

Significant Legislative Rule Analysis (SA)  
Management of Chronic Noncancer Pain  
December 9, 2010

**Section 1. What is the scope of the rule?**

Engrossed Substitute House Bill (ESHB) 2876 (Chapter 209, Laws of 2010) requires the following five boards and commissions to adopt rules on the management of chronic, noncancer pain:

- \* Medical Quality Assurance Commission (MQAC) – Physicians and physician assistants
- \* Nursing Care Quality Assurance Commission (NCQAC) – Advanced registered nurse practitioners (ARNPs)
- \* Dental Quality Assurance Commission (DQAC) – Dentists
- \* Osteopathic Board of Medicine and Surgery (BOMS) – Osteopathic physicians and osteopathic physician assistants
- \* Podiatric Medical Board (PMB) – Podiatric physicians

This significant analysis applies to each of the professions listed above. See Appendix A for a list of specific Washington Administrative Codes. Generally, the proposed rules are structured similarly for these professions. The analysis will include any differences in the proposed rules. The legislation also requires that the MQAC, BOMS, and PMB repeal existing pain management rules. Repealed rules, under RCW 34.05.328, are exempt from the requirement to complete an analysis and they are not analyzed in this document.

The legislation specifies mandatory elements for the adopted rules including:

- \* Dosing criteria,
- \* Guidance on when and how to seek specialty consultation,
- \* Guidance on tracking clinical progress, and
- \* Guidance on tracking opioid use.

To address the specified mandatory elements, the proposed rules:

- \* Describe the criteria required to be considered a pain management specialist,
- \* Establish the consultation exemption criteria,
- \* Determine what must be included in a patient evaluation,
- \* State what must be included in a written treatment plan and a written agreement for treatment,
- \* Set a requirement for periodic reviews of the course of treatment and the patient's health,
- \* Establish the triggers to require a consultation with a pain management specialist and the exigent and special circumstances to not obtain a consultation, and
- \* Set the provisions for a practitioner to be exempt from the consultation requirement.

**Section 2. What are the general goals and specific objectives of the proposed rule's authorizing statute?**

Pain management is a dynamic and challenging area of health care. The 2010 legislature passed ESHB 2876 (Chapter 209, Laws of 2010) in response to concerns about the consequences and risks of managing chronic noncancer pain. The general goal of the respective statutes for the seven professions is to reduce the risks associated with opioid use in the management of chronic noncancer pain (See Appendix A for a list of applicable statutes for the respective professions). The statute intends that a practitioner who prescribes opioids is able to do so in a safe and effective manner to protect the patient. The statutes establish specific criteria that must be contained in the adopted rules.

The statutes' objectives the rules implement are listed by the section title. The section titles are essentially the same for each profession's proposed rules.

1. Objective #1. Section Title: "To establish dosing criteria." To meet this objective the proposed rules:
  - a. Set a threshold for a morphine equivalent dosage that, if exceeded, may require consultation with a pain management specialist,
  - b. Establish the exigent or special circumstances under which the dosage amount may be exceeded without consultation with a pain management specialist,
  - c. Determine when repeated consultation with a pain management specialist is not necessary or appropriate.
2. Objective #2. Section Title: "Guidance on when and how to seek specialty consultation." To meet this objective the proposed rules:
  - a. Establish the exemptions to the consultation requirement including the minimum training and experience a practitioner must have to be considered a pain management specialist,
  - b. Set the morphine equivalent dose (MED) that if exceeded, requires a consultation.
3. Objective #3: Section Title: "Guidance on tracking clinical progress." To meet this objective the proposed rules:
  - a. Create requirements for a patient evaluation that includes the health history,
  - b. Establish the required elements for the initial patient evaluation including information for other consultations, results of any tests, the effect and nature and intensity of the pain, and a risk screening,
  - c. Detail the requirements for the health record including that it must be readily accessible and include specific components such as treatment plan and objectives, documentation of recognized indications for the use of pain medication, documentation of any prescribed medications, results of periodic reviews, any written agreements for treatment, and instructions to the patient.
4. Objective #4: Section Title: "Guidance on tracking opioid use." To meet this objective the proposed rules:
  - a. Include the requirements for a treatment plan,
  - b. Provide the requirements for documentation of the indications for the use of the pain medication, any medication prescribed, results of periodic reviews, written agreements for treatment, and instructions to the patient.
  - c. Require periodic review of the course of treatment.

