provider being investigated by the board in relation to the provider's pain management services.

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

CATEGORY C:
Regulatory or policy issues

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

(+) *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 practice governing pain management.

2013

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

NEW YORK

STATUTES

- Nurse Practice Act
  Education Law; Title VIII. The Professions; Article 139. Nursing

REGULATIONS

- Nursing Board Regulations
  Title 8. Education Department; Chapter II. Regulations of the Commissioner; Subchapter B. Regulation of Professions; Part 64. Nursing

OTHER GOVERNMENTAL POLICIES

No policies found

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

NEW YORK

STATUTES

Nurse Practice Act

NY CLS Educ § 6902

§ 6902. Definition of practice of nursing

1. The practice of the profession of nursing as a registered professional nurse is defined as diagnosing and treating human responses to actual or potential health problems through such services as casefinding, health teaching, health counseling, and provision of care supportive to or restorative of life and well-being, and executing medical regimens prescribed by a licensed physician, dentist or other licensed health care provider legally authorized under this title and in accordance with the commissioner's regulations. A nursing regimen shall be consistent with and shall not vary any existing medical regimen.

2. The practice of nursing as a licensed practical nurse is defined as performing tasks and responsibilities within the framework of casefinding, health teaching, health counseling, and provision of supportive and restorative care under the direction of a registered professional nurse or licensed physician, dentist or other licensed health care provider legally authorized under this title and in accordance with the commissioner's regulations.

3. (a) The practice of registered professional nursing by a nurse practitioner, certified under section six thousand nine hundred ten of this article, may include the diagnosis of illness and physical conditions and the performance of therapeutic and corrective measures within a specialty area of practice, in collaboration with a licensed physician qualified to collaborate in the specialty involved, provided such services are performed in accordance with a written practice agreement and written practice protocols. The written practice agreement shall include explicit provisions for the resolution of any disagreement between the collaborating physician and the nurse practitioner regarding a matter of diagnosis or treatment that is within the scope of practice of both. To the extent the practice agreement does not so provide, then the collaborating physician's diagnosis or treatment shall prevail.

(b) Prescriptions for drugs, devices and immunizing agents may be issued by a nurse practitioner, under this subdivision and section six thousand nine hundred ten of this article, in accordance with the practice agreement and practice protocols. The nurse practitioner shall obtain a certificate from the department upon successfully completing a program including an appropriate pharmacology component, or its equivalent, as established by the commissioner's regulations, prior to prescribing under this subdivision. The certificate issued under section six thousand nine hundred ten of this article shall state whether the nurse practitioner has successfully completed such a program or equivalent and is authorized to prescribe under this subdivision.

(c) Each practice agreement shall provide for patient records review by the collaborating physician in a timely fashion but in no event less often than every three months. The names of the nurse practitioner and the collaborating physician shall be clearly posted in the practice setting of the nurse practitioner.

(d) The practice protocol shall reflect current accepted medical and nursing practice. The protocols shall be filed with the department within ninety days of the commencement of the practice and may be updated periodically. The commissioner shall make regulations establishing the procedure for the review of protocols and the disposition of any issues arising from such review.

(e) No physician shall enter into practice agreements with more than four nurse practitioners who are not located on the same physical premises as the collaborating physician.

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

***CATEGORY D*:**
Undue prescription limitations

COMMENT: Requires formal collaborative practice and protocols with a physician.

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

2013

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

NEW YORK

REGULATIONS

Nursing Board Regulations

8 NYCRR § 64.4

§ 64.4 Nurse practitioner certification

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(e) Prescriptive privilege. An applicant who satisfies all requirements for certification as a nurse practitioner may be authorized to issue prescriptions pursuant to *section 6902(3)(b) of the Education Law* after completing instruction, satisfactory to the department, in New York State and Federal laws and regulations relating to prescriptions and recordkeeping.

8 NYCRR § 64.5

§ 64.5 Nurse practitioner practice

(a) Practice agreements and practice protocols shall be maintained in the practice setting of the nurse practitioner and collaborating physician and shall be available to the department for inspection.

(b) Practice agreements shall include provisions for referral and consultation, coverage for emergency absences of either the nurse practitioner or collaborating physician, resolution of disagreements between the nurse practitioner and collaborating physician regarding matters of diagnosis and treatment, and the review of patient records at least every three months by the collaborating physician; and may include such other provisions as determined by the nurse practitioner and collaborating physician to be appropriate.

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

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

***CATEGORY D*:**
Undue prescription limitations

COMMENT: Requires formal collaborative practice and protocols with a physician.

2013

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

NORTH CAROLINA

STATUTES

- Nurse Practice Act
  Chapter 90. Medicine and Allied Occupations; Article 9. Nurse Practice Act

REGULATIONS

- Nursing Board Regulations
  Title 21. Occupational Licensing Boards; Chapter 36. Board of Nursing

OTHER GOVERNMENTAL POLICIES

See Joint Policy from the North Carolina profile in Section IX

NORTH CAROLINA

STATUTES

Nurse Practice Act

N.C. Gen. Stat. § 90-171.20

§ 90-171.20. Definitions

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

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(7) The "practice of nursing by a registered nurse" consists of the following 10 components:

a. Assessing the patient's physical and mental health, including the patient's reaction to illnesses and treatment regimens.

b. Recording and reporting the results of the nursing assessment.

c. Planning, initiating, delivering, and evaluating appropriate nursing acts.

d. Teaching, assigning, delegating to or supervising other personnel in implementing the treatment regimen.

e. Collaborating with other health care providers in determining the appropriate health care for a patient but, subject to the provisions of *G.S. 90-18.2*, not prescribing a medical treatment regimen or making a medical diagnosis, except under supervision of a licensed physician.

f. Implementing the treatment and pharmaceutical regimen prescribed by any person authorized by State law to prescribe the regimen.

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

***CATEGORY D*:**
Undue prescription limitations

COMMENT: Requires formal collaborative practice with a physician.

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

2013

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

NORTH CAROLINA

REGULATIONS

Nursing Board Regulations

21 N.C.A.C. 36.0809

.0809 PRESCRIBING AUTHORITY

(a) The prescribing stipulations contained in this Rule apply to writing prescriptions and ordering the administration of medications.

(b) Prescribing and dispensing stipulations are as follows:

(1) Drugs and devices that may be prescribed by the nurse practitioner in each practice site shall be included in the collaborative practice agreement as outlined in Rule .0810(b) of this Section.

(2) Controlled Substances (Schedules II, IIN, III, IIIN, IV, V) defined by the State and Federal Controlled Substances Acts may be procured, prescribed or ordered as established in the collaborative practice agreement, providing all of the following requirements are met:

(A) the nurse practitioner has an assigned DEA number which is entered on each prescription for a controlled substance;

(B) dosage units for schedules II, IIN, III, and IIIN are limited to a 30 day supply; and

(C) the supervising physician(s) must possess the same schedule(s) of controlled substances as the nurse practitioner's DEA registration.

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

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

***CATEGORY D*:**
Undue prescription limitations

COMMENT: Requires use of a collaborative agreement with a physician.

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

***CATEGORY D*:**
Undue prescription limitations

2013

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University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

NORTH DAKOTA

STATUTES

- Nurse Practice Act
  Title 43. Occupations and Professions; Chapter 43-12.1. Nurse Practices Act

REGULATIONS

- Nursing Board Regulations
  Title 54. Board of Nursing

OTHER GOVERNMENTAL POLICIES

North Dakota Board of Nursing. *Role of the Nurse in Pain Management*. Adopted: May, 2006; Revised: November, 2010.

NORTH DAKOTA

STATUTES

Nurse Practice Act

N.D. Cent. Code, § 43-12.1-18

43-12.1-18. Nursing practice standards.

The board shall adopt rules establishing standards for nursing practice. Prescriptive practices must be consistent with the scope of practice of the advanced practice registered nurse.

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

COMMENT: Prescribing authority for Schedule II controlled substances is specified in regulations

REGULATIONS

Nursing Board Regulations

N.D. Admin. Code 54-05-03.1-03.2

54-05-03.1-03.2. Scope of practice as an advanced practice registered nurse.

1. Practice as an advanced practice registered nurse may include:

a. Perform a comprehensive assessment of clients and synthesize and analyze data within a nursing framework;

b. Identify, develop, plan, and maintain evidence-based, client-centered nursing care;

c. Prescribe a therapeutic regimen of health care, including diagnosing, prescribing, administering, and dispensing legend drugs and controlled substances;

d. Evaluate prescribed health care regimen;

e. Participate in nursing care management according to chapter 54-05-04 relating to standards for delegation and section 54-05-02-02.2 assigning of nursing interventions;

f. Promote a safe and therapeutic environment;

g. Provide health teaching and counseling to promote, attain, and maintain the optimum health level of clients;

h. Communicate and collaborate with the interdisciplinary team in the management of health care and the implementation of the total health care regimen;

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

2013

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Madison, Wisconsin

NORTH DAKOTA

OTHER GOVERNMENTAL POLICY

Nursing Board Statement

North Dakota: Role of the Nurse in Pain Management

PRACTICE STATEMENT

The North Dakota Board of Nursing seeks to safeguard the public's health and safety by providing guidance and regulation of the nursing profession including the profession's role in pain management. Accordingly, a balanced approach to pain management is required; one that addresses the potential for abuse without preventing clients from receiving the care they need and deserve. Therefore, the North Dakota Board of Nursing adopts this Practice Statement to assure health care providers, patients and their families that the policy of this Board supports, encourages, and expects competent comprehensive care for the treatment of pain.

Pain is one of the most common reasons clients seek medical attention, and is a symptom that is encountered by every health care provider. The American Pain Society estimates, 75 million people are partially or totally disabled by pain and 45% of all Americans seek care for persistent pain at some point in their lives. Health care professionals must be knowledgeable regarding effective and compassionate pain relief, while clients and their families should be assured such relief will be provided. Communication and collaboration between members of the healthcare team, the client and the family are essential in achieving adequate pain management. Ideally, the client directs the plan of care and the pain level to be achieved.

The North Dakota Nurse Practices Act Chapter 43-12.1, states that "Nursing" means the performance of acts utilizing specialized knowledge, skills, and abilities for people in a variety of settings, and includes providing supportive and restorative care and nursing treatment, medication administration, health counseling and teaching, for individuals experiencing changes in the normal health processes. The proper management of client's pain is a nursing function incorporated within the role of the nurse who is responsible and accountable for the care provided and for assuring the safety and well-being of the client (NDAC Chapter 54-05-02).

When adequate pain management is not achieved under the currently prescribed treatment plan, the nurse is responsible for reporting such findings to the prescriber and documenting this communication. Only the licensed health care practitioner with prescriptive authority may change the pharmaceutical management plan. According to the Nurse Practices Act, the nurse must act in "collaboration with other health care professionals in the implementation of the total health care regimen and execution of the health care regimen prescribed by a health care practitioner licensed under the laws of this state". (NDCC 43-12.1-2(5e).

RANGE DOSE ORDERS:
The nurse is often the health professional most involved in on-going pain assessment and implementing the pain management plan. The LPN may assist in the assessment, however the RN has the overall responsibility. In order to achieve adequate pain management, the RN and LPN must base decisions concerning the implementation of range dose orders based on a thorough pain assessment. Both the RN and LPN must be knowledgeable of the:

- medication to be administered,
- anticipated time of onset of the medication,
- time to peak effect, duration of action of the medication ,
- and side effects of the medication to be administered. (Gordon et al 2004)

Consistent with the licensee's scope of practice, both the RN and LPN is accountable for implementing the pain management plan including pharmacologic, non-pharmacologic and complimentary interventions utilizing their knowledge, skills and abilities and organization policy. (NDAC Section 54-05-01-03 & 54-05-02-03).

All nursing practice must meet the definitions of the law. The nurse's scope of practice is determined by the nurse's education, experience, knowledge, skills, and abilities. Each licensee is accountable for providing safe, effective care as well as utilizing ethical principles focused on optimum client care while taking all appropriate measure to relieve sufferina.

(+) *CRITERION 4:*
Encourages pain management

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes the need for a collaborative approach to 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.

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

2013

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University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

OHIO

STATUTES

- Nurse Practice Act
  Title 47. Occupations – Professions; Chapter 4723. Nurses

REGULATIONS

- Nursing Board Regulations
  4723. Ohio Board of Nursing

OTHER GOVERNMENTAL POLICIES

No policies found

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

OHIO

STATUTES

Nurse Practice Act

ORC Ann. 4723.48

§ 4723.48. Application for certificate to prescribe drugs and therapeutic devices

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(B) In the case of an applicant who on May 17, 2000, was approved to prescribe drugs and therapeutic devices under *section 4723.56 of the Revised Code*, as that section existed on that date, the initial certificate to prescribe that the board issues to the applicant under this section shall not be an externship certificate. The applicant shall be issued a certificate to prescribe that permits the recipient to prescribe drugs and therapeutic devices in collaboration with one or more physicians or podiatrists.

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

***CATEGORY D*:**
Undue prescription limitations

COMMENT: Requires formal collaborative practice with a physician.

ORC Ann. 4723.481

§ 4723.481. Restrictions on certificate holder; nurse personally furnishing drug or device

This section establishes standards and conditions regarding the authority of a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner to prescribe drugs and therapeutic devices under a certificate to prescribe issued under section 4723.481 of the Revised Code.

(A) A clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner shall not prescribe any drug or therapeutic device that is not included in the types of drugs and devices listed on the formulary established in rules adopted under section 4723.50 of the Revised Code.

(B) The prescriptive authority of a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner shall not exceed the prescriptive authority of the collaborating physician or podiatrist, including the collaborating physician's authority to treat chronic pain with controlled substances and products containing tramadol as described in section 4731.052 of the Revised Code.

(C) (1) Except as provided in division (C)(2) or (3) of this section, a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner may prescribe to a patient a schedule II controlled substance only if all of the following are the case:

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

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

***CATEGORY D*:**
Undue prescription limitations

(a) The patient has a terminal condition, as defined in section 2133.01 of the Revised Code.

(b) The collaborating physician of the clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner initially prescribed the substance for the patient.

(c) The prescription is for an amount that does not exceed the amount necessary for the patient's use in a single, twenty-four hour period.

(2) The restrictions on prescriptive authority in division (C)(1) of this section do not apply if a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner issues the prescription to the patient from any of the following locations:

(a) A hospital registered under section 3701.07 of the Revised Code;

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(f) A hospice care program, as defined in section 3712.01 of the Revised Code;

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2013

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

OHIO

STATUTES

Nurse Practice Act

ORC Ann. 4723.482

§ 4723.482. Items and fee to be included with application; instruction in advanced pharmacology and related topics

(A) Except as provided in divisions (C) and (D) of this section, an applicant shall include with the application submitted under *section 4723.48 of the Revised Code* all of the following:

(1) Evidence of holding a current, valid certificate of authority to practice as a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner that was issued by meeting the requirements of division (A) of *section 4723.41 of the Revised Code*;

(2) Evidence of successfully completing the course of study in advanced pharmacology and related topics in accordance with the requirements specified in division (B) of this section;

(3) The fee required by *section 4723.08 of the Revised Code* for a certificate to prescribe;

(4) Any additional information the board of nursing requires pursuant to rules adopted under *section 4723.50 of the Revised Code*.

