WSR 11-04-081
WITHDRAWAL OF PROPOSED RULES
DEPARTMENT OF SOCIAL AND HEALTH SERVICES
(By the Code Reviser's Office)
[Filed February 1, 2011, 8:40 a.m.]

WAC 388-531-1550, proposed by the department of social and health services in WSR 10-13-163 appearing in issue 10-15 of the State Register, which was distributed on August 4, 2010, is withdrawn by the code reviser's office under RCW 34.05.335(3), since the proposal was not adopted within the one hundred eighty day period allowed by the statute.

Kerry S. Radcliff, Editor
Washington State Register

WSR 11-04-086
PROPOSED RULES
DEPARTMENT OF HEALTH
(Board of Osteopathic Medicine and Surgery)
[Filed February 1, 2011, 5:18 p.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 10-13-102.

Title of Rule and Other Identifying Information: Chapter 246-853 WAC (osteopathic physicians) and chapter 246-854 WAC (osteopathic physician assistants), new sections for management of chronic noncancer pain. The proposed rules also repeal WAC 246-853-510, 246-853-520, 246-853-530 and 246-853-540 (osteopathic physicians) and 246-854-120, 246-854-130, 246-854-140 and 246-854-150 (osteopathic physician assistants).

Hearing Location(s): St. Francis Hospital, 34515 9th Avenue South, Garden Room, Federal Way, WA 98003, on March 18, 2011, at 9:00 a.m.

Date of Intended Adoption: March 18, 2011.

Submit Written Comments to: Erin Obenland, P.O. Box 47852, Olympia, WA 98504-7852, web site http://www3.doh.wa.gov/policyreview/, fax (360) 236-2901, by March 4, 2011.

Assistance for Persons with Disabilities: Contact Erin Obenland by March 4, 2011, TTY (800) 833-6388 or 711.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: ESHB 2876 (chapter 209, Laws of 2010) directs the board of osteopathic medicine and surgery to repeal existing pain management rules and adopt new rules for the management of chronic noncancer pain. The proposed rules include the mandatory elements for dosing criteria, guidance on specialty consultations, guidance on tracking clinical progress, and guidance on tracking opioid use. To address the mandatory elements, the proposed rules also describe the criteria to be considered a pain management specialist, describe elements for a patient evaluation and written treatment plan, describe when periodic reviews are required, and provide for practitioner exemptions for the consultation requirement.

Reasons Supporting Proposal: ESHB 2876 requires five health profession boards and commissions adopt rules on the management of chronic noncancer pain. These include the medical quality assurance commission, board of osteopathic medicine and surgery, nursing care quality assurance commission, dental quality assurance commission, and the podiatric medical board. The proposed rules will provide practitioners who treat patients with chronic noncancer pain with guidance and tools to reduce risks associated with opioid use.

Statutory Authority for Adoption: RCW 18.57.285, 18.57A.090, 18.57.005, and 18.57A.020.

Statute Being Implemented: RCW 18.57.285 and 18.57A.090.

Rule is not necessitated by federal law, federal or state court decision.

Name of Proponent: Washington state department of health, board of osteopathic medicine and surgery, governmental.

Name of Agency Personnel Responsible for Drafting, Implementation and Enforcement: Erin Obenland, 310 Israel Road S.E., Tumwater, WA 98501, (360) 236-4945.

No small business economic impact statement has been prepared under chapter 19.85 RCW. A small business economic impact statement was not prepared. The proposed rule would not impose more than minor costs on businesses in an industry.

A cost-benefit analysis is required under RCW 34.05.328. A preliminary cost-benefit analysis may be obtained by contacting Erin Obenland, P.O. Box 47852, Olympia, WA 98504-7852, phone (360) 236-4945, fax (360) 236-2901, e-mail erin.obenland@doh.wa.gov.

February 1, 2011
Blake T. Maresh
Executive Director

OSTEOPATHIC PHYSICIAN

NEW SECTION

WAC 246-853-660 Pain management—Intent. These rules govern the use of opioids in the treatment of patients for chronic noncancer pain.

NEW SECTION

WAC 246-853-661 Exclusions. The rules adopted under this section 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.

NEW SECTION

WAC 246-853-662 Definitions. The definitions in this section apply throughout the section 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.

(4) "Comorbidity" means a preexisting or coexisting physical or psychiatric disease or condition.