### **Section 3. What is the justification for the proposed rule package?**

The 2010 legislature expressed concern over the increase in opioid-related overdose deaths in Washington State. The proposed rules achieve each authorizing statute's goals and objectives because they provide guidance and specific criteria for practitioners on how to provide care safely and effectively for patients with chronic noncancer pain.

Manchikanti et.al published a paper on the 10-year perspective on therapeutic use, abuse, and non-medical use of opioids and their consequences. According to their research findings, Americans, although only constituting 4.6% of the world's population, consume 80% of the

global opioid supply, and 99% of the global hydrocodone supply<sup>1</sup>. Retail sales of commonly used opioid medications (including methadone, oxycodone, fentanyl base, hydromorphone, hydrocodone, morphine, meperidine, and codeine) in the US have increased from a total of 50.7 million grams in 1997 to 126.5 million grams in 2007. This is an overall increase of 149% with increases ranging from 222% for morphine, 280% for hydrocodone, 319% for hydromorphone, 525% for fentanyl base, 866% for oxycodone, to 1293% for methadone.

A study by Paulozzi et.al indicates that unintentional drug poisoning mortality rates increased on average 5.3% per year from 1979 to 1990 and 18.1% per year from 1990 to 2002 causing a rapid increase in the number of unintentional deaths<sup>2</sup>. According to their research findings, between 1999 and 2002, the number of opioid analgesic poisonings on death certificates increased 91.2%, while heroin and cocaine poisonings increased 12.4% and 22.8%, respectively. By 2002, opioid analgesic poisoning was listed in 5,528 deaths—more than either heroin or cocaine. The increase in deaths generally matched the increase in sales for each type of opioid. The increase in deaths involving methadone tracked the increase in methadone used as an analgesic rather than methadone used in narcotics treatment programs.

Several studies have shown that detrimental outcomes such as hospitalizations and deaths have also increased with the increased use of prescription pain medicines. Coolen et.al reporting for the national Center for Disease Control, found that 1,668 persons died from prescription opioid-related overdoses during the period 2004--2007<sup>3</sup> (6.4 deaths per 100,000 per year); 58.9% of decedents were male, the highest percentage of deaths (34.4%) was among persons aged 45--54 years, and 45.4% of deaths were among persons enrolled in Medicaid. The age-adjusted rate of death was 30.8 per 100,000 in the Medicaid-enrolled population, compared with 4.0 per 100,000 in the non-Medicaid population. Methadone, oxycodone, and hydrocodone were involved in 64.0%, 22.9%, and 13.9% of deaths, respectively.

In addition to concern with overdose deaths, the Centers for Disease Control (CDC) and the Substance Abuse and Mental Health Services Administration (SAMHSA) examined morbidity data in SAMHSA's Drug Abuse Warning Network (DAWN) associated with prescription drug overdoses. They looked at data from emergency department (ED) visits for 2004 and 2008 involving the nonmedical use of prescription drugs. It showed that the estimated number of ED visits for nonmedical use of opioid analgesics increased 111% (from 144,600 to 305,900 visits) and increased an additional 29% during 2007--2008<sup>4</sup>.

Like many others, Paulozzi et.al argue that the dramatic increase in prescriptions written for opioid analgesics is the result of shift in clinical consensus that opioid analgesics had a legitimate and important role in managing chronic pain and the risk of addiction should not prevent the use of prescription opioid analgesics to manage chronic, nonmalignant pain.

In Washington State, like in other states across the nation, after the liberalization of laws governing opioid prescribing for the treatment of chronic non-cancer pain by state medical

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<sup>1</sup> Manchikanti, Laxmaiah MD et. al. Therapeutic Use, Abuse, and Nonmedical Use of Opioids: A Ten-Year Perspective. *Pain Physician* 2010; 13:401-435 ISSN 1533-3159

<sup>2</sup> <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5923a1.htm>

<sup>3</sup> Overdose Deaths Involving Prescription Opioids Among Medicaid Enrollees --- Washington, 2004—2007, *MMWR*, October 30, 2009 / 58(42);1171-1175 <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5842a1.htm>

<sup>4</sup>Emergency Department Visits Involving Nonmedical Prescription Drugs, United States, 2004-2008 *Morbidity and Mortality Weekly Report (MMWR) Weekly*, June 18, 2010 / 59(23);705-709

boards in the late 1990s, and with the introduction of new pain management standards for inpatient and outpatient medical care implemented by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) in 2000, many physicians and organizations began advocating for increased use of opioids in the treatment of chronic pain. Opioids in general, and the most potent forms of opioids in particular, have dramatically increased<sup>5</sup>.