(B) With respect to the course of study in advanced pharmacology and related topics that must be successfully completed to obtain a certificate to prescribe, all of the following requirements apply:

(1) The course of study shall be completed not longer than three years before the application for the certificate to prescribe is filed.

(2) The course of study shall consist of planned classroom and clinical instruction for a total of not less than forty-five contact hours.

(3) The course of study shall meet the requirements to be approved by the board in accordance with standards established in rules adopted under *section 4723.50 of the Revised Code*.

(4) The content of the course of study shall be specific to the applicant's nursing specialty.

(5) The instruction provided in the course of study shall include all of the following:

(a) A minimum of thirty-six contact hours of instruction in advanced pharmacology that includes pharmacokinetic principles and clinical application and the use of drugs and therapeutic devices in the prevention of illness and maintenance of health;

(b) Instruction in the fiscal and ethical implications of prescribing drugs and therapeutic devices;

(c) Instruction in the state and federal laws that apply to the authority to prescribe;

(d) Instruction that is specific to schedule II controlled substances, including instruction in all of the following:

(i) Indications for the use of schedule II controlled substances in drug therapies;

(ii) The most recent guidelines for pain management therapies, as established by state and national organizations such as the Ohio pain initiative and the American pain society;

(iii) Fiscal and ethical implications of prescribing schedule II controlled substances;

(iv) State and federal laws that apply to the authority to prescribe schedule II controlled substances;

(v) Prevention of abuse and diversion of schedule II controlled substances, including identification of the risk of abuse and diversion, recognition of abuse and diversion, types of assistance available for prevention of abuse and diversion, and methods of establishing safeguards against abuse and diversion.

(e) Any additional instruction required pursuant to rules adopted under *section 4723.50 of the Revised Code*.

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

CATEGORY C:
Regulatory or policy issues

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

2013

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

OHIO

REGULATIONS

Nursing Board Regulations

OAC Ann. 4723-9-09

4723-9-09. Standards of prescribing for nurses with a certificate to prescribe.

(A) A nurse who holds a current valid certificate to prescribe may prescribe a drug or therapeutic device provided the prescription is in accordance with:

(1) The nurse's standard care arrangement;

(2) The scope of practice in the nurse's specialty area;

(3) The requirements of the formulary as set forth in *section 4723.50 of the Revised Code*; and

(4) The requirements of this chapter.

(B) The nurse's prescriptive authority shall not exceed the prescriptive authority of the collaborating physician, including but not limited to, any restrictions imposed on the physician's practice by action of the United States drug enforcement administration or the state medical board.

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OAC Ann. 4723-9-10

4723-9-10. Formulary.

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(D) A nurse with a current valid certificate to prescribe may prescribe a schedule II controlled substance only in situations where all of the following apply:

(1) A patient has a terminal condition;

(2) The nurse's collaborating physician initially prescribed the substance for the patient; and

(3) The prescription is for a quantity that does not exceed the amount necessary for the patient's use in a single, twenty-four hour period.

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OAC Ann. 4723-9-13

4723-9-13. Instruction specific to schedule II controlled substances.

(A) All clinical nurse specialists, certified nurse practitioners, and certified nurse-midwives, who hold a certificate to prescribe, including an externship certificate, prior to the effective date of this rule must obtain six contact hours of instruction specific to schedule II controlled substances on or before August 31, 2013 in order to be eligible to renew their certificate to prescribe, and present documentation satisfactory to the board of having completed the instruction.

(B) To meet this requirement, the course of instruction must:

(1) Include the following content:

(a) Indications and contraindications for the use of schedule II controlled substances in drug therapies, including risk, evaluation and mitigation strategies for the use of opiates in the treatment of chronic pain for non-terminal conditions, and the need for periodic assessment and documentation of the patient's functional status;

(b) The most recent guidelines and recommendations for pain management therapies and education, as established by state and national organizations such as the Ohio pain initiative, the American pain society and the United States food and drug administration (FDA);

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

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

CATEGORY C:
Regulatory or policy issues

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

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

CATEGORY D:
Undue prescription limitations

COMMENT: Requires formal collaborative practice with a physician.

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

CATEGORY D:
Undue prescription limitations

(+) *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 include improvements in patient functioning and quality of life.

2013

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

OKLAHOMA

STATUTES

- Nurse Practice Act
  Title 59. Professions and Occupations; Chapter 12. Nurses; Nursing Practice Act

REGULATIONS

- Nursing Board Regulations
  Title 485. Oklahoma Board of Nursing

OTHER GOVERNMENTAL POLICIES

No policies found

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

OKLAHOMA

STATUTES

Nursing Practice Act

59 Okl. St. § 567.3a

§ 567.3a. Definitions

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A Certified Nurse Practitioner shall be eligible, in accordance with the scope of practice of the Certified Nurse Practitioner, to obtain recognition as authorized by the Board to prescribe, as defined by the rules promulgated by the Board pursuant to this section and subject to the medical direction of a supervising physician. This authorization shall not include dispensing drugs, but shall not preclude, subject to federal regulations, the receipt of, the signing for, or the dispensing of professional samples to patients.

The Certified Nurse Practitioner accepts responsibility, accountability, and obligation to practice in accordance with usual and customary advanced practice registered nursing standards and functions as defined by the scope of practice/role definition statements for the Certified Nurse Practitioner;

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

***CATEGORY A*:**
Arbitrary standards for legitimate prescribing

COMMENT: No prescriptive authority for controlled substances is specified in the regulations.

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

***CATEGORY D*:**
Undue prescription limitations

COMMENT: Requires formal collaborative practice with a physician.

REGULATIONS

Nursing Board Regulations

O.A.C. § 485:10-16-5

485:10-16-5 Maintenance

(a) The advanced practice nurse may prescribe in writing, orally, or by other means of telecommunication, drugs or medical supplies which are not listed on the exclusionary formulary approved by the Board, and which are within the scope of practice for the advanced practice nurse, and that are not otherwise prohibited by law.

(b) The advanced practice nurse must have a supervising physician on file with the Board prior to prescribing drugs or medical supplies. Changes to the written statement between the advanced practice nurse and supervising physician shall be filed with the Board within 30 days of the change and shall be effective upon filing.

(c) The advanced practice nurse with prescriptive authority who prescribes Schedule III-V drugs will comply with state and Federal Drug Enforcement Administration (DEA) requirements prior to prescribing controlled substances.

(1) The advanced practice nurse with prescriptive authority will submit in writing the assigned DEA number to the Board of Nursing within fourteen (14) days of receipt.

(2) No more than a 30-day supply for Schedule III-V drugs shall be prescribed by the advanced practice nurse with prescriptive authority.

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

***CATEGORY A*:**
Arbitrary standards for legitimate prescribing

COMMENT: No prescriptive authority for controlled substances is specified.

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

***CATEGORY D*:**
Undue prescription limitations

COMMENT: Requires formal collaborative practice with a physician.

2013

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

STATUTES

- Nurse Practice Act
  Title 52. Occupations and Professions; Chapter 678. Nurses, Nursing Home Administrators

REGULATIONS

- Nursing Board Regulations
  Chapter 851. Oregon State Board of Nursing

OTHER GOVERNMENTAL POLICIES

Oregon State Board of Nursing. *Pain Management*. Adopted: June 17, 2004; Revised: February, 2012.

See Joint Policy from the Oregon profile in Section IX

OREGON

STATUTES

Nurse Practice Act

ORS § 678.101

678.101 Renewal of license; fee; certificate and privilege.

(1) Every person licensed to practice nursing shall apply for renewal of the license other than a limited license in every second year before 12:01 a.m. on the anniversary of the birthdate of the person in the odd-numbered year for persons whose birth occurred in an odd-numbered year andin the even-numbered year for persons whose birth occurred in an even-numbered year. Persons whose birthdate anniversary falls on February 29 shall be treated as if the anniversary were March 1.

(2) Each application shall be accompanied by a nonrefundable renewal fee payable to the Oregon State Board of Nursing.

(3) The board may not renew the license of a person licensed to practice nursing unless:

(a) The requirements of subsections (1) and (2) of this section are met; and

(b) Prior to payment of the renewal fee described in subsection (2) of this section the applicant completes, or provides documentation of previous completion of:

(A) A pain management education program approved by the board and developed in conjunction with the Pain Management Commission established under *ORS 413.570*; or

(B) An equivalent pain management education program, as determined by the board.

(4) The license of any person not renewed for failure to comply with subsections (1) to (3) of this section is expired and the person shall be considered delinquent and is subject to the delinquent fee specified in *ORS 678.410*.

(5) A registered nurse who has been issued a certificate as a nurse practitioner shall apply, personally or by appropriately postmarked letter, for renewal of the certificate and for renewal of the prescriptive privileges in every second year before 12:01 a.m. on the anniversary of the birthdate, as determined for the person's license to practice nursing.

ORS § 678.390

678.390 Authority of nurse practitioner and clinical nurse specialist to write prescriptions or dispense drugs; notice; requirements; revocation; rules.

(1) The Oregon State Board of Nursing may grant to a certified nurse practitioner or certified clinical nurse specialist the privilege of writing prescriptions, including prescriptions for controlled substances listed in schedules II, III, III N, IV and V.

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

CATEGORY C:
Regulatory or policy issues

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

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

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OREGON

REGULATIONS

Nursing Board Regulations

Or. Admin. R. 851-056-0000

851-056-0000 Definitions

(1) "Addiction" means a primary, chronic, neurobiological disease with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving. Neither physical dependence nor tolerance alone, as defined by these rules, constitutes addiction.

. . .

Or. Admin. R. 851-056-0026

851-056-0026 Rules Relating to Controlled Substances

. . .

(5) Prescribing controlled substances:

(a) Nurse practitioners and clinical nurse specialists shall only prescribe the controlled substances from Schedules II-V, as authorized by the Oregon State Board of Nursing. Clinical nurse specialists and nurse practitioners shall only prescribe at the level provided for on their DEA certificate.

(b) Schedule II controlled substances shall not be prescribed for the purpose of weight reduction or control. Schedule III-IV controlled substances may be prescribed for weight reduction in accordance with FDA product guidelines.

(c) Clinical nurse specialists and nurse practitioners shall not prescribe, dispense, or order controlled substances, including Methadone, for narcotic addiction treatment.

(6) Intractable or chronic pain management:

(a) Nurse practitioners and clinical nurse specialists may prescribe or administer controlled substances to a person in the course of their treatment for a diagnosed condition causing pain, defined in *OAR 851-056-0000(13)*.

. . .

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

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

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

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OTHER GOVERNMENTAL POLICY

Nursing Board Policy Statement

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies the potential impact of important barriers on the provision of effective pain care.

(+) *CRITERION 4:*
Encourages pain management

Oregon State Board of Nursing – Board Policy

Pain Management

Purpose

Adequate pain relief is a serious public health problem in the United States. Factors that can contribute to the frequency of inadequately managed pain can include: a lack of knowledge of medical standards; the perception that prescribing appropriate amounts of controlled substances will result in scrutiny by regulatory agencies; a misunderstanding of addiction and dependence; and, unfamiliarity with regulatory processes.

All health care providers who treat patients in pain (regardless of whether the pain is acute or chronic, a result of terminal illness or non-life-threatening injury or disease) should become knowledgeable about effective methods of pharmacological and non-pharmacological measures and interventions available for pain treatment.

This policy is designed to guide the practice of the Licensed Practical Nurse, Registered Nurse and Advanced Practice Nurse in promoting patient access to the appropriate, therapeutic and effective assessment, nursing diagnosis and management of acute and chronic pain. Each professional nurse practices pain management to the extent of their scope of practice.

Background

Pain is a nursing diagnosis and as such, nurses have primary responsibility for its assessment and management. The nurse is often the healthcare professional most involved in on-going pain assessment, implementing the prescribed pain management plan, evaluating the response to such interventions and adjusting medication levels, based on the individual's response.

Pain is multifactoral and therefore the management of pain may include the use of both pharmacologic and non-pharmacologic modalities. An individual's self-report of pain, along with level of functional impairment, are the optimal standards upon which pain management interventions are based. In the absence of ability to self-report level of pain, an appropriate non-verbal scale should be used.

The management of pain must be a priority for nurses and all others who provide care to individuals in pain. This policy is intended to:

1. Provide a balanced approach to pain management. A balanced approach addresses the potential for abuse without keeping individuals from receiving the level of care and pain management that is needed.
2. Promote the optimal level of nursing practice in pain management;
3. Establish a framework leading to sound clinical judgment in managing acute, chronic, and end-of-life pain.

(CONTINUED ON NEXT PAGE)

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

(+) *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.

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OREGON

OTHER GOVERNMENTAL POLICY

Nursing Board Policy Statement

(CONTINUED)

Definitions

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

1. **Acute Pain** is brief and responds to timely intervention, or subsides as healing takes place.
2. **Addiction** is a combination of cognitive, physiological and behavioral symptoms (such as compulsive craving and compulsive use of a controlled substance) in which the individual continues the use of a substance despite harm or adverse consequences. Neither physical dependence nor tolerance alone, as defined below, constitutes addiction.
3. **Breakthrough Pain** is pain that comes on suddenly for short periods of time and is not alleviated by the individuals' normal pain suppression management.
4. **Chronic Pain** is ongoing or frequently recurring, and may become unresponsive to intervention over time.
5. **Intractable Pain** means a pain state in which the cause cannot be removed or otherwise treated, and no relief or cure has been found after reasonable efforts.
6. **Medication Range Order** is an order that allows the nurse to titrate medication to the desired effect through chances in dose with fixed time intervals (American Society for Pain Management Nursing & American Pain Society, 2004). Example: "Morphine sulfate 1-2mg IV q2hours prn pain"
7. **Multimodal** is the use of medication and/or other therapies with different modes of action i.e. application of heat and cold along with acetaminophen.
8. **Neuropathic Pain** is caused by a lesion or a malfunction in the nervous system.
9. **Nociceptive Pain** is caused by active illness, injury or inflammatory process associated with actual or potential tissue damage.
10. **Non-opioid** is pain medication that does not contain opioids i.e. NSAIDS and acetaminophen
11. **Pain** is an unpleasant sensory and emotional experience related to adverse nociceptive or neuropathic stimuli.
12. **Pain assessment scale** is a pain assessment tool that is appropriate to the needs of the individual and the demand of the care situation that takes into account such variables as language, cognitive ability, age, culture, disability and other factors (International Association for the Study of Pain, 2006, Objectives).
13. **Physical Dependence** is the physiologic adaptation to the presence of a controlled substance, characterized by withdrawal when its use is stopped abruptly.
14. **Pseudoaddiction** is an iatrogenic syndrome resulting from poorly treated pain and may be mistaken for addiction.
15. **Substance abuse** is a pattern of substance use leading to clinically significant impairment or distress as manifested by one or more of the following:
    a. Recurrent substance use resulting in failure to fulfill obligations at work, school or home;
    b. Recurrent substance use when such use is physically hazardous;
    c. Recurrent substance-related legal problems; or,
    d. Continued substance use despite recurrent consequences socially or interpersonally.
16. **Tolerance** is the physiologic adaptation to a controlled substance over time, resulting in the need to increase the dose to achieve the same effect, or in a reduction of response with repeated administration.