(5) "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.

(6) "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.

(7) "Physical dependence" means a physiologic state of adaptation to a specific psychoactive substance characterized by the emergence of a withdrawal syndrome during abstinence that may be relieved in total or in part by readministration of the substance.

(8) "Psychological dependence" means a subjective sense of need for a specific substance, either for its positive effects or to avoid negative effects associated with its abstinence.

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

NEW SECTION

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.

(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.

NEW SECTION

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 indica-

tions 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.

NEW SECTION

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.

NEW SECTION

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);

(4) The requirement that all chronic pain management prescriptions are provided by a single prescriber and dispensed by a single pharmacy;

(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.

NEW SECTION

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 40 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.

NEW SECTION

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 completion of at least four hours of continuing education relating to this topic.

NEW SECTION

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.

NEW SECTION

WAC 246-853-670 Consultation. (1) Consultation. 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) Mandatory consultation at 120 milligrams morphine equivalent dose (MED). In the event an osteopathic physician prescribes a dosage amount that meets or exceeds the consultation threshold of 120 milligrams MED per day, a consultation with a pain management specialist is required, unless the consultation is exempted under WAC 246-853-671 (exigent) or 246-853-672 (exempt practitioner).

(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.

(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 this section, "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.

NEW SECTION

WAC 246-853-671 Exigent and special circumstances under which the 120 milligrams MED may be exceeded without consultation with a pain management specialist. An osteopathic physician is not required to consult with a pain management specialist when he or she has documented adherence to all standards of practice as defined in WAC 246-853-660 through 246-854-673 of this chapter 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 osteopathic physician documents reasonable attempts to obtain a consultation with a pain management specialist and the circumstances justifying prescribing above 120 milligrams 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.

NEW SECTION

WAC 246-853-672 Osteopathic physician exempt from consultation requirement. 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;

(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;

(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.

NEW SECTION

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 a national professional association, pain management association, or other credentialing entity approved by the medical quality assurance commission for physicians or the 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 osteopathic physician's current practice is the direct provision of pain management care.

(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 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.

(4) If a podiatric physician:

(a) A minimum of three years of clinical experience in a chronic pain management care setting;

(b) Credentialed in pain management by a Podiatric Medical Board-approved national professional association, pain association, or other credentialing entity; and

(c) 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; or

(d) 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.

PHYSICIAN ASSISTANT

NEW SECTION

WAC 246-854-240 Pain management—Intent. These rules govern the use of opioids in the treatment of patients for chronic noncancer pain.

NEW SECTION

WAC 246-854-241 Exclusions. The rules adopted under this section 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.

NEW SECTION

WAC 246-854-242 Definitions. The definitions in this section apply throughout the section 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.

(4) "Comorbidity" means a preexisting or coexisting physical or psychiatric disease or condition.

(5) "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 free-standing hospice facilities, hospitals, nursing homes, or other long-term care facilities.

(6) "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.

(7) "Physical dependence" means a physiologic state of adaptation to a specific psychoactive substance characterized by the emergence of a withdrawal syndrome during absti-

nence that may be relieved in total or in part by readministration of the substance.

(8) "Psychological dependence" means a subjective sense of need for a specific substance, either for its positive effects or to avoid negative effects associated with its abstinence.

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

NEW SECTION

WAC 246-854-243 Patient evaluation. The osteopathic physician assistant 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 osteopathic physician assistant.

(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.

(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 assistant; and

(f) The osteopathic physician assistant instructions to the patient.

NEW SECTION

WAC 246-854-244 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 assistant should adjust drug therapy to the individual health needs of the patient. The osteopathic physician assistant 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 assistant 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.

NEW SECTION

WAC 246-854-245 Informed consent. The osteopathic physician assistant 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.

NEW SECTION

WAC 246-854-246 Written agreement for treatment. Chronic noncancer pain patients should receive all chronic pain management prescriptions from one osteopathic physician assistant 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 assistant 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 assistant;

(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 and dispensed by a single pharmacy;

(5) The patient's agreement to not abuse alcohol or use other medically unauthorized substances;

(6) A written authorization for:

(a) The osteopathic physician assistant 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 assistant;

(7) A written authorization that the osteopathic physician assistant 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 assistant's response to the violation will be documented, as well as the rationale for changes in the treatment plan.