The Controlled Substances Act of 1970 (§ 827) created the requirement for manufacturers and distributors to report their controlled substances transactions to the U.S. Attorney General. The U.S. Attorney General delegates this authority to the Drug Enforcement Administration (DEA). To track this data, the DEA created Automation of Reports and Consolidated Orders System (ARCOS), an automated, comprehensive drug reporting system which monitors the flow of DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level - hospitals, retail pharmacies, practitioners, mid-level practitioners, and teaching institutions<sup>6</sup>. The table below shows increased sales for selective pain medicines in 1997 and in 2006.

**Opioid Medication Retail Sale  
Washington State 1997 to 2006**

<b>Pain Medicine</b>	<b>Year 1997</b>	<b>Year 2006</b>	<b>% Change</b>
Oxycodone (ID #9143)	145,595 grams	1,092,995 grams	651%
Hydrocodone (ID #9193)	180,011 grams	540,420 grams	200%
Methadone (ID #9250B)	22,950 grams	332,956 grams	1351%
Morphine (ID #9300)	151,303 grams	602,275 grams	298%

Source: ARCOS website

With this increased use, there is a growing issue with the number of patients that are taking high doses of medications. The Department of Social and Health and Services (DSHS) formed a Narcotic Review Project Plus (NRP+) to work with prescribers to: 1) promote safe and effective use of opioids, 2) reduce misuse of opioids, and 3) improve the quality of life of Medicare recipients. Information was presented to the Department of Health (DOH) regarding negative outcomes of high dose therapy. The following table from the Narcotic Review Project Plus (NRP +) workgroup, Sept. 22, 2010 presentation to DOH regarding unintentional poisoning shows that in 2009 there were 461 patients are on 1000+ dose of opioid base pain medication<sup>7</sup>.

<b>Average MED Per Day Over Year</b>	<b>Client Count</b>	<b>Average Total Months</b>	<b>Average Prescribers Per Month</b>	<b>Average Opioid Cost Per Client</b>
90-119	2100	8.65	1.27	454.86
120-179	2546	8.61	1.25	653.6
180-999	6416	8.87	1.21	1234.48
1000+	461	9.22	1.18	3521.31

<sup>5</sup> Manchikanti, Laxmaiah MD et. al.

<sup>6</sup> <http://www.dea.gov/arcos/index.html>

<sup>7</sup> Washington State Department of Health and Human Services (DSHS) Slideshow Presentation by NRP+ Unintentional Poisoning Workgroup to DOH, September 22, 2010.

Over time a percentage of patient’s body may develop a tolerance to pain medicines and these patients may request higher doses because the existing levels are not effective in managing the pain. Despite the escalating use and abuse of therapeutic opioids, nearly 15 to 20 years later, the scientific evidence for the effectiveness of opioids for chronic non-cancer pain remains unclear. Concerns continue regarding efficacy; problematic physiologic effects such as hyperalgesia, hypogonadism and sexual dysfunction; and adverse side effects – especially the potential for misuse and abuse – and the increase in opioid related deaths. The treatment of chronic pain, therapeutic opioid use and abuse, and the nonmedical use of prescription drugs have been topics of intense focus and debate.

The 2010 legislation, ESHB 2876, requires that the five boards and commissions adopt rules for the seven impacted professions. There are no feasible alternatives to rulemaking because the statutes require that rules be adopted for the management of chronic noncancer pain. The requirements must be in rule in order to be enforceable.

**Section 4. What are the costs and benefits of each rule included in the rules package? What is the total probable cost and total probable benefit of the rule package?**

Non-Significant Rule Identification Table

These rules are repealed as mandated:

- a. Medical physicians: WAC 246-919-800 through 246-919-830
- b. Osteopathic physicians: WAC 246-853-510 through 246-853-540
- c. Osteopathic physician assistants: WAC 246-854-120 through 246-854-150
- d. Podiatric physicians: WAC 246-922-510 through 246-922-540