(CONTINUED ON NEXT PAGE)

Pain & Policy Studies Group
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OREGON

OTHER GOVERNMENTAL POLICY

Nursing Board Policy Statement

(+) ***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: Clarifies for pharmacists the important distinction between drug-seeking behaviors resulting from poorly treated pain (i.e., pseudoaddiction) and drug-seeking behaviors related to abuse or addiction; this language identifies a potential clinical situation and attempts to lessen its impact on patient treatment.

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

CATEGORY A:
Issues related to healthcare professionals

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

(CONTINUED)

Scope of Practice

Consistent with the licensee's scope of practice, the nurse is accountable for implementing the pain management plan utilizing his/her knowledge base and documenting assessment of the individual's needs. It is the responsibility of the nurse to utilize critical thinking and integrate multimodal approaches for effective pain management.

The nurse has the authority to adjust medication levels within the dosage range stipulated by the prescriber and according to the institutions established procedures. When pain is not controlled under the currently prescribed treatment plan, the nurse is responsible for reporting such findings to the prescriber, advocating for an optimal pain management plan and documenting the continuum of care provided an individual with pain.

Advanced Practice Nurses who are authorized by law to prescribe or dispense drugs, including controlled substances see Division 56 for additional standards of practice.

Nursing Pain Management Knowledge and Skills

Principles of pain management include:

- Assessment – the process of pain management starts with an adequate assessment of the pain which can include but is not limited to:
  - Nature of the pain (including the use of an appropriate, evidence-based pain assessment scales)
  - Cause of the pain
  - Personal context of pain, including how pain impacts daily function and quality of life
- Development and implementation of an individualized pain management plan that is evidence-based and includes comprehensive and on-going pain assessment, including impact on daily functional ability, appropriate pharmacological and non-pharmacological modalities, and substantiation of adequate symptom control;
- Implement measures in the care plan that include non-pharmacological modalities, interventions, and comfort measures for pain management i.e. positioning, pillow placement, music, dimming lights, heat and cold etc.
- Document assessments, interventions, treatment and response;
- Utilization of controlled substances when appropriate including opioid analgesics in the management of all pain types;
- Collaboration and consultation with interdisciplinary teams;
- Recognition that:
  1. tolerance and physical dependence are normal consequences of sustained use of opioids and are not synonymous with addiction;
  2. pseudoaddiction may develop as a direct consequence of inadequate pain management and that pseudoaddiction can be distinguished from true addiction in that inappropriate drug seeking behaviors resolve when pain effectively treated;
  3. patients with chemical dependency may require special pain management involving controlled substances including opioids;
  4. individuals who suffer from extreme pain or disease progression may require increased doses of pain medication and the appropriate dose is the dose required to effectively manage the patient's pain in that particular circumstance;
- Adherence to system safe-guards that are designed to minimize the potential for abuse and diversion when controlled substances are used;
- Acceptance of an individual's self-determination and autonomy;
- Culturally sensitive patient, family/significant other, and/or caregiver pain management education.

(CONTINUED ON NEXT PAGE)

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

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

CATEGORY C:
Regulatory or policy issues

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

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

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

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OTHER GOVERNMENTAL POLICY

Nursing Board Policy Statement

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

(CONTINUED)

Pain Education and Training

The nurse is responsible and accountable for acquiring and maintaining current knowledge, skills and abilities necessary to practice in accordance with accepted standards of care for pain management. Such competencies may be acquired through basic, graduate or continuing education programs, as appropriate to the nurse's scope of practice. These competencies include, but are not limited to knowledge of the current federal and state laws and regulations for the prescription, dispensing, administration and destruction of controlled substances, current evidence-based guidelines developed by nationally recognized professional organizations in the assessment and management of pain and the use of pharmacological and non-pharmacological modalities (e.g. heat and cold therapies).

References and Resources

- A Joint Statement from 21 Health Organizations and the Drug Enforcement Administration, "Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act," October 2001.
- American Association of Critical-Care Nurses. (2008). Ask the experts. *Critical Care Nurse, 28*, 67-68. Retrieved from http://ccn.aacnjournals.org/content/28/66.full
- American Society for Pain Management Nursing & American Pain Society. (2004). The use of (as needed) range orders for opioids analgesics and management of acute pain. A consensus statement of American Society for Pain Management Nursing & American Pain Society. Retrieved from http://www.ampainsoc.org/advocacy/pdf/range.pdf
- Institute of Medicine report: "Relieving Pain in America" June 2001
  - http://iom.edu/Reports/2001/Relieving-Pain-in-America-A-Blueprint-for-Transforming-Prevention-Care-Education-Research.apsx
- International Association for the Study of Pain. (2006). Outline Curriculum on Pain for Schools of Nursing (2nd ed). Retrieved from
  - http://www.iasp-pain.org/AM/Template.cfm?Section=Home&Template=/CM/HTMLDisplay.cfm&ContentID=2320
- Massachusetts Board of Registration in Nursing, Division of Health Professions Licensure, Department of Public Health, July 2008. Advisory Ruling on Management of Pain, November 2010
  - http://www.mass.gov/eohhs/provider/licensing/occupational/nursing/nursing-practice/advisory-rulings/advisory-ruling-on-th-management-of-pain.html
- Oregon Pain Management Commission: http://www.oregon.gov/OHA/OHPR/PMC
- Oregon State Board of Nursing, Oregon Nurse Practice Act, 2012

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PENNSYLVANIA

STATUTES

- Nurse Practice Act
  Pennsylvania Statutes; Title 63. Professions and Occupations (State Licensed); Chapter 7. Nurses

REGULATIONS

- Nursing Board Regulations
  Title 49. Professional and Vocational Standards; Part I. Department of State; Subpart A. Professional and Occupational Affairs; Chapter 21. State Board of Nursing

OTHER GOVERNMENTAL POLICIES

No policies found

PENNSYLVANIA

STATUTES

Nurse Practice Act

63 P.S. § 218.3

§ 218.3. Prescriptive authority for certified registered nurse practitioners

(a) A certified registered nurse practitioner may prescribe medical therapeutic or corrective measures if the nurse:

(1) has successfully completed at least forty-five (45) hours of coursework specific to advanced pharmacology at a level above that required by a professional nursing education program;

(2) is acting in collaboration with a physician as set forth in a written agreement which shall, at a minimum, identify the following:

(i) the area of practice in which the nurse is certified;

(ii) the categories of drugs from which the nurse may prescribe or dispense; and

(iii) the circumstances and how often the collaborating physician will personally see the patient; and

(3) is acting in accordance with regulations promulgated by the board.

(b) A certified registered nurse practitioner who satisfies the requirements of subsection (a) may prescribe and dispense those categories of drugs that certified registered nurse practitioners were authorized to prescribe and dispense by board regulations in effect on the effective date of this section, subject to the restrictions on certain drug categories imposed by those regulations. The board shall add to or delete from the categories of authorized drugs in accordance with the provisions of section 8.4.

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

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

***CATEGORY D*:**
Undue prescription limitations

COMMENT: Requires use of a collaborative agreement with a physician.

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PENNSYLVANIA

REGULATIONS

Nursing Board Regulations

49 Pa. Code § 21.283

§ 21.283. Authority and qualifications for prescribing, dispensing and ordering drugs

(a) A CRNP with prescriptive authority approval may, when acting in collaboration with a physician as set forth in a prescriptive authority collaborative agreement and within the CRNP's specialty, prescribe and dispense drugs and give written or oral orders for drugs and other medical therapeutic or corrective measures. These orders may include:

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49 Pa. Code § 21.284

§ 21.284. Prescribing and dispensing parameters

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(d) Restrictions on CRNP prescribing and dispensing practices are as follows:

(1) A CRNP may write a prescription for a Schedule II controlled substance for up to a 30-day supply as identified in the collaborative agreement.

(2) A CRNP may prescribe a Schedule III or IV controlled substance for up to a 90 day supply as identified in the collaborative agreement.

(e) A CRNP may not delegate prescriptive authority.

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

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

CATEGORY D:
Undue prescription limitations

COMMENT: Requires use of a collaborative agreement with a physician.

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

CATEGORY D:
Undue prescription limitations

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RHODE ISLAND

STATUTES

- Nurse Practice Act
  Title 5. Businesses and Professions; Chapter 34. Nurses

REGULATIONS

- Nursing Board Regulations
  Agency 14. Department of Health; Sub-Agency 140. Office of Health Professionals Regulation; Chapter 022. Licensing of Nurses and Standards for the Approval of Basic Nursing Education Programs

OTHER GOVERNMENTAL POLICIES

No policies found

RHODE ISLAND

STATUTES

Nurse Practice Act

R.I. Gen. Laws § 5-34-49

§ 5-34-49. Prescriptive authority

(a) The board of nursing shall grant prescribing, ordering, dispensing and furnishing authority.

(b) An APRN licensed by the board of nursing may prescribe, order, procure, administer, dispense and furnish over the counter, legend and controlled substances pursuant to applicable state and federal laws, when the APRN has completed an educational program as described in this chapter that includes courses in pathophysiology, pharmacology and physical assessment and is within the APRN's role and population focus.

(c) Prescribing, ordering, dispensing and furnishing shall include the authority to:

(1) Diagnose, prescribe and institute therapy or referrals of patients to health care agencies, health care providers and community resources;

(2) Prescribe, procure, administer, dispense and furnish pharmacological agents, including over the counter, legend and controlled substances; and

(3) Plan and initiate a therapeutic regimen that includes ordering and prescribing non-pharmacological interventions, including, but not limited to, durable medical equipment, medical devices, nutrition, blood and blood products, and diagnostic and supportive services including, but not limited to, home health care, hospice, and physical and occupational therapy.

(d) Prescriptive privileges for the certified nurse practitioner shall include all the authority under the APRN license including:

(1) Prescription of legend medications and prescription of controlled substances from schedules II, III, IV and V that are established in regulation; and

(2) May be certified to prescribe controlled substances from Schedule I.

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

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RHODE ISLAND

REGULATIONS

Nursing Board Regulations

CRIR 14-140-022

14 140 022. Licensing of Nurses and Standards for the Approval of Basic Nursing Education Programs

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Section 10.0 Other Requirements for Certified Registered Nurse Practitioners, Certified Registered Nurse Anesthetists and Psychiatric and Mental Health Clinical Nurse Specialists.

10.1 Prescriptive privileges for the certified registered nurse practitioner:

a) shall be granted under the governance and supervision of the Department, Board of Nurse Registration and Nursing Education; and

b) shall include prescription of legend medications; and

c) shall not include controlled substances from schedule I of Chapter 21-28 of the General Laws, entitled "Controlled Substances Act"; and

d) shall include controlled substances from schedules V, IV, III and II of Chapter 21-28-2.08 of the Rhode Island General Laws, as amended; provided that the applicant has obtained a controlled substances registration from the Department.

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11.0 Standards of Nursing Practice

Pain Assessment

11.5 All health care providers licensed by this state to provide health care services and all health care facilities licensed under Chapter 23-17 of the Rhode Island General Laws, as amended, shall assess patient pain in accordance with the requirements of the Rules and Regulations Related to Pain Assessment (R5-37.6-PAIN) promulgated by the Department.

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

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

2013

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SOUTH CAROLINA

STATUTES

- Nurse Practice Act
  Title 40. Professions and Occupations; Chapter 33. Nurses

REGULATIONS

- Nursing Board Regulations *(No provisions found)*
  Code of Regulations; Chapter 91. Department of Labor, Licensing and Regulation – State Board of Nursing

OTHER GOVERNMENTAL POLICIES

See Joint Policy from the South Carolina profile in Section IX

SOUTH CAROLINA

STATUTES

Nurse Practice Act

S.C. Code Ann. § 40-33-34

§ 40-33-34. Performance of delegated medical acts; qualifications; protocols; prescriptive authorization; anesthesia care.

(A) An advanced practice registered nurse applicant shall furnish evidence satisfactory to the board that the applicant:

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(F)(1) Authorized prescriptions by a nurse practitioner, certified nurse-midwife, or clinical nurse specialist with prescriptive authority:

(a) must comply with all applicable state and federal laws;

(b) is limited to drugs and devices utilized to treat common well-defined medical problems within the specialty field of the nurse practitioner or clinical nurse specialist, as authorized by the physician and listed in the approved written protocols. The Board of Nursing, Board of Medical Examiners, and Board of Pharmacy jointly shall establish a listing of classifications of drugs that may be authorized by physicians and listed in approved written protocols;

(c) do not include prescriptions for Schedule II controlled substances; however, Schedules III through V controlled substances may be prescribed if listed in the approved written protocol and as authorized by Section 44-53-300;

(d) must be signed by the NP, CNM, or CNS with the prescriber's identification number assigned by the board and all prescribing numbers required by law. The prescription form must include the name, address, and phone number of the NP, CNM, or CNS and physician and must comply with the provisions of Section 39-24-40. A prescription must designate a specific number of refills and may not include a nonspecific refill indication;

(e) must be documented in the patient record of the practice and must be available for review and audit purposes.

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

***CATEGORY A*:**
Arbitrary standards for legitimate prescribing

COMMENT: No prescriptive authority for controlled substances is specified.

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

***CATEGORY D*:**
Undue prescription limitations

COMMENT: Requires formal collaborative practice and protocols with a physician.

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SOUTH DAKOTA

STATUTES

- Nurse Practice Act
  Title 36. Professions and Occupations; Chapter 36-9. Nurses

REGULATIONS

- Nursing Board Regulations
  Title 20. Department of Revenue and Regulation; Article 48. Nurses

OTHER GOVERNMENTAL POLICIES

No policies found

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SOUTH DAKOTA

STATUTES

Nurse Practice Act

S.D. Codified Laws § 36-9A-12

§ 36-9A-12. Scope of advance practice nursing and medical function permitted to nurse practitioner

A nurse practitioner may perform the following overlapping scope of advanced practice nursing and medical functions pursuant to *§ 36-9A-15*, including:

(1) The initial medical diagnosis and the institution of a plan of therapy or referral;

(2) The prescription of medications and provision of drug samples or a limited supply of labeled medications, including controlled drugs or substances listed on Schedule II in chapter 34-20B for one period of not more than thirty days, for treatment of causative factors and symptoms. Medications or sample drugs provided to patients shall be accompanied with written administration instructions and appropriate documentation shall be entered in the patient's medical record;

(3) The writing of a chemical or physical restraint order when the patient may do personal harm or harm others;

(4) The completion and signing of official documents such as death certificates, birth certificates, and similar documents required by law; and

(5) The performance of a physical examination for participation in athletics and the certification that the patient is healthy and able to participate in athletics.