NEW SECTION

WAC 246-854-247 Periodic review. The osteopathic physician assistant 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 40 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 assistant 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 assistant's evaluation of progress towards treatment objectives.

(2) The osteopathic physician assistant 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 assistant 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 assistant should periodically review information from any available prescription monitoring program or emergency department-based information exchange.

(4) The osteopathic physician assistant should periodically review any relevant information from a pharmacist provided to the osteopathic physician assistant.

NEW SECTION

WAC 246-854-248 Long-acting opioids, including methadone. Long-acting opioids, including methadone, should only be prescribed by an osteopathic physician assistant who is familiar with its risks and use, and who are prepared to conduct the necessary careful monitoring. Special attention should be given to patients who are initiating such treatment. The osteopathic physician assistant prescribing long-acting opioids or methadone should have a one-time completion of at least four continuing education hours relating to this topic.

NEW SECTION

WAC 246-854-249 Episodic care. (1) When evaluating patients for episodic care, such as emergency or urgent care, the osteopathic physician assistant 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 assistant 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 246-854-246(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.

NEW SECTION

WAC 246-854-250 Consultation. (1) Consultation. The osteopathic physician assistant 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) Mandatory consultation at 120 milligrams morphine equivalent dose (MED). In the event a practitioner prescribes a dosage amount that meets or exceeds the consultation threshold of 120 milligrams MED per day, a consultation with a pain management specialist is required, unless the consultation is exempted under WAC 246-854-251 (exigent) or 246-854-252 (exempt practitioner).

(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 assistant;

(iii) An electronic consultation between the pain management specialist and the osteopathic physician assistant; or

(iv) An audio-visual evaluation conducted by the pain management specialist remotely, where the patient is present with either the osteopathic physician assistant or a licensed health care practitioner designated by the osteopathic physician assistant or the pain management specialist.

(b) An osteopathic physician assistant 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 assistant, the osteopathic physician assistant 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 this section, "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.

NEW SECTION

WAC 246-854-251 Exigent and special circumstances under which the 120 milligrams MED may be exceeded without consultation with a pain management specialist. A physician assistant is not required to consult with a pain management specialist when he or she has documented adherence to all standards of practice as defined in WAC 246-854-240 through 246-854-253 of this chapter 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 physician assistant documents reasonable attempts to obtain a consultation with a pain management specialist and the circumstances justifying prescribing above 120 milligrams MED per day without first obtaining a consultation; or

(4) The physician assistant documents the patient's pain and function is stable and the patient is on a nonescalating dosage of opioids.

NEW SECTION

WAC 246-854-252 Osteopathic physician assistant exempt from consultation requirement. The physician assistant is exempt from the consultation requirement in WAC 246-854-250 if one or more of the following qualifications are met:

(1) The sponsoring physician is a pain management specialist under WAC 246-854-253;

(2) The sponsoring physician and the physician assistant have 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.

(3) The physician assistant is a pain management practitioner working in a multidisciplinary chronic pain treatment center, or a multidisciplinary academic research facility.

NEW SECTION

WAC 246-854-253 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) If a physician, a minimum of three years of clinical experience in a chronic pain management care setting; and

(i) Credentialed in pain management by a national professional association, pain management association, or other credentialing entity approved by the medical quality assurance commission for physicians or the 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 current practice is the direct provision of pain management care.

(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 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.

(4) If a podiatric physician:

(a) A minimum of three years of clinical experience in a chronic pain management care setting;

(b) Credentialed in pain management by a Podiatric Medical Board-approved national professional association, pain association, or other credentialing entity; and

(c) 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; or

(d) 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.

WSR 11-04-087

PROPOSED RULES

DEPARTMENT OF HEALTH

(Nursing Care Quality Assurance Commission)

[Filed February 1, 2011, 5:32 p.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 10-13-100.

Title of Rule and Other Identifying Information: WAC 246-840-460 through 246-840-493, new sections for management of noncancer pain, advanced registered nurse practitioners.

Hearing Location(s): Department of Health, Point Plaza East, Room 152/153, 310 Israel Road S.E., Tumwater, WA 98504, on March 18, 2011, at 9:30 a.m.

Date of Intended Adoption: March 18, 2011.

Submit Written Comments to: Terry J. West, Department of Health, P.O. Box 47864, Olympia, WA 98504, web site http://www3.doh.wa.gov/policyreview/, fax (360) 236-4738, by March 11, 2011.