**Table: Non-Significant Rule Identification**

#	Section Title	Section Subject	Reason
1	Pain management – Intent	Intent of the rules	Identify what the rules govern. It does not establish enforceable standards and does not meet criteria for analysis for a “significant legislative rule” under RCW 34.05.328 <sup>8</sup>
2	Exclusions	Type of care exclusion	This section clarifies the types of care that are excluded from the rules. This section does not establish enforceable standards and does not meet criteria for analysis for a “significant legislative rule” under RCW 34.05.328.
3	Definitions	Definitions	Defines the terms used in the rule. Definitions are not enforceable standards. Proposed standards are analyzed below.
4	Long-acting opioids including methadone	Recommendation for 4-hour continuing education class for practitioners	Provides guidance for practitioners who prescribe long-acting opioids or methadone. The rule recommends that practitioners complete four hours of continuing education related to prescribing long-acting opioids and methadone. This may be

<sup>8</sup>The proposed rule 1) does not subject someone who violates the proposed rule to a penalty or sanction, 2) does not create, change or repeal any qualification or standard for issuing, suspending or revoking a license or permit, and 3) does not adopt a new policy or make a significant amendment to a policy or regulatory program.

		who prescribe long-acting opioids including methadone.	completed as part of the practitioner’s current continuing education requirements. The proposal does not increase the total number of required continuing education credits. Does not meet criteria of a “significant legislative rule” under RCW 34.05.328.
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Significant Rule Analysis

In order to assess the potential impact of the proposed rules, the Department of Health surveyed practitioners from the following professions that serve on their respective board or commission:

- Physicians and physician assistants
- Osteopathic physicians and osteopathic physician assistants
- Podiatric physicians
- Dentists
- Advanced registered nurse practitioners or certified registered nurse anesthetists

Participants provided time and cost estimates to complete the required actions and tasks included in the proposed rules. The survey results are attached in Appendix B. In addition to this summary table, the time and cost estimates, generally provided in a range, are included for each applicable significant section.

**A. Section Title: Patient evaluation**

Rule Overview: The proposed rules require practitioners to obtain, evaluate, and document the patient’s health history and physical examination in their health record prior to treating them for chronic noncancer pain.

Rule Cost/Benefit Analysis: The standards reinforce the need to do a patient evaluation. Practitioners indicated in the survey that these activities generally take one hour or less to complete. Although they are specified in the proposed rule, the assumption is that these activities are already considered practice standards or the “standard of care” for the applicable professions. The survey revealed that practitioners are already completing these activities. There should be minimal to no cost associated with this rule.

**B. Section Title: Treatment plan**

Rule Overview: The proposed rules require practitioners to create a written treatment plan that states the objectives used to determine if the treatment is successful. Practitioners are also encouraged to adjust the drug therapy as necessary for a patient after treatment begins. The proposed rules also install safeguards to address potential abuse and misuse including requiring photo identification of the person picking up the prescription.

Rule Cost/Benefit Analysis: The proposed rules reinforce the need for a treatment plan. A documented treatment plan will enhance patient safety and ensure that precautions are in place to avoid or eliminate a risk of over-prescribing pain medications. Practitioners indicated in the survey that creating a treatment plan will generally take less than 20 minutes to complete. The

assumption is that many practitioners already create treatment plans for chronic noncancer pain patients. There should be minimal to no cost associated with this rule.

### **C. Section Title: Informed consent**

Rule Overview: The proposed rules require practitioners to discuss the risks and benefits of treatment options with patients or persons designated by or responsible for the patient, if the patient does not have health care decision-making authority.

Rule Cost/Benefit Analysis: This requirement reinforces the need for informed consent. Practitioners indicated that it generally takes between 10 and 20 minutes to obtain an informed consent. Although the informed consent requirement is specified in the proposed rule, the assumption is that this activity is already considered a practice standard or “standard of care” for the applicable professions to discuss the risks and benefits of treatment options with the patient or designee. There should be minimal to no cost associated with this rule.

### **D. Section Title: Written agreement for treatment**

Rule Overview: The proposed rules have permissive and mandatory elements. The permissive element recommends that chronic noncancer pain patients should receive prescriptions from one practitioner and one pharmacy where possible. The mandatory element includes a requirement for practitioners to write, and have the patient sign, a written agreement when treating high risk patients (i.e., patients with a high risk for medication abuse, that have a history of substance abuse, or with psychiatric comorbidities).

Rule Cost/Benefit Analysis: The written agreement includes responsibilities for the patient which should enhance patient safety. Practitioners indicated that it generally takes less than 10 minutes to obtain a written agreement. The assumption is that many practitioners already obtain written treatment agreements when treating high risk pain patients. There should be minimal to no cost associated with this rule.

