

Significant Legislative Rule Analysis

WAC 246-853-675 (Osteopathic Physicians)
and

WAC 246-854-255 (Osteopathic Physician
Assistants)

Amended Sections of Rule Concerning Opioid
Prescribing

August 20, 2019

SECTION 1:

Describe the proposed rule, including a brief history of the issue, and explain why the proposed rule is needed.

Washington state is experiencing an opioid abuse and overdose crisis. In 2018, over 700 individuals died from opioid related overdose. On September 30, 2016, Governor Jay Inslee signed Executive Order 16-09, *Addressing the Opioid Use Public Health Crisis*, formally directing activities including, but not limited to, prevention of inappropriate opioid prescribing and reduction of opioid misuse and abuse. In 2017, and as part of the effort to address the opioid crisis, the Washington state legislature found that medically prescribed opioids intended to treat pain contributed to the opioid epidemic, and while Washington continued to proactively address prescribing and tracking opioid prescriptions, additional effort was needed to ensure proper prescribing and use of opioids. The legislature created the framework for a multi-dimensional approach to opioid prescribing, tracking of opioid prescriptions, and access to treatment that identified specific areas of need. These included requiring the boards and commissions of health care professionals with prescriptive authority to adopt rules establishing requirements for prescribing opioid drugs, with the overall goal of increasing public health and safety by reducing the number of people who inadvertently became addicted to opioids.

Substitute Senate Bill (SSB) 5380 (chapter 314, Laws of 2019) requires five boards and commissions associated with the Department of Health (department) to adopt rules expanding the patient notification requirements and the right to refuse when prescribing opioid drugs. Specifically named were the Podiatric Medical Board, the Washington Medical Commission, the Nursing Care Quality Assurance Commission, the Dental Care Quality Commission, and the Board of Osteopathic Medicine and Surgery (board).

The board proposes these amendments to align with the requirements of and the legislative intent of SSB 5380. Rules are needed to establish a framework and structure for prescribing opioid medications. The proposed rules reinforce the requirements in law and recognize instances where clinical judgement is appropriate by providing practice guidance without being overly prescriptive, and are designed to reduce the risks associated with opioid use in the management of pain, while increasing public health and safety.

SECTION 2:

Is a Significant Analysis required for this rule?

The proposed rules require a significant analysis as described in RCW 34.05.328(5)(c)(iii) because they make significant amendments to a policy or regulatory program.

SECTION 3:

Clearly state in detail the general goals and specific objectives of the statute that the rule implements.

Chapter 18.57 RCW describes the regulatory framework for the practice of osteopathic medicine and surgery. RCW 18.57.005 provides that the overall goal of the board is to ensure the public health and safety as a prerequisite to granting and renewing licensure under the chapter.

Specifically, chapter 314, Laws of 2019 requires that the board adopt additional requirements for patient notification and the right to refuse when prescribing opioids by January 1, 2020.

The proposed rules implement the statute’s goals and objectives by:

- Expanding the framework, structure, and guidance for prescribing opioid drugs consistent with the requirements of chapter 314, Laws of 2019; and
- Supporting the overarching goal of RCW 18.57.005 by protecting and promoting public health, safety, and welfare.

Chapter 18.57A RCW describes the regulatory framework for the scope and practice of osteopathic physician assistants. The board adopts rules regarding scope of practice, education, and supervision of osteopathic physician assistants. Osteopathic physician assistants are supervised by osteopathic physicians. RCW 18.57.005 provides that the overall goal of the board is to ensure the public health and safety as a prerequisite to granting and renewing licensure under the chapter, and this goal extends to osteopathic physician assistants. Specifically, chapter 314, Laws of 2019 requires that the board adopt additional requirements for patient notification and the right to refuse when prescribing opioids by January 1, 2020.

The proposed rules implement the statute’s goals and objectives by:

- Expanding the framework, structure, and guidance for prescribing opioid drugs consistent with the requirements of chapter 314, Laws of 2019; and
- Supporting the overarching goal of RCW 18.57.005 by protecting and promoting public health, safety, and welfare.

SECTION 4:

Explain how the board determined that the rule is needed to achieve these general goals and specific objectives. Analyze alternatives to rulemaking and the consequences of not adopting the rule.

The goals and objectives of the statutes are met by providing clearly written and appropriate rules. SSB 5380 specifically requires the board to perform rule making. The proposed amended sections of rules are responsive to the characteristics of the changing healthcare landscape, and augment existing tools that support providers and others addressing the opioid crisis. The proposed rules represent the board’s commitment to achieving its statutorily defined goals and objectives by creating rules that align with statutory directives.