S.D. Codified Laws § 36-9A-15

§ 36-9A-15.

The term, collaborative agreement, as used in this chapter, means a written agreement authored and signed by the nurse practitioner or nurse midwife and the physician with whom the nurse practitioner or nurse midwife is collaborating. A collaborative agreement defines or describes the agreed upon overlapping scope of advanced practice nursing and medical functions that may be performed, consistent with *§ 36-9A-12* or *36-9A-13*, and contains such other information as required by the boards. A copy of each collaborative agreement shall be maintained on file with and be approved by the boards prior to performing any of the acts contained in the agreement.

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

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

***CATEGORY D*:**
Undue prescription limitations

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

***CATEGORY D*:**
Undue prescription limitations

COMMENT: Requires use of a collaborative agreement with a physician.

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SOUTH DAKOTA

REGULATIONS

Nursing Board Regulations

ARSD 20:62:04:01

20:62:04:01. Authorized prescriptions

A nurse practitioner or nurse midwife may prescribe and dispense legend drugs and controlled substances listed in Schedules II, III, or IV in Chapter 34-20B, as provided in *SDCL 36-9A-12* and *36-9A-13*, while practicing under the supervision of a physician named in the practice agreement who is registered to prescribe and dispense controlled substances.

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

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

***CATEGORY D*:**
Undue prescription limitations

COMMENT: Requires use of a collaborative agreement with a physician.

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

***CATEGORY D*:**
Undue prescription limitations

COMMENT: References limits to prescribing codified in statute.

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TENNESSEE

STATUTES

- Nurse Practice Act
  Title 63. Professions of the Healing Arts; Chapter 7. Nursing

REGULATIONS

- Nursing Board Regulations
  Rules of the Tennessee Board of Nursing

OTHER GOVERNMENTAL POLICIES

No policies found

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TENNESSEE

STATUTES

Nurse Practice Act

Tenn. Code Ann. § 63-7-123

63-7-123. Certified nurse practitioners -- Drug prescriptions -- Temporary certificate -- Rules and regulations.

(a) The board shall issue a certificate of fitness to nurse practitioners who meet the qualifications, competencies, training, education and experience, pursuant to *§ 63-7-207(14)*, sufficient to prepare such persons to write and sign prescriptions and/or issue drugs within the limitations and provisions of *§ 63-1-132*.

(b) (1) A nurse who has been issued a certificate of fitness as a nurse practitioner pursuant to *§ 63-7-207* and this section shall file a notice with the board, containing the name of the nurse practitioner, the name of the licensed physician having supervision, control and responsibility for prescriptive services rendered by the nurse practitioner and a copy of the formulary describing the categories of legend drugs to be prescribed and/or issued by the nurse practitioner. The nurse practitioner shall be responsible for updating this information.

(2) The nurse practitioner who holds a certificate of fitness shall be authorized to prescribe and/or issue controlled substances listed in Schedules II, III, IV and V of title 39, chapter 17, part 4 upon joint adoption of physician supervisory rules concerning controlled substances pursuant to subsection (d).

(B) Notwithstanding subdivision (b)(2)(A), a nurse practitioner shall not prescribe Schedules II, III and IV controlled substances unless such prescription is specifically authorized by the formulary or expressly approved after consultation with the supervising physician before the initial issuance of the prescription or dispensing of the medication.

(C) A nurse practitioner who had been issued a certificate of fitness may only prescribe or issue a Schedule II or III opioid listed on the formulary for a maximum of a non-refillable, thirty-day course of treatment unless specifically approved after consultation with the supervising physician before the initial issuance of the prescription or dispensing of the medication. This subdivision (b)(2)(C) shall not apply to prescriptions issued in a hospital, a nursing home licensed under title 68, or inpatient facilities licensed under title 33.

(3) (A) Any prescription written and signed or drug issued by a nurse practitioner under the supervision and control of a supervising physician shall be deemed to be that of the nurse practitioner. Every prescription issued by a nurse practitioner pursuant to this section shall be entered in the medical records of the patient and shall be written on a preprinted prescription pad bearing the name, address, and telephone number of the supervising physician and of the nurse practitioner, and the nurse practitioner shall sign each prescription so written. Where the preprinted prescription pad contains the names of more than one (1) physician, the nurse practitioner shall indicate on the prescription which of those physicians is the nurse practitioner's primary supervising physician by placing a checkmark beside or a circle around the name of that physician.

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

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

CATEGORY D:
Undue prescription limitations

COMMENT: Requires formal collaborative practice and protocols with a physician.

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TENNESSEE

REGULATIONS

Nursing Board Regulations

Tenn. Comp. R. & Regs. R. 1000-04-.08

1000-04-.08 TREATMENT OF PAIN.

The purpose of this rule is to recognize that some controlled substances are indispensable for the treatment of pain, and are useful for relieving and controlling many other related symptoms that patients may suffer. It is the position of the Board of Nursing that these drugs may be prescribed for the treatment of pain and other related symptoms after a reasonably based diagnosis has been made, in adequate doses, and for appropriate lengths of time, which in some cases may be as long as the pain or related symptoms persist. The Board recognizes that pain, including intractable pain, and many other related symptoms are subjective complaints and that the appropriateness and the adequacy of drug and dose will vary from individual to individual. The Advanced Practice Nurse, who possesses a certificate of fitness issued by the Board and possesses a Drug Enforcement Administration (DEA) Certificate to Prescribe Controlled Substances, is expected to exercise sound judgment in treating pain and related symptoms with controlled substances.

(1) Definitions. The following words and terms, as used in this rule shall have the following meanings in the context of providing medications for pain and related symptoms.

(a) Abuser of narcotic drugs / controlled substances - A person who takes a drug or drugs for other than legitimate medical purposes.

(b) Intractable pain - 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.

(c) Non-therapeutic in nature or manner - A medical use or purpose that is not legitimate.

(d) Prescribing pharmaceuticals or practicing consistent with the public health and welfare - Prescribing pharmaceuticals and practicing Advanced Practice Nursing for a legitimate purpose in the usual course of professional practice.

(2) An Advanced Practice Nurse who does not choose to provide long-term pain management to patients with intractable pain shall offer the patient a referral to a practitioner whose primary practice is in the treatment of severe, chronic, intractable pain with methods including the use of opiates. If the patient requests such a referral the APN shall assist in the transition to another provider for the purpose of pain management.

[CONTINUED ON NEXT PAGE]

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

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Madison, Wisconsin

TENNESSEE

REGULATIONS

Nursing Board Regulations

[CONTINUED]

(3) An Advanced Practice Nurse possessing a certificate of fitness issued by the Board and a DEA certificate who provides care for persons with intractable pain with or without opiates is expected to demonstrate current knowledge of long-term pain management.

(4) Guidelines - The Tennessee Board of Nursing will use the following guidelines to determine whether an Advanced Practice Nurse's conduct violates T.C.A. § 63-7-115 (a) (1) (A) through (G) in regard to the prescribing, administering, ordering, or dispensing of pain medications and other drugs necessary to address their side effects.

(a) The treatment of pain, including intractable pain, with controlled substances serves a legitimate purpose when done in the usual course of professional practice.

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

(b) An Advanced Practice Nurse duly authorized to practice in Tennessee and to prescribe controlled substances in this state shall not be subject to disciplinary action by the Board for prescribing, ordering, administering, or dispensing controlled substances for the treatment and relief of pain, including intractable pain, in the usual course of professional practice for a legitimate purpose in compliance with applicable state and federal law.

(c) Prescribing, ordering, administering, or dispensing controlled substances for pain will be considered to be for a legitimate purpose if based upon accepted scientific knowledge of the treatment of pain, including intractable pain, not in contravention of applicable state or federal law, and if prescribed, ordered, administered, or dispensed in compliance with the following guidelines where appropriate and as is necessary to meet the individual needs of the patient.

1. The record shall include a documented medical history and physical examination by the Advanced Practice Nurse who possesses a certificate of fitness and a DEA certificate and is providing the medication. Historical data shall include pain history, any pertinent evaluations by another provider, history of and potential for substance abuse, pertinent coexisting diseases and conditions, psychological functions and the presence of a recognized medical indication for the use of a controlled substance;

(+) *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 include improvements in patient functioning and quality of life.

2. A written treatment plan tailored for individual needs of the patient shall include objectives such as pain relief and/or improved physical and psychosocial function, and shall consider need for further testing, consultations, referrals, or use of other treatment modalities dependent on patient response;

3. The Advanced Practice Nurse who possesses a certificate of fitness and a DEA certificate shall discuss the risks and benefits of the use of controlled substances with the patient or guardian;

[CONTINUED ON NEXT PAGE]

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

Pain & Policy Studies Group
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Madison, Wisconsin

TENNESSEE

REGULATIONS

Nursing Board Regulations

[CONTINUED]

4. At each periodic interval in which the Advanced Practice Nurse, who possesses a certificate of fitness and a DEA certificate and is providing care, evaluates the patient for continuation or change of medications, the patient record shall include progress toward reaching treatment objectives, any new information about the etiology of the pain, and an update on the treatment plan.

(d) In determining the need for any disciplinary action in regard to the Advanced Practice Nurse who possesses a certificate of fitness and a DEA certificate, each case of prescribing for chronic pain will be evaluated on an individual basis as to whether the nurse is prescribing and practicing in a manner consistent with public health and welfare. The Board of Nursing will evaluate for proper documentation, therapeutic prescribing in a manner using drugs that are recognized to be appropriate pharmacologically for the diagnosis, treatment outcomes including improvement in functioning, and recognition that some types of pain cannot be completely relieved.

(e) Quantity of pharmaceuticals and chronicity of prescribing will be evaluated on the basis of the documented appropriate diagnosis and treatment of the recognized medical indication, documented persistence of the recognized medical indication, and properly documented follow-up evaluation with appropriate continuing care as set out in this rule.

(f) An Advanced Practice Nurse may use any number of treatment modalities for the treatment of pain, including intractable pain, which are consistent with legitimate medical purposes.

(g) These rules shall not be construed so as to apply to the treatment of acute pain with controlled substances for purposes of short-term care.

(+) *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 healthcare practice.

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

Pain & Policy Studies Group
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Madison, Wisconsin

TEXAS

STATUTES

- Medical Practice Act
  Occupations Code; Title 3. Health Professions; Subtitle B. Physicians

- Nurse Practice Act
  Occupations Code; Title 3. Health Professions; Subtitle E. Regulation of Nursing

REGULATIONS

- Nursing Board Regulations
  Title 22. Examining Boards; Part 11. Texas Board of Nursing

OTHER GOVERNMENTAL POLICIES

No policies found

TEXAS

STATUTES

Medical Practice Act

Tex. Occ. Code § 157.0511

§ 157.0511. Delegation of Prescribing and Ordering Drugs and Devices

(a) A physician's authority to delegate the prescribing or ordering of a drug or device under this subchapter is limited to:

(1) nonprescription drugs;

(2) dangerous drugs; and

(3) controlled substances to the extent provided by Subsections (b) and (b-1).

(b) Except as provided by Subsection (b-1), a physician may delegate the prescribing or ordering of a controlled substance only if:

(1) the prescription is for a controlled substance listed in Schedule III, IV, or V as established by the commissioner of the Department of State Health Services under Chapter 481, Health and Safety Code;

(2) the prescription, including a refill of the prescription, is for a period not to exceed 90 days;

(3) with regard to the refill of a prescription, the refill is authorized after consultation with the delegating physician and the consultation is noted in the patient's chart; and

(4) with regard to a prescription for a child less than two years of age, the prescription is made after consultation with the delegating physician and the consultation is noted in the patient's chart.

(b-1) A physician may delegate the prescribing or ordering of a controlled substance listed in Schedule II as established by the commissioner of the Department of State Health Services under Chapter 481, Health and Safety Code, only:

(1) in a hospital facility-based practice under Section 157.054, in accordance with policies approved by the hospital's medical staff or a committee of the hospital's medical staff as provided by the hospital bylaws to ensure patient safety, and as part of the care provided to a patient who:

(A) has been admitted to the hospital for an intended length of stay of 24 hours or greater; or

(B) is receiving services in the emergency department of the hospital; or

(2) as part of the plan of care for the treatment of a person who has executed a written certification of a terminal illness, has elected to receive hospice care, and is receiving hospice treatment from a qualified hospice provider.

(b-2) The board shall adopt rules that require a physician who delegates the prescribing or ordering of a drug or device to register with the board the name and license number of the physician assistant or advanced practice registered nurse to whom a delegation is made. The board may develop and use an electronic online delegation registration process for registration under this subsection.

(c) This subchapter does not modify the authority granted by law for a licensed registered nurse or physician assistant to administer or provide a medication, including a controlled substance listed in Schedule II as established by the commissioner of the Department of State Health Services under Chapter 481, Health and Safety Code, that is authorized by a physician under a physician's order, standing medical order, standing delegation order, or protocol.

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

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

***CATEGORY D*:**
Undue prescription limitations

COMMENT: Requires formal collaborative practice with a physician.

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TEXAS

STATUTES

Nurse Practice Act

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

CATEGORY A:
Issues related to healthcare professionals

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

Tex. Occ. Code § 301.1581

§ 301.1581. Information Provided to License Holders

At least once each biennium, the board shall provide to license holders information on:

(1) prescribing and dispensing pain medications, with particular emphasis on Schedule II and Schedule III controlled substances;

(2) abusive and addictive behavior of certain persons who use prescription pain medications;

(3) common diversion strategies employed by certain persons who use prescription pain medications, including fraudulent prescription patterns; and

(4) the appropriate use of pain medications and the differences between addiction, pseudo-addiction, tolerance, and physical dependence.

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Madison, Wisconsin

TEXAS

REGULATIONS

Nursing Board Regulations

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

22 TAC § 222.8

§ 222.8. Authority to Order and Prescribe Controlled Substances

(a) APRNs with full licensure and a valid prescription authorization number are eligible to obtain authority to order and prescribe certain categories of controlled substances. The APRN must comply with all federal and state laws and regulations relating to the ordering and prescribing of controlled substances in Texas, including but not limited to, requirements set forth by the Texas Department of Public Safety and the United States Drug Enforcement Administration.

(b) Orders and prescriptions for controlled substances in Schedules III through V may be authorized, provided the following criteria are met:

(1) Prescriptions for a controlled substance in Schedules III through V, including a refill of the prescription, shall not exceed a 90 day supply. This requirement includes a prescription, either in the form of a new prescription or in the form of a refill, for the same controlled substance that a patient has been previously issued within the time period described by this subsection.

(2) Beyond the initial 90 days, the refill of a prescription for a controlled substance in Schedules III through V shall not be authorized prior to consultation with the delegating physician and notation of the consultation in the patient's chart.

(3) A prescription of a controlled substance in Schedules III through V shall not be authorized for a child less than two years of age prior to consultation with the delegating physician and notation of the consultation in the patient's chart.