Assistance for Persons with Disabilities: Contact Terry West by March 11, 2011, TTY (800) 833-6388 or 711.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: ESHB 2876 (chapter 209, Laws of 2010) directs the nursing care quality assurance commission to adopt rules for the management of chronic noncancer pain. The proposed rules include the mandatory elements for dosing criteria, guidance on specialty consultations, guidance on tracking clinical progress, and guidance on tracking opioid use. To address the mandatory elements, the proposed rules also describe the requirements to be considered a pain management specialist, describe elements for a patient evaluation and written treatment plan, describe when periodic reviews are required, and provide for practitioner exemptions from the consultation requirement.

Reasons Supporting Proposal: The 2010 legislation (ESHB 2876) requires the medical quality assurance commission, board of osteopathic medicine and surgery, nursing care quality assurance commission, dental quality assurance commission, and the podiatric medical board to adopt rules for the management of chronic noncancer pain. The proposed rules will provide practitioners who treat patients with chronic noncancer pain with guidance and tools to reduce the risks associated with opioid use.

Statutory Authority for Adoption: RCW 18.79.400, 18.79.110.

Statute Being Implemented: RCW 18.79.400.

Rule is not necessitated by federal law, federal or state court decision.

Agency Comments or Recommendations, if any, as to Statutory Language, Implementation, Enforcement, and Fiscal Matters: The rules were prepared with consensus from the five required boards and commissions.

Name of Proponent: Nursing care quality assurance commission, governmental.

Name of Agency Personnel Responsible for Drafting, Implementation and Enforcement: Terry J. West, P.O. Box 47864, Olympia, WA 98504, (360) 236-4712.

No small business economic impact statement has been prepared under chapter 19.85 RCW. The proposed rules would not impose more than minor costs on a business or industry.

A cost-benefit analysis is required under RCW 34.05.328. A preliminary cost-benefit analysis may be obtained by contacting Terry J. West, P.O. Box 47864, Olympia, WA 98504, phone (360) 236-4712, fax (360) 236-4738, e-mail terry.west@doh.wa.gov.

February 1, 2011
Paula R. Meyer, MSN, RN
Executive Director

ADVANCED PRACTICE—PAIN MANAGEMENT

NEW SECTION

WAC 246-840-460 Pain management—Intent. These rules govern the use of opioids in the treatment of patients for chronic noncancer pain.

NEW SECTION

WAC 246-840-463 Exclusions. The rules adopted under this subpart 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.

NEW SECTION

WAC 246-840-465 Definitions. The definitions in this section apply throughout this subpart 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.

(4) "Comorbidity" means a pre-existing or coexisting physical or psychiatric disease or condition.

(5) "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 free-standing hospice facilities, hospitals, nursing homes, or other long-term care facilities.

(6) "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.

(7) "Physical dependence" means a physiologic state of adaptation to a specific psychoactive substance characterized by the emergence of a withdrawal syndrome during abstinence that may be relieved in total or in part by readministration of the substance.

(8) "Psychological dependence" means a subjective sense of need for a specific substance, either for its positive effects or to avoid negative effects associated with its abstinence.

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

NEW SECTION

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.

(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.

NEW SECTION

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.

NEW SECTION

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.

NEW SECTION

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);

(4) The requirement that all chronic pain management prescriptions are provided by a single prescriber and dispensed by a single pharmacy;

(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.

NEW SECTION

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.

(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.

NEW SECTION

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. Advanced registered nurse practitioners prescribing long-acting opioids or methadone should have a one-

time completion of at least four hours of continuing education relating to this topic.

NEW SECTION

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 advanced registered nurse 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.

NEW SECTION

WAC 246-840-485 Consultation. (1) **Consultation.** The advanced registered nurse practitioner 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) **Mandatory consultation at one hundred twenty milligrams morphine equivalent dose (MED).** 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 per day, a consultation with a pain management specialist is required, unless the consultation is exempted under WAC 246-840-487 or 246-840-490.

(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.

(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 at any time. For the purposes of this section, "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.

NEW SECTION

WAC 246-840-487 Exigent and special circumstances under which the one hundred twenty milligrams MED may be exceeded without consultation with a pain management specialist. An advanced registered nurse practitioner is not required to consult with a pain management specialist 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 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.