### **E. Section Title: Periodic review**

Rule Overview: The proposed rules require practitioners to periodically review the patient’s course of treatment, the patient’s state of health, and any new information about the etiology (cause) of the pain. The proposed rules describe the mandatory elements of the periodic review, which include but are not limited to patient compliance with the written treatment plan, determining if a patient’s pain, function or quality of life has improved or diminished, and assessing the appropriateness of continued use of the current treatment plan.

Rule Cost/Benefit Analysis: Both practitioners and patients will benefit from periodically reviewing information about their patients. This will enhance patient safety by ensuring that regular reviews occur to ensure treatment objectives are met and the patient is progressing as planned. Practitioners indicated that it generally takes less than 20 minutes to perform a periodic review. The assumption is that many practitioners already periodically review the course of treatment for patients with chronic health issues. There should be minimal to no cost associated with this rule.

## **F. Section Title: Episodic care**

Rule Overview: The proposed rules require practitioners, when evaluating a patient for episodic care (i.e., emergency or urgent care), to review any available prescription monitoring program information that could include emergency department-based information exchange or other tracking system. The proposed rules also direct practitioners working in episodic locations to avoid providing opioids for chronic pain management. The proposed rules additionally require episodic care practitioners to report known violations of any known written agreement for treatment.

Rule Cost/Benefit Analysis: Practitioners will benefit from obtaining information about their patient in locations that provide episodic care. Practitioners indicated that it generally takes 20 minutes or less to evaluate an emergency room based prescription monitoring program for a patient in an episodic care facility. Practitioners also indicated that if they check other tracking systems, it will take an additional 20 minutes to perform this task. Implementing this required evaluation will require practitioners to spend time reviewing existing information, but it will enhance patient safety by reducing the potential for abuse and misuse of prescription drugs for patients being treatment for chronic noncancer pain.

## **G. Section Title: Consultation**

Rule Overview: The legislation requires practitioners to consult with a pain management specialist under criteria that must be adopted by rule. The proposed rules:

1. Provide for two categories of consultation: Consultation (permissive) and Mandatory Consultation at 120 milligrams morphine equivalent dose (MED).
2. Identifies 120 milligram morphine equivalent dose (MED), as the threshold that if met or exceeded requires a mandatory consultation with a pain management specialist. Workgroup members researched the threshold levels recommended by various national and state organizations. Members of the public and experts provided information during the workgroup meetings that indicated the daily MED daily threshold that practitioners currently use ranges between 110 MED and 200 MED. The CDC has adopted the 120 MED daily threshold and the workgroup determined that 120 MED is the least burdensome level for practitioners and the safest for the majority of patients.
3. Set the requirements for the consultation including methods of consultation and the documentation for the consultation.
4. Do not limit another entity's ability to contractually require a consultation at any time.

Rule Cost/Benefit Analysis: This requirement will improve patient safety. Practitioners indicated that it will generally take between 10 to 30 minutes to refer a patient to a pain specialist, depending on the circumstances. The proposed rules provide exemptions to this requirement if a practitioner is unable to obtain a consultation. It may take time for a practitioner to use the consultation process, but the benefit of obtaining a consultation is that the practitioner will receive input from a pain management specialist and improve patient safety.

## **H. Section Title: Exigent and special circumstances under which the 120 milligrams MED may be exceeded without consultation with a pain management specialist**

Rule Overview: The proposed rules cite the patient condition(s) that may allow practitioners to exceed the 120 (MED) dosage threshold without a consultation and include a requirement for practitioners to document the circumstances.

Rule Cost/Benefit Analysis: Practitioners can exceed the MED threshold without obtaining a consultation, if any of the following conditions exist:

- a) The patient is already following a tapering schedule,
- b) The patient requires treatment for acute pain which temporarily calls for an escalation in opioid dosage.
- c) The practitioner has documented the reasonable attempts of obtaining a consultation with a pain management specialist and the circumstances that justify prescribing above the 120 milligrams MED daily threshold.
- d) The practitioner has documented the patient's pain, that they are on a non-escalating dosage of opioids, and that their functions are stable.

The conditions in the proposed rule will result in enhanced patient safety.

#### **I. Section Title: Practitioners exempt from consultation requirement**

Rule Overview: The proposed rules provide the qualifications that exempt practitioners from the requirement to obtain a consultation. These qualifications include:

1. The practitioner is a pain management specialist, or
2. The practitioner has completed continuing education hours on chronic pain management with at least two hours dedicated to long-acting opioids to include methadone, or
3. The practitioner is a pain management practitioner working in a multidisciplinary chronic pain treatment center.