(c) Orders and prescriptions for controlled substances in Schedule II may be authorized only:

(1) in a hospital facility-based practice, in accordance with policies approved by the hospital's medical staff or a committee of the hospital's medical staff as provided by the hospital's bylaws to ensure patient safety and as part of care provided to a patient who:

(A) has been admitted to the hospital for an intended length of stay of 24 hours or greater; or

(B) is receiving services in the emergency department of the hospital; or

(2) as part of the plan of care for the treatment of a person who has executed a written certification of a terminal illness, has elected to receive hospice care, and is receiving hospice treatment from a qualified hospice provider.

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

***CATEGORY D*:**
Undue prescription limitations

COMMENT: Requires formal collaborative practice with a physician.

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

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

***CATEGORY D*:**
Undue prescription limitations

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UTAH

STATUTES

- Nurse Practice Act
  Title 58. Occupations and Professions; Chapter 31b. Nurse Practice Act

REGULATIONS

- Nursing Board Regulations
  Commerce; R156. Occupational and Professional Licensing; R156-31b. Nurse Practice Act Rule

OTHER GOVERNMENTAL POLICIES

No policies found

UTAH

STATUTES

Nurse Practice Act

Utah Code Ann. § 58-31b-102

§ 58-31b-102. Definitions

In addition to the definitions in *Section 58-1-102*, as used in this chapter:

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(13) "Practice of advanced practice registered nursing" means the practice of nursing within the generally recognized scope and standards of advanced practice registered nursing as defined by rule and consistent with professionally recognized preparation and education standards of an advanced practice registered nurse by a person licensed under this chapter as an advanced practice registered nurse. Advanced practice registered nursing includes:

(a) maintenance and promotion of health and prevention of disease;

(b) diagnosis, treatment, correction, consultation, and referral for common health problems;

(c) prescription or administration of prescription drugs or devices including:

(i) local anesthesia;

(ii) schedule IV-V controlled substances; and

(iii) schedule II-III controlled substances in accordance with a consultation and referral plan; or

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

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

***CATEGORY D*:**
Undue prescription limitations

COMMENT: Requires formal collaborative practice with a physician.

REGULATIONS

Nursing Board Regulations

U.A.C. R156-31b-102

R156-31b-102. Definitions.

In addition to the definitions in Title 58, Chapters 1 and 31b, as defined or used in this rule:

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(38) "Practitioner", as used in Sections R156-31b-701 and 701a, means a person authorized by law to prescribe treatment, medication, or medical devices, and who acts within the scope of such authority.

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

COMMENT: Prescriptive authority for Schedule II controlled substances is specified in statute.

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Madison, Wisconsin

VERMONT

STATUTES

- Nurse Practice Act
  Title 26. Professions and Occupations; Chapter 28. Nurses

REGULATIONS

- Nursing Board Regulations
  Agency 04. Secretary of State; Sub-Agency 030. Office of Professional Regulation; Chapter 170. Administrative Rules of the Board of Nursing

OTHER GOVERNMENTAL POLICIES

No policies found

VERMONT

STATUTES

Nurse Practice Act

26 V.S.A. § 1572

§ 1572. Definitions

As used in this chapter:

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(2) "Registered nursing" means the practice of nursing which includes:

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(M) Addressing patient pain.

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(4) "Advanced practice registered nurse" means a licensed registered nurse authorized to practice in this state who, because of specialized education and experience is endorsed to perform acts of medical diagnosis and to prescribe medical, therapeutic or corrective measures under administrative rules adopted by the board.

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

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

REGULATIONS

Nursing Board Regulations

CVR 04-030-170

04 030 170. Administrative Rules for the Board of Nursing

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Part 15. Advanced Nursing Practice.

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15.2 General Provisions This section regulates the issuance of an APRN license and is promulgated pursuant to 26 *V.S.A. §1574*.

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(g) APRNs may prescribe medications consistent with their scope of practice and in compliance with all applicable statutes and regulations.

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

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VIRGINIA

STATUTES

- Medical Practice Act
  Title 54.1. Professions and Occupations; Subtitle III. Professions and Occupations Regulated by Boards within the Department of Health Professions; Chapter 29. Medicine and Other Healing Arts

- Nurse Practice Act *(No provisions found)*
  Title 54.1. Professions and Occupations; Subtitle III. Professions and Occupations Regulated by Boards within the Department of Health Professions; Chapter 30. Nursing

REGULATIONS

- Nursing Board Regulations
  Title 18. Professional and Occupational Licensing; Agency No. 90. Board of Nursing

OTHER GOVERNMENTAL POLICIES

No policies found

VIRGINIA

STATUTES

Medical Practice Act

Va. Code Ann. § 54.1-2957.01

§ 54.1-2957.01. Prescription of certain controlled substances and devices by licensed nurse practitioners

A. In accordance with the provisions of this section and pursuant to the requirements of Chapter 33 (§ 54.1-3300 et seq.), a licensed nurse practitioner, other than a certified registered nurse anesthetist, shall have the authority to prescribe Schedule II through Schedule VI controlled substances and devices as set forth in Chapter 34 (§ 54.1-3400 et seq.). Nurse practitioners shall have such prescriptive authority upon the provision to the Board of Medicine and the Board of Nursing of such evidence as they may jointly require that the nurse practitioner has entered into and is, at the time of writing a prescription, a party to a written or electronic practice agreement with a patient care team physician that clearly states the prescriptive practices of the nurse practitioner. Such written or electronic practice agreements shall include the controlled substances the nurse practitioner is or is not authorized to prescribe and may restrict such prescriptive authority as described in the practice agreement. Evidence of a practice agreement shall be maintained by a nurse practitioner pursuant to § 54.1-2957. Practice agreements authorizing a nurse practitioner to prescribe controlled substances or devices pursuant to this section shall either be signed by the patient care team physician who is practicing as part of a patient care team with the nurse practitioner or shall clearly state the name of the patient care team physician who has entered into the practice agreement with the nurse practitioner.

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

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VIRGINIA

REGULATIONS

Nursing Board Regulations

18VAC90-40-10. Definitions.

The following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise:

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"Practice agreement" means a written or electronic agreement jointly developed by the patient care team physician and the nurse practitioner for the practice of the nurse practitioner that also describes the prescriptive authority of the nurse practitioner, if applicable.

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18VAC90-40-30. Authority to prescribe, general.

A. No licensed nurse practitioner shall have authority to prescribe certain controlled substances and devices in the Commonwealth of Virginia except in accordance with this chapter and as authorized by the boards.

B. The boards shall approve prescriptive authority for applicants who meet the qualifications set forth in 18VAC90-40-40 of this chapter.

18VAC90-40-40. Qualifications for initial approval of prescriptive authority.

An applicant for prescriptive authority shall meet the following requirements:

1. Hold a current, unrestricted license as a nurse practitioner in the Commonwealth of Virginia; and

2. Provide evidence of one of the following:

a. Continued professional certification as required for initial licensure as a nurse practitioner; or

b. Satisfactory completion of a graduate level course in pharmacology or pharmacotherapeutics obtained as part of the nurse practitioner education program within the five years prior to submission of the application; or

c. Practice as a nurse practitioner for no less than 1000 hours and 15 continuing education units related to the area of practice for each of the two years immediately prior to submission of the application; or

d. Thirty contact hours of education in pharmacology or pharmacotherapeutics acceptable to the boards taken within five years prior to submission of the application. The 30 contact hours may be obtained in a formal academic setting as a discrete offering or as noncredit continuing education offerings and shall include the following course content:

(1) Applicable federal and state laws;

(2) Prescription writing;

(3) Drug selection, dosage, and route;

(4) Drug interactions;

(5) Information resources; and

(6) Clinical application of pharmacology related to specific scope of practice.

3. Develop a practice agreement between the nurse practitioner and the patient care team physician as required in 18VAC90-40-90; and

4. File a completed application and pay the fees as required in 18VAC90-40-70.

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

COMMENT: Prescriptive authority for Schedule II controlled substances is specified in statute.

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WASHINGTON

STATUTES

- Nurse Practice Act
  Title 18. Businesses and Professions; Chapter 18.79. Nursing Care

REGULATIONS

- Nursing Board Regulations
  Title 246. Health, Department of Professional Standards and Licensing; Chapter 840. Practical and Registered Nursing

OTHER GOVERNMENTAL POLICIES

No policies found

WASHINGTON

STATUTES

Nurse Practice Act

Rev. Code Wash. (ARCW) § 18.79.250

§ 18.79.250. Advanced registered nurse practitioner -- Activities allowed

An advanced registered nurse practitioner under his or her license may perform for compensation nursing care, as that term is usually understood, of the ill, injured, or infirm, and in the course thereof, she or he may do the following things that shall not be done by a person not so licensed, except as provided in *RCW 18.79.260* and *18.79.270*:

(1) Perform specialized and advanced levels of nursing as recognized jointly by the medical and nursing professions, as defined by the commission;

(2) Prescribe legend drugs and Schedule V controlled substances, as defined in the Uniform Controlled Substances Act, chapter 69.50 RCW, and Schedules II through IV subject to *RCW 18.79.240(1)(r)* or (s) within the scope of practice defined by the commission;

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

(3) Perform all acts provided in *RCW 18.79.260*;

(4) Hold herself or himself out to the public or designate herself or himself as an advanced registered nurse practitioner or as a nurse practitioner.

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Madison, Wisconsin

WASHINGTON

STATUTES

Nurse Practice Act

Rev. Code Wash. (ARCW) § 18.79.400

§ 18.79.400. Pain management rules – Criteria for new rules

(1) By June 30, 2011, the commission shall adopt new rules on chronic, noncancer pain management that contain the following elements:

(a) (i) Dosing criteria, including:

(A) A dosage amount that must not be exceeded unless a physician first consults with a practitioner specializing in pain management; and

(B) Exigent or special circumstances under which the dosage amount may be exceeded without consultation with a practitioner specializing in pain management.

(ii) The rules regarding consultation with a practitioner specializing in pain management must, to the extent practicable, take into account:

(A) Circumstances under which repeated consultations would not be necessary or appropriate for a patient undergoing a stable, ongoing course of treatment for pain management;

(B) Minimum training and experience that is sufficient to exempt a physician from the specialty consultation requirement;

(C) Methods for enhancing the availability of consultations;

(D) Allowing the efficient use of resources; and

(E) Minimizing the burden on practitioners and patients;

(b) Guidance on when to seek specialty consultation and ways in which electronic specialty consultations may be sought;

(c) Guidance on tracking clinical progress by using assessment tools focusing on pain interference, physical function, and overall risk for poor outcome; and

(d) Guidance on tracking the use of opioids, particularly in the emergency department.

(2) The commission shall consult with the agency medical directors' group, the department of health, the University of Washington, and the largest professional association of physicians in the state.

(3) The rules adopted under this section do not apply:

(a) To the provision of palliative, hospice, or other end-of-life care; or

(b) To the management of acute pain caused by an injury or a surgical procedure.

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (regulations) for the board to improve 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 include improvements in patient functioning and quality of life.

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University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

WASHINGTON

REGULATIONS

Nursing Board Regulations

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

WAC § 246-840-420

WAC 246-840-420. Authorized prescriptions by ARNP with prescriptive authority.

(1) Prescriptions for drugs, medical equipment and therapies must comply with all applicable state and federal laws and be within the ARNP's scope of practice.

(2) The advanced registered nurse practitioner must sign all prescriptions and include the initials ARNP or NP.

(3) An ARNP may not, under RCW 18.79.240(1) and chapter 69.50 RCW, prescribe controlled substances in Schedule I.

(4) Any ARNP with prescriptive authority who prescribes controlled substances must be registered with the drug enforcement administration.

WAC § 246-840-575

WAC 246-840-575. Curriculum for approved nursing education programs.

The curriculum must provide diverse learning experiences consistent with program outcomes. Clinical experiences must include opportunities to learn and provide care to clients from diverse ethnic and cultural backgrounds. The emphasis placed on these areas and the scope encompassed shall be in keeping with the purpose and outcomes of the program.

(1) The length, organization, content, methods of instruction, and placement of courses must be consistent with the purpose and outcomes of the program.

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(e) All nursing courses shall include:

(i) Comprehensive content on: Client needs; safe, effective care environment; health promotion and maintenance; psychosocial integrity and physiological integrity.

(ii) Clinical experiences in the care of persons at each stage of the human life cycle, with opportunities for the student to learn and have direct involvement in, responsibility and accountability for the provision of basic nursing care and comfort for clients with acute and chronic illnesses, pharmacological and parenteral therapies and pain management. The emphasis placed on these areas, the scope encompassed, and other allied experiences offered shall be consistent with the purpose and outcomes of the program.

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

COMMENT: Prescriptive authority for Schedule II controlled substances is specified in statute.

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

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (educational experiences) for nursing programs to ensure that pain management is an essential part of patient care.

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University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

WASHINGTON

REGULATIONS

Nursing Board Regulations

WAC § 246-840-460 et seq

WAC 246-840-460. Pain management -- Intent.

These rules govern the use of opioids in the treatment of patients for chronic noncancer pain.

WAC 246-840-463. Exclusions.

The rules adopted under *WAC 246-840-460* through *246-840-493* do not apply to:

(1) The provision of palliative, hospice, or other end-of-life care; or

(2) The management of acute pain caused by an injury or surgical procedure.

WAC 246-840-465. Definitions.

The definitions in this section apply in *WAC 246-840-460* through *246-840-493* unless the context clearly requires otherwise.

(1) "Acute pain" means 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, often less than three months in duration, and usually less than six months.

(2) "Addiction" means a primary, chronic, neurobiologic disease with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include:

(a) Impaired control over drug use;

(b) Craving;

(c) Compulsive use; or

(d) Continued use despite harm.

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

(3) "Chronic noncancer pain" means a state in which noncancer 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.

(4) "Comorbidity" means a pre-existing or coexisting physical or psychiatric disease or condition.

(5) "Episodic care" means medical care provided by a provider other than the designated primary provider in the acute care setting, for example, urgent care or emergency department.

(6) "Hospice" means a model of care that focuses on relieving symptoms and supporting patients with a life expectancy of six months or less. Hospice involves an interdisciplinary approach to provide health care, pain management, and emotional and spiritual support. The emphasis is on comfort, quality of life and patient and family support. Hospice can be provided in the patient's home as well as freestanding hospice facilities, hospitals, nursing homes, or other long-term care facilities.

(7) "Morphine equivalent dose" means a conversion of various opioids to a morphine equivalent dose by the use of accepted conversion tables.

(8) "Multidisciplinary pain clinic" means a clinic or office that provides comprehensive pain management and may include care provided by multiple available disciplines, for example, physicians, osteopathic physicians, physician assistants, advanced registered nurse practitioners, physical therapists, occupational therapists, and other complementary therapies.

(9) "Palliative" means care that improves the quality of life of patients and their families facing life-threatening illness. With palliative care particular attention is given to the prevention, assessment, and treatment of pain and other symptoms, and to the provision of psychological, spiritual, and emotional support.

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Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

WASHINGTON

REGULATIONS

Nursing Board Regulations

WAC § 246-853-660 et seq

WAC 246-840-467. Patient evaluation.