NEW SECTION

WAC 246-840-490 Advanced registered nurse practitioners exempt from consultation requirement. The advanced registered nurse practitioner is exempt from the consultation requirement in WAC 246-840-480 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.

NEW SECTION

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 a medical quality assurance commission-approved national professional association, pain association, or other credentialing entity; 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 current practice is the direct provision of pain management care.

(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 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.

(4) If a podiatrist:

(a) A minimum of three years of clinical experience in a chronic pain management care setting;

(b) Credentialed in pain management by a podiatric medical board-approved national professional association, pain association, or other credentialing entity; and

(c) 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 podiatrist's current practice is the direct provision of pain management care; or

(d) 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 podiatric medical board.

WSR 11-04-088

PROPOSED RULES

DEPARTMENT OF HEALTH

(Dental Quality Assurance Commission)

[Filed February 2, 2011, 8:53 a.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 10-13-099.

Title of Rule and Other Identifying Information: Chapter 246-817 WAC, Pain management, the proposed rules add new sections for management of chronic noncancer pain by dentists.

Hearing Location(s): Department of Health, Point Plaza East, Room 152/153, 310 Israel Road S.E., Tumwater, WA 989501 [98501], on March 25, 2011, at 8:00 a.m.

Date of Intended Adoption: March 25, 2011.

Submit Written Comments to: Jennifer Santiago, P.O. Box 47852, Olympia, WA 98504-7852, web site http://www3.doh.wa.gov/policyreview/, fax (360) 236-2901, by March 18, 2011.

Assistance for Persons with Disabilities: Contact Jennifer Santiago by March 18, 2011, TTY (800) 833-6388 or 711.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: ESHB 2876 (chapter 209, Laws of 2010) directs the dental quality assurance commission to adopt new rules for the management of chronic noncancer pain. The proposed rules include the mandatory elements for dosing criteria, guidance on specialty consultations, guidance on tracking clinical progress, and guidance on tracking opioid use. To address the mandatory elements, the proposed rules also define the criteria to be considered a pain management specialist, describe elements for patient evaluation and written treatment plan, describe when periodic reviews are required, and provide for practitioner exemptions from the consultations requirement.

Reasons Supporting Proposal: ESHB 2876 requires that five boards and commissions, medical quality assurance commission, board of osteopathic medicine and surgery, nursing care quality assurance commission, dental quality assurance commission, and the podiatric medical board adopt rules on the management of chronic noncancer pain. The proposed rules will provide practitioners who treat patients with chronic noncancer pain with guidance and tools to reduce the risks associated with opioid use.

Statutory Authority for Adoption: RCW 18.32.785, 18.32.0365.

Statute Being Implemented: RCW 18.32.785.

Rule is not necessitated by federal law, federal or state court decision.

Name of Proponent: Dental quality assurance commission, governmental.

Name of Agency Personnel Responsible for Drafting, Implementation and Enforcement: Jennifer Santiago, 310 Israel Road S.E., Tumwater, WA 98501, (360) 236-4893.

No small business economic impact statement has been prepared under chapter 19.85 RCW. The proposed rule would not impose more than minor costs on businesses in an industry.

A cost-benefit analysis is required under RCW 34.05.328. A preliminary cost-benefit analysis may be obtained by contacting Jennifer Santiago, P.O. Box 47852, Olympia, WA 98504, phone (360) 236-4893, fax (360) 236-2901, e-mail jennifer.santiago@doh.wa.gov.

February 2, 2011
Andrew A. Vorono, Chair
Dental Quality Assurance Commission

PAIN MANAGEMENT

NEW SECTION

WAC 246-817-901 Pain management—Intent. These rules govern the use of opioids in the treatment of patients for chronic noncancer pain.

NEW SECTION

WAC 246-817-905 Exclusions. The rules adopted under this section 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.

NEW SECTION

WAC 246-817-910 Definitions. The definitions in this section apply throughout the section 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.

(4) "Comorbidity" means a preexisting or coexisting physical or psychiatric disease or condition

(5) "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 free-standing hospice facilities, hospitals, nursing homes, or other long-term care facilities.

(6) "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.

(7) "Physical dependence" means a physiologic state of adaptation to a specific psychoactive substance characterized by the emergence of a withdrawal syndrome during abstinence that may be relieved in total or in part by readministration of the substance.