The proposed rules do not impose additional CE requirements above that which is already required, additional education, or additional training or experience on all practitioners in the profession. The proposed rules for the osteopathic physician provide for this profession's three-year renewal cycle and require 18 hours of continuing education within the three-year renewal cycle.

#### Rule Cost/Benefit Analysis:

The proposed rule identifies qualifications that exempt practitioners from the requirement to complete a consultation, when the practitioners demonstrate a proficiency in treating chronic noncancer pain patients. If practitioners do not already satisfy the qualifications, they can complete them within a short period of time; e.g., twelve hours of continuing education may be obtained through a two-day continuing education class. Therefore, there are no regulatory compliance costs for this proposed rule.

#### **J. Section Title: Pain management specialist**

Rule Overview: The proposed rules identify criteria for physicians, osteopathic physicians, advanced nurse practitioners, dentists, or podiatric physicians to be considered a pain management specialist. Physician assistants work under the direct supervision of physicians and osteopathic physicians and may not become a pain management specialist. Therefore, physician assistants are not included the list of practitioners that may be considered a pain management specialist. The criteria to be considered a pain management specialist include:

- (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 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 18 continuing education hours in pain management during the past two years, and
    - iii. At least 30 percent of the physician or 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 18 continuing education hours in pain management during the past two years, and
  - (d) At least 30 percent of the ARNP’s current practice is the direct provision of pain management care.
- (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 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 Podiatric Medical Board-approved national professional association, pain association, or other credentialing entity, and
  - (d) Successful completion of a minimum of at least 18 hours of continuing education in pain management during the past two years, and at least 30 percent of the podiatric physician’s current practice is the direct provision of pain management care.

Rule Cost/Benefit Analysis:

According to practitioners and the public, there is a shortage of pain management specialists in the state and they are in high demand. Patients may have long wait-times to see a pain management specialist. Overall the proposed rules required practitioners to either choose to complete one of the exemptions provided under the section “Exempt from consultation requirement”, or meet one of the qualifications listed in this section of the rule. This section of the rule does not require practitioners to be a pain management specialist in order to treat patients

with chronic noncancer pain. For those practitioners who elect to pursue this designation they will have to meet one of the identified criteria. Practitioners indicated that it could take up to 1,600 hours to meet one of the qualifications, depending upon the practitioner's current training, education, experience, etc.

If a practitioner, who is not currently board certified in one of the listed specialties, wants to be considered a pain management specialist, the practitioner may choose to either sit for the board certification or obtain a credential by an entity approved by the applicable board or commission. The cost for a physician or osteopathic physician to sit for the board certification exam can be up to \$3,000.

#### Rule Package Cost-Benefit Conclusion

As stated previously, the legislature is aware of a growing trend in emergency room visits, overdoses, and deaths associated with the increased use of prescription drugs to treat chronic noncancer pain. The previous sections describes the elements of a program that will assist practitioners and their patients to gain awareness of and address potential factors that could lead to emergency room visits, overdoses, or death. Although, as described above, there are several newly required actions for practitioners who prescribe pain medications for patients with chronic noncancer pain, the Department of Health and the boards and commissions have determined that the probable benefits of implementing these rules outweigh the costs of complying with the requirements. As a result, it has been determined that the probable benefits of the proposed rules outweigh the probable costs.

#### **Section 5. What alternative versions of the rule did we consider? Is the proposed rule the least burdensome approach?**

**Alternative #1:** In the consultation section stakeholders requested that the pediatric population be excluded from the rules.

#### **Least burdensome determination**

The statutes do not provide any exemptions for a specific patient population. The workgroup members from the boards and commissions determined that a pediatrician should always be consulted for patients under eighteen years of age or when the dosage increases. This is a permissive requirement; it should not impose a significant burden on the practitioner and is in keeping with the legislative intent of enhancing patient safety.

**Alternative #2:** In the consultation section some stakeholders and interested persons stated that the rules should not include an MED and should not target opioids.

#### **Least burdensome determination**

The statute requires that the rules set dosing criteria and specifies opioids. The legislative intent is that the rules include a maximum amount that should not be exceeded unless specific criteria are met. It was determined there is no alternative. The workgroup discussed a range of between 110 MED and 200 MED. The workgroup recommended and it was determined that a 120 MED was the least burdensome level for practitioners and the safest for the majority of patients.

**Alternative #3:** Many stakeholders, including practitioners and patients, have commented that the state should not write these rules and should not write laws about pain management because it takes away the rights of practitioners to practice as they see fit.