The advanced registered nurse practitioner shall obtain, evaluate, and document the patient's health history and physical examination in the health record prior to treating for chronic noncancer pain.

(1) The patient's health history shall include:

(a) Current and past treatments for pain;

(b) Comorbidities; and

(c) Any substance abuse.

(2) The patient's health history should include:

(a) A review of any available prescription monitoring program or emergency department-based information exchange; and

(b) Any relevant information from a pharmacist provided to advanced registered nurse practitioners.

(3) The initial patient evaluation shall include:

(a) Physical examination;

(b) The nature and intensity of the pain;

(c) The effect of the pain on physical and psychological function;

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

(e) A risk screening of the patient for potential comorbidities and risk factors using an appropriate screening tool. The screening should address:

(i) History of addiction;

(ii) Abuse or aberrant behavior regarding opioid use;

(iii) Psychiatric conditions;

(iv) Regular concomitant use of benzodiazepines, alcohol, or other central nervous system medications;

(v) Poorly controlled depression or anxiety;

(vi) Evidence or risk of significant adverse events, including falls or fractures;

(vii) Receipt of opioids from more than one prescribing practitioner or practitioner group;

(viii) Repeated visits to emergency departments seeking opioids;

(ix) History of sleep apnea or other respiratory risk factors;

(x) Possible or current pregnancy; and

(xi) History of allergies or intolerances.

(4) The initial patient evaluation should include:

(a) Any available diagnostic, therapeutic, and laboratory results; and

(b) Any available consultations.

(CONTINUED ON NEXT PAGE)

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REGULATIONS

Nursing Board Regulations

WAC § 246-853-660 et seq

(5) The health record shall be maintained in an accessible manner, readily available for review, and should include:

(a) The diagnosis, treatment plan, and objectives;

(b) Documentation of the presence of one or more recognized indications for the use of pain medication;

(c) Documentation of any medication prescribed;

(d) Results of periodic reviews;

(e) Any written agreements for treatment between the patient and the advanced registered nurse practitioner; and

(f) The advanced registered nurse practitioner's instructions to the patient.

WAC 246-840-470. Treatment plan.

(1) The written treatment plan shall state the objectives that will be used to determine treatment success and shall include, at a minimum:

(a) Any change in pain relief;

(b) Any change in physical and psychosocial function; and

(c) Additional diagnostic evaluations or other planned treatments.

(2) After treatment begins the advanced registered nurse practitioner should adjust drug therapy to the individual health needs of the patient. Advanced registered nurse practitioners shall include indications for medication use on the prescription and require photo identification of the person picking up the prescription in order to fill. Advanced registered nurse practitioners shall advise the patient that it is the patient's responsibility to safeguard all medications and keep them in a secure location.

(3) 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.

WAC 246-840-473. Informed consent.

The advanced registered nurse practitioner shall discuss the risks and benefits of treatment options with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is without health care decision-making capacity.

WAC 246-840-475. Written agreement for treatment.

Chronic noncancer pain patients should receive all chronic pain management prescriptions from one advanced registered nurse practitioner and one pharmacy whenever possible. If the patient is at high risk for medication abuse, or has a history of substance abuse, or psychiatric comorbidities, the prescribing advanced registered nurse practitioner shall use a written agreement for treatment with the patient outlining patient responsibilities. This written agreement for treatment shall include:

(1) The patient's agreement to provide biological samples for urine/serum medical level screening when requested by the advanced registered nurse practitioner;

(2) The patient's agreement to take medications at the dose and frequency prescribed with a specific protocol for lost prescriptions and early refills;

(3) Reasons for which drug therapy may be discontinued (e.g., violation of agreement);

(CONTINUED ON NEXT PAGE)

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

(+) *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 include improvements in patient functioning and quality of life.

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Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
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WASHINGTON

REGULATIONS

Nursing Board Regulations

WAC § 246-853-660 et seq

(4) The requirement that all chronic pain management prescriptions are provided by a single prescriber or multidisciplinary pain clinic and dispensed by a single pharmacy or pharmacy system;

(5) The patient's agreement to not abuse alcohol or use other medically unauthorized substances;

(6) A written authorization for:

(a) The advanced registered nurse practitioner to release the agreement for treatment to local emergency departments, urgent care facilities, and pharmacies; and

(b) Other practitioners to report violations of the agreement back to the advanced registered nurse practitioner;

(7) A written authorization that the advanced registered nurse practitioner may notify the proper authorities if he or she has reason to believe the patient has engaged in illegal activity;

(8) Acknowledgment that a violation of the agreement may result in a tapering or discontinuation of the prescription;

(9) Acknowledgment that it is the patient's responsibility to safeguard all medications and keep them in a secure location; and

(10) Acknowledgment that if the patient violates the terms of the agreement, the violation and the advanced registered nurse practitioner's response to the violation will be documented, as well as the rationale for changes in the treatment plan.

WAC 246-840-477. Periodic review.

The advanced registered nurse practitioner shall periodically review the course of treatment for chronic noncancer pain, the patient's state of health, and any new information about the etiology of the pain. Generally, periodic reviews shall take place at least every six months. However, for treatment of stable patients with chronic noncancer pain involving nonescalating daily dosages of forty milligrams of a morphine equivalent dose (MED) or less, periodic reviews shall take place at least annually.

(1) During the periodic review, the advanced registered nurse practitioner shall determine:

(a) Patient's compliance with any medication treatment plan;

(b) If pain, function, or quality of life have improved or diminished using objective evidence, considering any available information from family members or other caregivers; and

(c) If continuation or modification of medications for pain management treatment is necessary based on the advanced registered nurse practitioner's evaluation of progress towards treatment objectives.

(2) The advanced registered nurse practitioner shall assess the appropriateness of continued use of the current treatment plan if the patient's progress or compliance with current treatment plan is unsatisfactory. The advanced registered nurse practitioner shall consider tapering, changing, or discontinuing treatment when:

(a) Function or pain does not improve after a trial period;

(b) There is evidence of significant adverse effects;

(c) Other treatment modalities are indicated; or

(d) There is evidence of misuse, addiction, or diversion.

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REGULATIONS

Nursing Board Regulations

(CONTINUED ON NEXT PAGE)

(3) The advanced registered nurse practitioner should periodically review information from any available prescription monitoring program or emergency department-based information exchange.

(4) The advanced registered nurse practitioner should periodically review any relevant information from a pharmacist provided to the advanced registered nurse practitioner.

WAC § 246-853-660 et seq

WAC 246-840-480. Long-acting opioids, including methadone.

Long-acting opioids, including methadone, should only be prescribed by an advanced registered nurse practitioner who is familiar with its risks and use, and who is prepared to conduct the necessary careful monitoring. Special attention should be given to patients who are initiating such treatment. An advanced registered nurse practitioner prescribing long-acting opioids or methadone should have a one-time (lifetime) completion of at least four hours of continuing education relating to this topic.

WAC 246-840-483. Episodic care.

(1) When evaluating patients for episodic care, such as emergency or urgent care, the advanced registered nurse practitioner should review any available prescription monitoring program, emergency department-based information exchange, or other tracking system.

(2) Episodic care practitioners should avoid providing opioids for chronic pain management. However, if opioids are provided, the episodic care practitioner should limit the use of opioids for a chronic noncancer pain patient to the minimum amount necessary to control the pain until the patient can receive care from a primary care practitioner.

(3) Prescriptions for opioids written by an episodic care practitioner shall include indications for use or the International Classification of Disease (ICD) code and shall be written to require photo identification of the person picking up the prescription in order to fill.

(4) If a patient has signed a written agreement for treatment and has provided a written authorization to release the agreement under *WAC 246-840-475(6)* to episodic care practitioners, then the episodic care practitioner should report known violations of the agreement back to the patient's treatment practitioner who provided the agreement for treatment.

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WASHINGTON

REGULATIONS

Nursing Board Regulations

WAC 246-840-485. Consultation -- Recommendations and requirements.

(1) The advanced registered nurse practitioner shall consider and document referring the patient for additional evaluation and treatment as needed to achieve treatment objectives. Special attention should be given to those chronic noncancer pain patients who are under eighteen years of age, or who are at risk for medication misuse, abuse, or diversion. The management of pain in patients with a history of substance abuse or with comorbid psychiatric disorders may require extra care, monitoring, documentation, and consultation with, or referral to, an expert in the management of such patients.

(2) The mandatory consultation threshold for adults is one hundred twenty milligrams morphine equivalent dose (MED)(oral). In the event an advanced registered nurse practitioner prescribes a dosage amount that meets or exceeds the consultation threshold of one hundred twenty milligrams MED (orally) per day, a consultation with a pain management specialist as described in *WAC 246-840-493,* is required, unless the consultation is exempted under *WAC 246-840-487* or *246-840-490*. Great caution should be used when prescribing opioids to children with chronic noncancer pain and appropriate referrals to a specialist is encouraged.

(a) The mandatory consultation shall consist of at least one of the following:

(i) An office visit with the patient and the pain management specialist;

(ii) A telephone consultation between the pain management specialist and the advanced registered nurse practitioner;

(iii) An electronic consultation between the pain management specialist and the advanced registered nurse practitioner; or

(iv) An audio-visual evaluation conducted by the pain management specialist remotely, where the patient is present with either the advanced registered nurse practitioner or a licensed health care practitioner designated by the advanced registered nurse practitioner or the pain management specialist.

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

CATEGORY B:
Issues related to patients

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

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

WASHINGTON

REGULATIONS

Nursing Board Regulations

WAC § 246-853-660 et seq

(b) An advanced registered nurse practitioner shall document each mandatory consultation with the pain management specialist. Any written record of the consultation by the pain management specialist shall be maintained as a patient record by the specialist. If the specialist provides a written record of the consultation to the advanced registered nurse practitioner, the advanced registered nurse practitioner shall maintain it as part of the patient record.

(3) Nothing in this chapter shall limit any person's ability to contractually require a consultation with a pain management specialist as defined in *WAC 246-840-493,* at any time. For the purposes of *WAC 246-840-460* through*246-840-493*, "person" means an individual, a trust or estate, a firm, a partnership, a corporation (including associations, joint stock companies, and insurance companies), the state, or a political subdivision or instrumentality of the state, including a municipal corporation or a hospital district.

WAC 246-840-487. Consultation -- Exemptions for exigent and special circumstances.

An advanced registered nurse practitioner is not required to consult with a pain management specialist as described in *WAC 246-840-493* when he or she has documented adherence to all standards of practice as defined in *WAC 246-840-460* through *246-840-493* and when any one or more of the following conditions apply:

(1) The patient is following a tapering schedule;

(2) The patient requires treatment for acute pain which may or may not include hospitalization, requiring a temporary escalation in opioid dosage, with expected return to or below their baseline dosage level;

(3) The advanced registered nurse practitioner documents reasonable attempts to obtain a consultation with a pain management specialist and the circumstances justifying prescribing above one hundred twenty milligrams morphine equivalency dosage (MED) per day without first obtaining a consultation; or

(4) The advanced registered nurse practitioner documents the patient's pain and function is stable and the patient is on a nonescalating dosage of opioids.

WAC 246-840-490. Consultation -- Exemptions for the advanced registered nurse practitioner.

The advanced registered nurse practitioner is exempt from the consultation requirement in *WAC 246-840-485* if one or more of the following qualifications are met:

(1) The advanced registered nurse practitioner is a pain management specialist under *WAC 246-840-493*;

(2) The advanced registered nurse practitioner has successfully completed, within the last two years, a minimum of twelve continuing education hours on chronic pain management approved by the profession's continuing education accrediting organization, with at least two of these hours dedicated to long acting opioids, to include methadone;

(3) The advanced registered nurse practitioner is a pain management practitioner working in a multidisciplinary chronic pain treatment center, or a multidisciplinary academic research facility; or

(4) The advanced registered nurse practitioner has a minimum three years of clinical experience in a chronic pain management setting, and at least thirty percent of his or her current practice is the direct provision of pain management care.

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Pain & Policy Studies Group
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WASHINGTON

REGULATIONS

Nursing Board Regulations

WAC § 246-853-660 et seq

WAC 246-840-493. Pain management specialist.

A pain management specialist shall meet one or more of the following qualifications:

(1) If a physician or osteopathic physician:

(a) Board certified or board eligible by an American Board of Medical Specialties-approved board (ABMS) or by the American Osteopathic Association (AOA) in physical medicine and rehabilitation, rehabilitation medicine, neurology, rheumatology, or anesthesiology; or

(b) Has a subspecialty certificate in pain medicine by an ABMS-approved board; or

(c) Has a certification of added qualification in pain management by the AOA; or

(d) A minimum of three years of clinical experience in a chronic pain management care setting; and

(i) Credentialed in pain management by an entity approved by the Washington state medical quality assurance commission for physicians or the Washington state board of osteopathic medicine and surgery for osteopathic physicians; and

(ii) Successful completion of a minimum of at least eighteen continuing education hours in pain management during the past two years; and

(iii) At least thirty percent of the physician's or osteopathic physician's current practice is the direct provision of pain management care or is in a multidisciplinary pain clinic.

(2) If a dentist: Board certified or board eligible in oral medicine or orofacial pain by the American Board of Oral Medicine or the American Board of Orofacial Pain.

(3) If an advanced registered nurse practitioner (ARNP):

(a) A minimum of three years of clinical experience in a chronic pain management care setting;

(b) Credentialed in pain management by a Washington state nursing care quality assurance commission-approved national professional association, pain association, or other credentialing entity;

(c) Successful completion of a minimum of at least eighteen continuing education hours in pain management during the past two years; and

(d) At least thirty percent of the ARNP's current practice is the direct provision of pain management care or is in a multidisciplinary pain clinic.

(4) If a podiatric physician:

(a) Board certified or board eligible in a specialty that includes a focus on pain management by the American Board of Podiatric Surgery, the American Board of Podiatric Orthopedics and Primary Podiatric Medicine, or other accredited certifying board as approved by the Washington state podiatric medical board; or

(b) A minimum of three years of clinical experience in a chronic pain management care setting; and

(c) Credentialed in pain management by a Washington state podiatric medical board, approved national professional association, pain association, or other credentialing entity; and

(d) Successful completion of a minimum of at least eighteen hours of continuing education in pain management during the past two years, and at least thirty percent of the podiatric physician's current practice is the direct provision of pain management care.

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Madison, Wisconsin

WEST VIRGINIA

STATUTES

- Nurse Practice Act
  Title 30. Professions and Occupations; Article 7. Registered Professional Nurses

REGULATIONS

- Nursing Board Regulations
  Title 19. Legislative Rule; West Virginia Board of Examiners for Registered Professional Nurses

OTHER GOVERNMENTAL POLICIES

See Joint Policy from the West Virginia profile in Section IX

WEST VIRGINIA

STATUTES

Nurse Practice Act

W. Va. Code § 30-7-15a

§ 30-7-15a. Prescriptive authority for prescription drugs; collaborative relationship with physician requirements; promulgation of rules; classification of drugs to be prescribed; coordination with other boards; coordination with board of pharmacy.