(8) "Psychological dependence" means a subjective sense of need for a specific substance, either for its positive effects or to avoid negative effects associated with its abstinence.

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

NEW SECTION

WAC 246-817-915 Patient evaluation. The dentist 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 dentist.

(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.

(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 dentist; and

(f) The dentist's instructions to the patient.

NEW SECTION

WAC 246-817-920 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 dentist should adjust drug therapy to the individual health needs of the patient. The dentist 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 dentist 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.

NEW SECTION

WAC 246-817-925 Informed consent. The dentist 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.

NEW SECTION

WAC 246-817-930 Written agreement for treatment. Chronic noncancer pain patients should receive all chronic pain management prescriptions from one dentist 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 dentist 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 dentist;

(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 and dispensed by a single pharmacy;

(5) The patient's agreement to not abuse alcohol or use other medically unauthorized substances;

(6) A written authorization for:

(a) The dentist 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 dentist.

(7) A written authorization that the dentist 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 dentist's response to the violation will be documented, as well as the rationale for changes in the treatment plan.

NEW SECTION

WAC 246-817-935 Periodic review. The dentist 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 non-escalating daily dosages of 40 milligrams of a

morphine equivalent dose (MED) or less, periodic reviews shall take place at least annually.

(1) During the periodic review, the dentist 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 dentist's evaluation of progress towards treatment objectives.

(2) The dentist 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 dentist 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 dentist should periodically review information from any available prescription monitoring program or emergency department-based information exchange.

(4) The dentist should periodically review any relevant information from a pharmacist provided to the dentist.

NEW SECTION

WAC 246-817-940 Long-acting opioids, including methadone. Long-acting opioids, including methadone, should only be prescribed by a dentist 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. Dentists prescribing long-acting opioids or methadone should have a one-time completion of at least four hours of continuing education relating to this topic.

NEW SECTION

WAC 246-817-945 Episodic care. (1) When evaluating patients for episodic care, such as emergency or urgent care, the dentist 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 dentist 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 246-817-930(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.

NEW SECTION

WAC 246-817-950 Consultation. (1) **Consultation**. The dentist 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) **Mandatory consultation at 120 milligrams morphine equivalent dose (MED).** In the event a dentist prescribes a dosage amount that meets or exceeds the consultation threshold of 120 milligrams MED per day, a consultation with a pain management specialist is required, unless the consultation is exempted under section WAC 246-817-955 or section 246-817-960.

(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 dentist;

(iii) An electronic consultation between the pain management specialist and the dentist; or

(iv) An audio-visual evaluation conducted by the pain management specialist remotely, where the patient is present with either the dentist or a licensed health care practitioner designated by the dentist or the pain management specialist.

(b) A dentist 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 dentist, the dentist 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 this section, "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.

NEW SECTION

WAC 246-817-955 Exigent and special circumstances under which the 120 milligrams MED may be exceeded without consultation with a pain management specialist. A dentist is not required to consult with a pain management specialist when he or she has documented adherence to all standards of practice as defined in sections

WAC 246-817-901 through 246-817-965 of this chapter 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 dentist documents reasonable attempts to obtain a consultation with a pain management specialist and the circumstances justifying prescribing above 120 milligrams MED per day without first obtaining a consultation; or

(4) The dentist documents the patient's pain and function is stable and the patient is on a non-escalating dosage of opioids.

NEW SECTION

WAC 246-817-960 Dentists exempt from consultation requirement. The dentist is exempt from the consultation requirement in section WAC 246-817-950 if one or more of the following qualifications are met:

(1) The dentist is a pain management specialist under section WAC 246-817-965;

(2) The dentist 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 dental practitioner is a pain management practitioner working in a multidisciplinary chronic pain treatment center, or a multidisciplinary academic research facility; or

(4) The dentist 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.

NEW SECTION

WAC 246-817-965 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 a national professional association, pain association, or other credentialing entity approved by the Medical Quality Assurance Commission for physicians or the 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 current practice is the direct provision of pain management care.

(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 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.

(4) If a podiatrist:

(a) A minimum of three years of clinical experience in a chronic pain management care setting;

(b) Credentialed in pain management by a Podiatric Medical Board-approved national professional association, pain association, or other credentialing entity; and

(c) 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 podiatrist's current practice is the direct provision of pain management care; or

(d) 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 Podiatric Medical Board.