**Least burdensome determination**

The statute requires that the five boards and commissions adopt rules on the management of chronic noncancer pain. The legislative intent is to reduce the risks associated with opioid use in the management of chronic, noncancer pain. The boards and commissions have determined that the proposed rules provide the least burdensome approach and requirements. There are no alternatives to adopting rules.

**Section 6. Did you determine that the rule does not require anyone to take an action that violates another federal or state law?**

The rule does not require those to whom it applies to take an action that violates requirements of federal or state law.

**Section 7. Did we determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless the difference is required in federal or state law?**

The rules do not impose more stringent performance requirements on private entities than on public entities.

**Section 8. Did you determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, did we determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary?**

The rule does not differ from any applicable federal regulation or statute.

**Section 9. Did we demonstrate that the rule has been coordinated, to the maximum extent possible, with other federal, state, and local laws applicable to the same activity or subject matter?**

There are no other applicable laws.

## Appendix A

### Significant Legislative Rule Analysis (SA) Management of Chronic Noncancer Pain

### Revised Codes of Washington (RCW) and Washington Administrative Code (WAC) Reference List by Practitioner License

#### **Medical Quality Assurance Commission – RCW 18.71.450 and RCW 18.71A.100**

##### Physician

- WAC 246-919-850 Pain management – Intent.
- WAC 246-919-851 Exclusions.
- WAC 246-919-852 Definitions.
- WAC 246-919-853 Patient evaluation.
- WAC 246-919-854 Treatment plan.
- WAC 246-919-855 Informed consent.
- WAC 246-919-856 Written agreement for treatment.
- WAC 246-919-857 Periodic review.
- WAC 246-919-858 Long-acting opioids, including methadone.
- WAC 246-919-859 Episodic care.
- WAC 246-919-860 Consultation.
- WAC 246-919-861 Exigent and special circumstances under which the 120 milligrams MED may be exceeded without consultation with a pain management specialist.
- WAC 246-919-862 Physician exempt from consultation requirement.
- WAC 246-919-863 Pain Management Specialist.

##### Physician Assistant

- WAC 246-918-800 Pain management – Intent.
- WAC 246-918-801 Exclusions.
- WAC 246-918-802 Definitions.
- WAC 246-918-803 Patient evaluation.
- WAC 246-918-804 Treatment plan.
- WAC 246-918-805 Informed consent.
- WAC 246-918-806 Written agreement for treatment.
- WAC 246-918-807 Periodic review.
- WAC 246-918-808 Long-acting opioids, including methadone.
- WAC 246-918-809 Episodic Care.
- WAC 246-918-810 Consultation.
- WAC 246-918-811 Exigent and special circumstances under which the 120 milligrams MED may be exceeded without consultation with a pain management specialist.
- WAC 246-918-812 Physician assistant exempt from consultation requirement.
- WAC 246-918-813 Pain Management Specialist.

#### **Nursing Care Quality Assurance Commission – RCW 18.79.400**

- WAC 246-840-460 Pain management--Intent.
- WAC 246-840-463 Exclusions.
- WAC 246-840-465 Definitions.

- WAC 246-840-467 Patient evaluation.
- WAC 246-840-470 Treatment plan.
- WAC 246-840-473 Informed consent.
- WAC 246-840-475 Written agreement for treatment.
- WAC 246-840-477 Periodic review.
- WAC 246-840-480 Long-acting opioids, including methadone.
- WAC 246-840-483 Episodic care.
- WAC 246-840-485 Consultation.
- 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.
- WAC 246-840-490 Advanced registered nurse practitioners exempt from consultation requirement.
- WAC 246-840-493 Pain management specialist.

#### **Dental Quality Assurance Commission - RCW 18.32.785**

- WAC 246-817-901 Pain management – Intent.
- WAC 246-817-905 Exclusions.
- WAC 246-817-910 Definitions.
- WAC 246-817-915 Patient evaluation.
- WAC 246-817-920 Treatment plan.
- WAC 246-817-925 Informed consent.
- WAC 246-817-930 Written agreement for treatment.
- WAC 246-817-935 Periodic review.
- WAC 246-817-940 Long-acting opioids, including methadone.
- WAC 246-817-945 Episodic Care.
- WAC 246-817-950 Consultation.
- WAC 246-817-955 Exigent and special circumstances under which the 120 milligrams MED may be exceeded without consultation with a pain management specialist.
- WAC 246-817-960 Dentists exempt from consultation requirement.
- WAC 246-817-965 Pain Management Specialist.