(a) The board may, in its discretion, authorize an advanced nurse practitioner to prescribe prescription drugs in a collaborative relationship with a physician licensed to practice in West Virginia and in accordance with applicable state and federal laws. An authorized advanced nurse practitioner may write or sign prescriptions or transmit prescriptions verbally or by other means of communication.

(b) For purposes of this section an agreement to a collaborative relationship for prescriptive practice between a physician and an advanced practice registered nurse shall be set forth in writing. Verification of such agreement shall be filed with the board by the advanced nurse practitioner. The board shall forward a copy of such verification to the Board of Medicine and the Board of Osteopathic Medicine. Collaborative agreements shall include, but not be limited to, the following:

(1) Mutually agreed upon written guidelines or protocols for prescriptive authority as it applies to the advanced nurse practitioner's clinical practice;

(2) Statements describing the individual and shared responsibilities of the advanced nurse practitioner and the physician pursuant to the collaborative agreement between them;

(3) Periodic and joint evaluation of prescriptive practice; and

(4) Periodic and joint review and updating of the written guidelines or protocols.

(c) The board shall promulgate legislative rules in accordance with the provisions of chapter twenty-nine-a [*§§ 29A-1-1* et seq.] of this code governing the eligibility and extent to which an advanced nurse practitioner may prescribe drugs. Such rules shall provide, at a minimum, a state formulary classifying those categories of drugs which shall not be prescribed by advanced nurse practitioners, including, but not limited to, Schedules I and II of the Uniform Controlled Substances Act, anticoagulants, antineoplastics, radio-pharmaceuticals and general anesthetics. Drugs listed under schedule III shall be limited to a seventy-two hour supply without refill.

(d) The board shall consult with other appropriate boards for the development of the formulary.

(e) The board shall transmit to the Board of Pharmacy a list of all advanced nurse practitioners with prescriptive authority. The list shall include:

(1) The name of the authorized advanced nurse practitioner;

(2) The prescriber's identification number assigned by the board; and

(3) The effective date of prescriptive authority.

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

***CATEGORY D*:**
Undue prescription limitations

COMMENT: Requires formal collaborative practice and protocols with a physician.

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

***CATEGORY A*:**
Arbitrary standards for legitimate prescribing

COMMENT: Does not permit prescribing of Schedule II controlled substances.

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Madison, Wisconsin

WEST VIRGINIA

REGULATIONS

Nursing Board Regulations

W. Va. CSR § 19-8-3

§ 19-8-3. Application and Eligibility for Limited Prescriptive Authority.

3.1. The Board shall grant prescriptive authority to an advanced nurse practitioner applicant who meets all eligibility requirements specified in *W. Va. Code § 30-7-15b* and to the certified nurse-midwife applicant who meets all eligibility requirements specified in *W. Va. Code § 30-15-7b* and the following:

3.1.a. Prior to application to the Board for approval for limited prescriptive authority, the applicant shall successfully complete accredited course of instruction in pharmacology during undergraduate study; and an advanced pharmacotherapy graduate level course approved by the Board of not less than 45 pharmacology contact hours; provide documentation of the use of pharmacotherapy in clinical practice in the education program; and provide evidence of 15 pharmacology contact hours in advanced pharmacotherapy completed within 2 years prior to application for prescriptive authority. The applicant shall submit official transcripts or certificates documenting completion of pharmacology and pharmacotherapy course work. The Board may request course outlines and/or descriptions of courses if necessary to evaluate the pharmacology course content and objectives.

3.1.b. The advanced nurse practitioner or certified nurse-midwife shall submit a notarized application for prescriptive authority on forms provided by the Board with the following:

3.1.b.1. A fee set forth in the Board's rule, Fee for Services Rendered by the Board, 19CSR12.

3.1.b.2. A voided sample of the prescription form.

3.1.b.3. Written verification of an agreement to a collaborative relationship with a licensed physician for prescriptive practice on forms provided by the Board. The applicant shall certify on this form that the collaborative agreement includes the following:

3.1.b.3.A. Mutually agreed upon written guidelines or protocols for prescriptive authority as it applies to the advanced nurse practitioner's or certified nurse-midwife's clinical practice;

3.1.b.3.B. Statements describing the individual and shared responsibilities of the advanced nurse practitioner or certified nurse-midwife and the physician pursuant to the collaborative agreement between them;

3.1.b.3.C. A provision for the periodic and joint evaluation of the prescriptive practice; and

3.1.b.3.D. A provision for the periodic and joint review and updating of the written guidelines or protocols.

3.1.b.3.E. Additional documentation at the request of the Board.

W. Va. CSR § 19-8-5

§ 19-8-5. Drugs Excluded from Prescriptive Authority.

5.1. The advanced nurse practitioner or certified nurse-midwife shall not prescribe from the following categories of drugs:

5.1.a. Schedules I and II of the Uniform Controlled Substances Act;

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

***CATEGORY D*:**
Undue prescription limitations

COMMENT: Requires formal collaborative practice and protocols with a physician.

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

***CATEGORY A*:**
Arbitrary standards for legitimate prescribing

COMMENT: Does not permit prescribing of Schedule II controlled substances.

2013

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Madison, Wisconsin

WISCONSIN

STATUTES

- Nurse Practice Act
  Regulation and Licensing; Chapter 441. Board of Nursing

REGULATIONS

- Nursing Board Regulations
  Board of Nursing

OTHER GOVERNMENTAL POLICIES

Wisconsin Board of Nursing. *Pain Management*. Adopted: April 19, 2007; Revised: February 14, 2013.

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

WISCONSIN

STATUTES

Nurse Practice Act

Wis. Stat. § 441.16

441.16. Prescription privileges of nurses.

(1) In this section:

(a) "Device" has the meaning given in s. 450.01 (6)
(b) "Drug" has the meaning given in s. 450.01 (10) and includes all of the following:

1. Prescription drugs, as defined in s. 450.01 (20) (a)

2. Controlled substances, as defined in s. 961.01 (4)

(c) "Prescription order" has the meaning given in s. 450.01 (21)

(2) Subject to s. 441.07 (1g), the board shall grant a certificate to issue prescription orders to an advanced practice nurse who meets the education, training, and examination requirements established by the board for a certificate to issue prescription orders, and who pays the fee specified under s. 440.05 (1) . An advanced practice nurse certified under this section may provide expedited partner therapy in the manner described in s. 448.035.

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

2013

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WISCONSIN

REGULATIONS

Nursing Board Regulations

Wis. Adm. Code N 8.02

N 8.02 Definitions

As used in this chapter:

(1) "Advanced practice nurse" means a registered nurse who possesses the following qualifications:

(a) The registered nurse has a current license to practice professional nursing in this state, or has a current license to practice professional nursing in another state which has adopted the nurse licensure compact;

(b) The registered nurse is currently certified by a national certifying body approved by the board as a nurse practitioner, certified nurse-midwife, certified registered nurse anesthetist or clinical nurse specialist; and,

(c) For applicants who receive national certification as a nurse practitioner, certified nurse-midwife, certified registered nurse anesthetist or clinical nurse specialist after July 1, 1998, the registered nurse holds a master's degree in nursing or a related health field granted by a college or university accredited by a regional accrediting agency approved by the board of education in the state in which the college or university is located.

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

(2) "Advanced practice nurse prescriber" means an advanced practice nurse who has been granted a certificate to issue prescription orders under s. 441.16 (2), Stats.

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Wis. Adm. Code N 8.10

N 8.10 Case management and collaboration with other health care professionals

(1) Advanced practice nurse prescribers shall communicate with patients through the use of modern communication techniques.

(2) Advanced practice nurse prescribers shall facilitate collaboration with other health care professionals, at least 1 of whom shall be a physician, through the use of modern communication techniques.

(3) Advanced practice nurse prescribers shall facilitate referral of patient health care records to other health care professionals and shall notify patients of their right to have their health care records referred to other health care professionals.

(4) Advanced practice nurse prescribers shall provide a summary of a patient's health care records, including diagnosis, surgeries, allergies and current medications to other health care providers as a means of facilitating case management and improved collaboration.

(5) The board shall promote communication and collaboration among advanced practice nurses, physicians and other health care professionals, including notification to advanced practice nurses of mutual educational opportunities and available communication networks.

(6) To promote case management, the advanced practice nurse prescriber may order laboratory testing, radiographs or electrocardiograms appropriate to his or her area of competence as established by his or her education, training, or experience.

(7) Advanced practice nurse prescribers shall work in a collaborative relationship with a physician. The collaborative relationship is a process in which an advanced practice nurse prescriber is working with a physician, in each other's presence when necessary, to deliver health care services within the scope of the practitioner's professional expertise. The advanced practice nurse prescriber and the physician must document this relationship.

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

CATEGORY D:
Undue prescription limitations

COMMENT: Requires formal collaborative practice with a physician.

2013

Pain & Policy Studies Group
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Madison, Wisconsin

WISCONSIN

OTHER GOVERNMENTAL POLICY

Nursing Board Policy Statement

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies the potential impact of important barriers on the provision of effective pain care.

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

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for providers the important distinction between 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, and practitioners who provide it.

The Wisconsin Board of Nursing
White Paper on Pain Management

Safe and competent care of the management of pain involves appropriate and effective assessment by the professional nurse. Under treatment of pain continues to be a major public health problem.

Inadequate pain control may result from nurses' lack of knowledge about pain assessment and management and/or their misunderstanding of the safety and efficacy of opioid analgesics, drugs that are essential for the management of moderate to severe pain.

The Board of Nursing recognizes that the profession nurse shares in the responsibility for the assessment and management of pain. The Board encourages professional nurses to view effective pain management as part of nursing practice for all patients with pain, whether it is acute or chronic. It is especially important for patients who are experiencing pain at the end of life. Professional nurses should be knowledgeable about the safe and effective methods of pain management as well as the statutory requirements related to the use of controlled substances.

The Board recognizes that opioid analgesics are subject to abuse by individuals who seek them for mood altering and other psychological effects rather than for legitimate medical purposes. The professional nurse who administers these drugs in the course of treatment should be diligent and incorporate established safeguards into their practices to minimize the potential for abuse and diversion of controlled substances.

The Board also recognizes that opioids can cause life-threatening respiratory depression if they are not administered at appropriate doses and at appropriate dosing intervals. Nurses should be knowledgeable about the signs and symptoms of impeding respiratory depression and about the risk factors that increase the likelihood of the occurrence of this drug side effect. However, excessive and inappropriate concerns about respiratory depression should not lead to nursing practices that deprive patients of doses needed for effective pain control, especially to those patients who are experiencing pain at the end of life.

The Board of Nursing is disseminating this white paper to support and encourage safe, competent and high quality nursing care for persons with pain.

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

(+) *CRITERION 4:*
Encourages pain management

2013

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WYOMING

STATUTES

- Nurse Practice Act
  Title 33. Professions and Occupations; Chapter 21. Nurses

REGULATIONS

- Nursing Board Regulations
  Agency 024. Department of Administration and Information;
  Sub-Agency 054. Board of Nursing

OTHER GOVERNMENTAL POLICIES

See Joint Policy from the Wyoming profile in Section IX

WYOMING

STATUTES

Nurse Practice Act

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

Wyo. Stat. § 33-21-120

§ 33-21-120. Definitions.

(a) As used in this act:

(i) "Advanced practice registered nurse (APRN)" means a nurse who:

(A) May prescribe, administer, dispense or provide nonprescriptive and prescriptive medications including prepackaged medications, except schedule I drugs as defined in *W.S. 35-7-1013* and *35-7-1014*;

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REGULATIONS

Nursing Board Regulations

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

WCWR 024-054-004

CHAPTER 4. ADVANCED PRACTITIONERS OF NURSING

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Section 8. Prescriptive Authority.

(a) The board may authorize an advanced practitioner of nursing or "APN" to prescribe drugs, within the recognized scope of advanced specialty practice, and in accordance with all applicable state and federal laws; including, but not limited to the Wyoming Pharmacy Act [*WS 33-24-101* through *33-24-204*], the Wyoming Controlled Substances Act of 1971 [*WS 35-7-1001* through *35-7-1101*], the Federal Controlled Substances Act *[21 U.S.C. 801* et seq.], their applicable Rules and Regulations.

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2013

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APPENDIX A: RECOMMENDED RECENT POLICY – RELATED READINGS

The following recent material provides background information on policy issues related to pain, controlled substances, and professional practice:

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APPENDIX B: WHAT CAN STATE LEGISLATURES AND AGENCIES DO TO IMPROVE PAIN MANAGEMENT?

The initial, crucial, step legislatures and state agencies can take to improve pain management is to study the problem. Although the problems and solutions differ from state to state, one state often can benefit from the efforts and experiences of others, so reviewing what other states have done is recommended

The most common and probably the most valuable method is to create a multidisciplinary task force, commission, or advisory committee to study carefully the legal, fiscal, and other barriers to pain management for all types of pain patients in the state (chronic cancer and non-cancer, post-surgical, sickle-cell, HIV/AIDS, etc). For this process it is important to review relevant state policies mentioned below and throughout this report, and then make and implement recommendations in legislation (policy, budget), regulations, guidelines, public information, education, training, program development, etc. States with sunrise/sunset review criteria should consider subjecting those statutes and regulations that affect pain management to those criteria (in addition to the criteria set out in this *Evaluation Guide*).

Below are a series of questions relevant to addressing appropriate pain management in various types of governmental, regulatory, and healthcare policies.

1. Controlled substances policy

Does the state Controlled Substances Act recognize the essential medical uses of controlled substances, as in federal law and as recommended by the National Conference of Commissioners on Uniform State Laws?

Do state statutes or regulations restrict prescribing of controlled substances by creating unalterable requirements or standards, such as:

- limiting to a short period the number of days for which a prescription for a controlled substance is valid,
- complete exclusion of people with particular characteristics from receiving prescriptions for pain medications (regardless of treatment feasibility),
- defining “unprofessional conducts” to include “excessive prescribing,” without specifying the standards or criteria used to make such a determination, and
- legal terminology that confuses addiction with physical dependence on opioids used in the course of pain therapy?

2. Healthcare policy

Do the relevant practice acts or board regulations contain any provisions, including the ones described above, that would be unduly restrictive or confusing when applied to the prescribing of controlled substances for the treatment of pain?

Have the boards of medicine, osteopathy, pharmacy, and nursing adopted guidelines or policies clarifying that the board recognizes that the appropriate use of controlled substances for the treatment of pain is accepted professional practice and setting forth the principles that a practitioner can follow to confidently avoid the risk of disciplinary sanctions by a regulatory agency in the state for legitimate practice?

Appendix B: What Can State Legislatures and Agencies do to Improve Pain Management?

Do the state's professional schools for medicine, pharmacy, and nursing provide adequate instruction about pain and palliative care?

Are the boards' statutes, regulations, or guidelines adequately disseminated or available to licensees and others?

3. Facility regulation (hospital, hospice, nursing home, home care, etc.)

What is the attitude of the state regulators of health care facilities?

Do licensing, certification, or inspection criteria include assessment and treatment of pain and training of patient care staff?

Is technical assistance on pain and symptom management available?

Are there inappropriate restrictions, requirements, formularies, or financial constraints on the delivery of pain management?

4. State health policy

Are there inappropriate financial constraints on the delivery of pain management?

Do managed care organizations have policies addressing pain assessment, treatment, reimbursement, and appropriate access to specialists?

Does state Medicaid policy adequately reimburse the controlled drugs used in pain and symptom management? Does it unduly restrict which drugs are covered and in what amounts?

Does Workers Compensation adequately address the treatment needs for people with severe pain that is prolonged and debilitating?

Does the state cancer control plan emphasize pain management and palliative care for cancer patients in the state, and does the plan include actions that should be taken to improve state policy and access to quality pain and palliative care.

Is there a State Pain Initiative or other pain or palliative care group that promotes improved pain management and policy? Is there adequate communication among government agencies and state pain initiatives or leading pain practitioners? Do state regulators participate in the initiative's activities?

Does the public have access to information about pain and symptom management including cancer and chronic non-cancer pain, and where to go for help? Are any organizations undertaking proactive efforts to provide information?

Does the toll-free number for cancer information also include information about pain management?

APPENDIX B: WHAT CAN STATE LEGISLATURES AND AGENCIES DO TO IMPROVE PAIN MANAGEMENT?

5. Law enforcement and regulatory policy

Do the state agencies that are involved in drug law enforcement and monitoring of controlled substances prescribing, dispensing, and patient use have adequate safeguards against the inappropriate scrutiny of practitioners who legitimately prescribe and dispense controlled substances and the maintenance of confidentiality of patient information (i.e., what standards do they use for initiating or continuing investigations, or what input do they get in establishing standards and from whom)?

Have state legal officials (such as the Attorney General) reviewed state policies relevant to pain management and end-of-life matters, such as advance directives and durable power of attorney, as recommended by the National Association of Attorneys General?

APPENDIX C: REGULATORY SYSTEMS AND PAIN MANAGEMENT?

The purpose of this section is to describe briefly the regulatory systems and recent trends that affect pain management. There are several regulatory systems that influence access to and delivery of pain management. These include the regulation of patient care facilities, reimbursement, drug regulation, and the licensing of health professionals. This section discusses the latter two.

1. Drug regulation

There are three tiers of drug regulation: International, federal, and state. The latter two will be discussed here; publications about international regulation are available on the PPSG website at www.painpolicy.wisc.edu.

Federal and state laws provide for three general levels of drug control, including "over-the-counter" drugs, "prescription" drugs, and "controlled substances." Under federal and state laws, over-the-counter drugs, such as aspirin, are the least controlled and are available directly to the consumer at a wide variety of retail establishments without a physician's order. Prescription drugs, such as antibiotics, which have greater potency and risks, must be approved as safe and effective for human use by the FDA according to authority under the Federal Food, Drug and Cosmetic Act. Their availability for medical use is pursuant to a prescription from a physician, dentist, podiatrist, or other professional licensed to prescribe. Prescription drugs also are regulated at the state level by food and drug laws, and by pharmacy laws that typically are administered by state pharmacy boards. Manufacturers and wholesalers are subject to provisions regarding the production, marketing, advertising, and distribution of prescription drugs. Federal and state laws provide penalties for obtaining prescription drugs without a prescription. As a class, prescription drugs may be prescribed for other than their specifically labeled indications if there is a medical rationale.

Controlled substances laws provide an additional layer of control over the distribution of prescription drugs that have a potential for producing psychological or physical dependence, as a means of preventing abuse, trafficking, and diversion. The federal Controlled Substances Act (CSA) contains numerous provisions regarding the possession, manufacture, and trafficking in illicit controlled substances, for which criminal penalties are established; at the same time, the CSA recognizes that controlled substances are necessary for public health and that their availability for medical and scientific purposes must be assured. Therefore, despite increased control measures, the requirements of the CSA are not intended to interfere with the medical uses of prescription drugs. The CSA specifies five classification schedules that carry different penalties for unlawful uses; requirements for prescriptions also vary depending on the schedule. Schedule I contains all drugs that have no approved medical use, such as the opioid heroin. Schedules II-IV contain drugs that have been approved by the FDA for medical use, including the opioid analgesics. Opioid analgesics with the highest potential for abuse are in Schedule II and include morphine, hydromorphone, methadone, oxycodone, and fentanyl. Opioids such as hydrocodone combinations and codeine combinations currently are in Schedule III, while Schedule IV also contains codeine in smaller dosages. Schedule V contains some opioids in smaller amounts, which may be over-the-counter cough preparations. All schedules also include non-opioids.

Under the CSA, it is not lawful for practitioners to use Schedule II drugs (i.e., methadone) for the purpose of maintenance or detoxification of narcotic addiction; this activity requires separate registration by the federal government and in some states. The use of drugs approved for this purpose, such as methadone and buprenorphine (which is in Schedule III), must be in compliance with federal and state regulations. Methadone, however, may be prescribed as an analgesic according to the same rules for prescribing any other Schedule II opioid analgesic.

APPENDIX C: REGULATORY SYSTEMS AND PAIN MANAGEMENT?

All persons or business entities must be registered with the Drug Enforcement Administration (and with state agencies in some states) to manufacture, distribute, handle, dispense or prescribe controlled substances. Registrants' purchases of Schedule II controlled substances and Schedule III narcotics are made using a special order form to monitor all transfers of these controlled substances within a "closed system." Prescriptions for Schedule II medications are permitted to be issued in written form or, since 2010, electronically. Schedule II medications cannot be refilled, whereas five refills are permitted for medications in Schedules III and IV. Oral prescriptions for Schedule II medications can be issued only in medical emergencies and under specific circumstances. Federal law also allows for the partial dispensing and faxing (but not oral or electronic data transmission) of prescriptions under certain circumstances. Federal laws do not limit the amount of the prescription or the duration of prescribing. There are penalties, both criminal and civil, for violation of federal requirements. The federal requirements are available at http://www.access.gpo.gov/nara/cfr/waisidx_03/21cfrv9_03.html.

The states have adopted versions of the CSA that use the same classification system, generally using a model Uniform Controlled Substances Act (UCSA) prepared by the National Conference of Commissioners on Uniform State Laws in 1970. All of the state Acts permit prescribing of controlled substances in Schedules II - V, although most do not specifically reflect the recognition by federal law of the medical uses of controlled substances. A 1994 revision of the model UCSA was prepared to correct these deficiencies, but only a few states have adopted the changes. The criminal provisions of the state Acts are enforced by state and local police agencies, while the drug regulatory aspects of state controlled substances laws are administered by a variety of state agencies, including departments of regulation and licensing (e.g., medical or pharmacy boards). These agencies often have regulations that govern the prescribing and dispensing of controlled substances more so than under federal law. Penalties for violation of prescribing requirements vary greatly. Some states also have limited the amount that can be prescribed at one time, and continue to limit the validity of a controlled substance prescription to as little as a few days or a week. Some have overly broad definitions of "addict" that could include patients with pain who are physically dependent on their medication; some states completely prohibit prescribing to persons with an addictive disease, or require they be reported to a state agency.

A number of years ago, some states began enacting "Prescription Monitoring Programs" (PMPs), which required practitioners to use government-issued prescription forms when prescribing controlled substances in certain schedules (see Table 3). The purpose of PMPs is to provide law enforcement, prescribers, and dispensers with information on "doctor shoppers," "scammers," and dishonest practitioners. Although representatives of PMPs have indicated that such programs are not intended to interfere with medical practice, and that precautions have been taken to avoid interference, some in the medical field expressed concern that PMPs (which required a government-issued prescription form for Schedule II controlled substances only) have a "chilling effect" on prescribing due to practitioners' concerns about being investigated for "excessive" prescribing. Indeed, several studies suggested that, after implementation of such programs, the prescribing of Schedule II medications being monitored declined substantially, and may have caused an increase in the prescribing of drugs in lower (less restricted) schedules that may have been less appropriate clinically for the patient's condition. This general decline in prescribing was interpreted by law enforcement authorities to indicate a reduction in inappropriate prescribing.

APPENDIX C: REGULATORY SYSTEMS AND PAIN MANAGEMENT?

Since the mid 1990s, states began to adopt PMPs that use an electronic data transmission (EDT) system. An EDT system requires the pharmacist to send prescription information electronically to the state agency that administers the program, which can obviate the need for a government-issued prescription form. Most of these EDT programs monitor medications at least in Schedules II-IV (not just Schedule II) and do not require a government-issued prescription form – one state, however, continues to use a government-issued form for Schedule II controlled substances in conjunction with an EDT program. See Table 3 for a description of currently operational prescription monitoring programs.

Regulation of healthcare professionals

The regulation of professional practice in medicine, osteopathy, pharmacy, nursing, and other professions occurs at the state, not federal, level (although federal agencies can substantially affect professional practice by denying or revoking controlled substances registration). State legislatures have adopted statutes to protect the public; these provide authority for a state agency to license and discipline members of the profession. Typically, the law creates a board, such as a medical board, that is responsible for licensing the members of the profession, as well as disciplining licensees for violating standards of professional conduct (these are usually expressed in the board's statute or in regulations). Boards have the power to adopt regulations to implement their statutory authority. The enactment of statutes and adoption of regulations are both subject to public scrutiny and, generally, public comment. A fixed number of board members with staggered terms typically is appointed by the Governor, sometimes in consultation with the profession's state society and sometimes with several appointments by the Legislature. Typically, there will be at least some members who are not licensees of the board, including representatives from other healthcare professions and members of the general public (called "public members").

Board investigation of a licensee is usually initiated by a complaint or by referral from another agency. Boards differ greatly as to the procedures used for inquiry and investigation into complaints – some boards are required by law to investigate each complaint received, while others can exercise discretion. Investigations may or may not be prompt, and may be dropped due to insufficient evidence or may proceed to disciplinary action, which can range from a warning, to education, to a limitation or removal of prescribing privilege or of the professional license. Board disciplinary actions are conducted pursuant to the state's Administrative Procedure Act; the licensee may appeal the decision to state courts. Boards also manage non-disciplinary programs to assist in the identification, treatment, and recovery of impaired professionals.

Each category of professional licensing board has a national organization that serves all the state boards – for medical boards it is the Federation of State Medical Boards; for pharmacy boards it is the National Association of Boards of Pharmacy; for nursing boards it is the National Council of State Boards of Nursing. The national organizations can be involved in a number of activities, such as: (1) the sponsorship of annual meetings, (2) the appointment of study task forces to address specific issues relevant to the regulation of that profession, and (3) a range of other technical assistance and information activities, including newsletters, statistics about licenses and discipline, and preparation of model statutes, regulations, and professional practice guidelines.

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47 States with Operational Prescription Monitoring Programs

State	Year Current Program Became Operational	Current Program Type	Schedules/ drugs covered	Initial Program(s) Type	Year of Previous Program Enactment
Alabama	2006	Electronic	C-II, III, IV, V		
Alaska	2011	Electronic	C-I, II, III, IV, V under federal law C-IA, IIA, IIIA, IVA, VA under state law		
Arizona	2008	Electronic	C-II, III, IV		
Arkansas	2013	Electronic	C-II, III, IV, V		
California	2005 (CURES)	Electronic/single-copy serialized security form	C-II, III, IV, V	Triplicate, serialized/Electronic, C-II only (CURES) Triplicate alone	1996 1939
Colorado	2008	Electronic	C-II, III, IV, V		
Connecticut	2008	Electronic	C-II, III, IV, V		
Delaware	2012	Electronic	C-II, III, IV, V		
Florida	2011	Electronic	C-II, III, IV, V		
Georgia	2013	Electronic	C-II, III, IV, V		
Hawaii	2002	Electronic	C-II, III, IV	Duplicate/Electronic, C-II only Duplicate, C-II only	1996 1943
Idaho	2004	Electronic	C-II, III, IV	Duplicate/Electronic Triplicate	1997 1967
Illinois	2011	Electronic	C-II, III, IV, V	Electronic, C-II only Triplicate, C-II only	1999 1961
Indiana	2008 (INSPECT)	Electronic	C-II, III, IV, V	Electronic, C-II only Triplicate, C-II only	1994 1987
Iowa	2009	Electronic	C-II, C-III & IV		
Kansas	2011	Electronic	C-II, III, IV		
Kentucky	2005 (KASPER)	Electronic	C-II, III, IV, V	Electronic, C-II, III, IV, V	1999
Louisiana	2009	Electronic	C-II, III, IV, V		
Maine	2004	Electronic	C-II, III, IV		
Maryland	2013	Electronic	C-II, III, IV, V		
Massachusetts	2010	Electronic	C-II, III, IV, V	Electronic, C-II only	1992

Michigan	2003	Electronic	C-II, III, IV, V	Single-copy, serialized/Electronic Triplicate	1993 1988
Minnesota	2010	Electronic	C-II, III, IV		
Mississippi	2009	Electronic	C-II, III, IV, V		
Montana	2013	Electronic	C-II, III, IV, V		
Nevada	1997	Electronic	C-II, III, IV		
New Jersey	2011	Electronic	C-II, III, IV,V		
New Mexico	2005	Electronic	C-II, III, IV	Electronic, C-II only	1994-2000
New York	2006	Electronic/serialized security form	C-II, III, IV, V	Single-copy, serialized/ Electronic, C-II & benzos Triplicate, C-II only	1998 1972
North Carolina	2007	Electronic	C-II, III, IV, V		
North Dakota	2007	Electronic	C-II, III, IV, V		
Ohio	2006	Electronic	C-II, III, IV, V		
Oklahoma	2006	Electronic	C-II, III, IV, V	Electronic, C-II only	1990
Oregon	2011	Electronic	C-II, III, IV		
Pennsylvania	1973	Electronic	C-II		
Rhode Island	1997	Electronic	C-II, III	Duplicate, C-II only	1979
South Carolina	2008	Electronic	C-II, III, IV		
South Dakota	2012	Electronic	C-II, III, IV		
Tennessee	2006	Electronic	C-II, III, IV, V		
Texas*	2008	Electronic/serialized security form	C-II, III, IV, V	Single-copy, serialized/ Electronic C-II only Triplicate	1997 1981
Utah	1995	Electronic	C-II, III, IV, V		
Vermont	2009	Electronic	C-II, III, IV		
Virginia	2006	Electronic	C-II, III, IV	Electronic (limited to SW region), C-II only	2003
Washington	2011	Electronic	C-II, III, IV, V		

West Virginia[a]	1995	Electronic	C-II, III, IV		
Wisconsin	2012	Electronic	C-II, III, IV		
Wyoming	2004	Electronic	C-II, III, IV		

Notes:
(1) Current as of 06/01/2014; prescription monitoring programs are subject to change.
(2) Washington's previous program, utilizing triplicate prescriptions, was used for disciplinary purposes only and was not included.
** Indicates prescribers are required to obtain state-issued prescription forms.* [a] The West Virginia program was discontinued in 1998, but re-authorized in 2002.