#### **Osteopathic Board of Medicine and Surgery – RCW 18.57.285 and RCW 18.57A.090**

##### Physician

- WAC 246-853-660 Pain management – Intent.
- WAC 246-853-661 Exclusions.
- WAC 246-853-662 Definitions.
- WAC 246-853-663 Patient evaluation.
- WAC 246-853-664 Treatment plan.
- WAC 246-853-665 Informed consent.
- WAC 246-853-666 Written agreement for treatment.
- WAC 246-853-667 Periodic review.
- WAC 246-853-668 Long-acting opioids, including methadone.
- WAC 246-853-669 Episodic Care.
- WAC 246-853-670 Consultation.

- WAC 246-853-671 Exigent and special circumstances under which the 120 milligrams MED may be exceeded without consultation with a pain management specialist.
- WAC 246-853-672 Osteopathic physician exempt from consultation requirement.
- WAC 246-853-673 Pain Management Specialist.

#### Physician Assistant

- WAC 246-854-240 Pain management – Intent.
- WAC 246-854-241 Exclusions.
- WAC 246-854-242 Definitions.
- WAC 246-854-243 Patient evaluation.
- WAC 246-854-244 Treatment plan.
- WAC 246-854-245 Informed consent.
- WAC 246-854-246 Written agreement for treatment.
- WAC 246-854-247 Periodic review.
- WAC 246-854-248 Long-acting opioids, including methadone.
- WAC 246-854-249 Episodic Care.
- WAC 246-854-250 Consultation.
- WAC 246-854-251 Exigent and special circumstances under which the 120 milligrams MED may be exceeded without consultation with a pain management specialist.
- WAC 246-854-252 Osteopathic physician assistant exempt from consultation requirement.
- WAC 246-854-253 Pain Management Specialist.

#### **Podiatric Medical Board – RCW 18.22.240**

- WAC 246-922-660 Pain management – Intent.
- WAC 246-922-661 Exclusions.
- WAC 246-922-662 Definitions.
- WAC 246-922-663 Patient evaluation.
- WAC 246-922-664 Treatment plan.
- WAC 246-922-665 Informed consent.
- WAC 246-922-666 Written agreement for treatment.
- WAC 246-922-667 Periodic review.
- WAC 246-922-668 Long-acting opioids, including methadone.
- WAC 246-922-669 Episodic Care.
- WAC 246-922-670 Consultation.
- WAC 246-922-671 Exigent and special circumstances under which the 120 milligrams MED may be exceeded without consultation with a pain management specialist.
- WAC 246-922-672 Podiatric physicians exempt from consultation requirement.
- WAC 246-922-673 Pain Management Specialist.

Appendix B

Significant Legislative Rule Analysis (SA)  
Management of Chronic Noncancer Pain

Summary of Survey Results from Proposed Pain Management Rules

	Survey Questions	Estimated time needed (minutes)				
		< = 10	11 to 20	21 to 30	> 30	N
1-1.	Complete a health history	4	6	4	0	1
1-2.	Perform a physical examination	8	5	1	0	1
1-3.	Maintain patient's health record	8	6	0	0	1
2	Time to create and obtain a written treatment plan	5	6	2	1	1
3	Time to obtain informed consent	8	6	1	0	0
4	Time to oversee high risk patients signing their written treatment plan (per patient)	12	1	1	0	1
5	Time to conduct a periodic review	4	8	2	0	1
6-1.	ER based information exchange	8	2	2	0	3
6-2.	Other tracking systems	8	2	2	0	3
7-1.	Time to refer to pain specialist	6	3	3	1	2
7-2.	Time estimate to obtain a consultation (per patient). (1 to 6 weeks 5)	1	2	3	2	2

	Survey Questions	Estimated time needed (hours)				
		< = 10	11 to 20	21 to 30	> 30	N
9-1.	How much time (Hour) to meet the qualification	3	2	1	2	7

	Survey Questions	Estimated Costs				
		< = \$1,000	\$1,001 to \$2,000	\$2,001 to \$3,000	> \$3,000	N
9-2.	How much costs to meet the qualification	1	3	1	1	9

	Survey Questions	Office Hourly rate				
		< = \$1,00	\$1,01 to \$2,00	\$2,01 to \$3,00	> \$3,00	N
10	What is your hourly billing rate?	4	4	1	4	2