If the proposed rules are not adopted, the board will not meet the legislative directive to engage in rulemaking. Rulemaking is appropriate to promote a clear, consistent framework for practitioners who prescribe opioid drugs and to align rules with the law. The proposed rules increase patient safety and are responsive to the need to increase statewide efforts to ensure proper prescribing and use of opioids.

SECTION 5:

Explain how the board determined that the probable benefits of the rule are greater than the probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.

The portions of the proposed rules that are significant are analyzed below.

Section Analysis

Amended WAC 246-853-675 and WAC 246-854-255 – Patient notification, secure storage, and disposal

Rule Overview: The proposed rule restates the requirements in RCW 18.57.810, RCW 18.57A.810 and RCW 69.50.317 that practitioners provide patients with information concerning the risks associated with the use of opioids consistent with the patient’s medical condition and treatment phase. This provision of information is considered to be patient notification.

Patient notification must occur at specific phases and points of treatment, including the first issuance of a prescription for an opioid, and during specific phases of treatment. Patient notification must also include information regarding safe and secure storage of opioid prescription drugs, proper disposal processes for unused opioid prescription drugs, and their right to refuse opioids.

In addition, the proposed rule clarifies situations where the notification requirements would not apply. Specifically, notification requirements would not apply to emergent care, situations where pain represents a significant health risk, procedures involving administration of medications, when a patient is unable to grant or revoke consent, or for medication assisted treatment (MAT) for substance use disorders. These exemptions are included because SSB 5380 only applies to prescriptions and these exemptions clarify settings in which direct administration is occurring. The amendment also restates a requirement in RCW 69.50.317 that the patient’s parent or guardian must be included in the discussion if the patient is under 18 years of age.

Cost/Benefit Analysis: The proposed rule restates the need for patient notification designed to make sure that patients receiving opioid medications are fully informed of the risks, benefits, and responsibilities associated with opioid medication use and clarifies when notification requirements would not apply.

Practitioners may incur a one-time administrative costs when initially gathering and reproducing educational materials for patient distribution and developing forms and other materials. The department will help to reduce this burden by updating and making documents available online for providers to access. Although a full analysis of life expectancy and the value of resulting improved health following patient notification weighed against the overall cost of providing notification is beyond the scope of this analysis, such an analysis could be a consideration when evaluating the overall impact of the proposed patient notification requirement. However, the benefit of achieving favorable patient outcomes by providing patient education and notification clearly outweighs any administrative or operating costs that may be imposed on the regulated community.

SECTION 6:

Identify alternative versions of the rule that were considered, and explain how the board determined that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives state previously.

The board held a rule workshops on July 11 and July 19, 2019 where draft language was presented to both the board members and the public. The board ensured stakeholders were informed and included in the workshops to minimize the burden of these rules.

To encourage public participation, comment, and engagement, a notification was sent to the board's GovDelivery distribution list.

Least Burdensome Determination

The board's stakeholder process encouraged interested parties to:

- Identify burdensome areas of the draft rules;
- Propose initial or draft rule changes; and
- Refine those changes.

The end result of the process is a final proposed rule set that will provide clear guidance, compliance with statutory requirements, and will achieve the statutorily identified general goals and specific objectives described in chapter 18.57 RCW, chapter 18.57A RCW, and SSB 5380.

Alternatives Considered

Alternative 1 – Do not amend or change existing rules.

This alternative is not consistent with the directives of SSB 5380 requiring boards/commissions to adopt opioid prescribing rules by January 1, 2020. The statute requires the board to develop and adopt rules for patient notification and their right to refuse opioids.

Alternative 2 – Do not consider adding clarifications and use only exact bill language in rule update.

This alternative could lead to potentially dangerous unintentional consequences for physicians and patients. The board determined clarifications are necessary to ensure practitioner compliance.

Alternative 3 – Do not require documentation of patient notification.

This alternative is not consistent with the directives of SSB 5380 requiring prescribers to document their discussion with the patient.

Alternative 4 – Do not require discussion of alternatives to opioids for pain management as it would be duplicative of language in other areas of the opioid prescribing rules.

This alternative was not included because the prior rules did not require the alternatives be discussed. The prior rules required the prescriber to provide alternatives to opioids in writing.

Alternative 5 – Include language addressing the concern that a patient who refuses opioids with one prescriber would have the expectation that any other prescriber would know of the refusal and not offer the patient opioids.

This alternative was considered, but is not included in the rules. The commission determined this concern would be best addressed by updating the patient information resources.

SECTION 7:

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

The rule does not require those to whom it applies to take action that violates the requirements of federal or state law. The department and board have reviewed CDC and FDA guidance regarding opioid prescribing and determined there is no conflict.

SECTION 8:

Determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law.

The rule does not impose more stringent performance requirements on private entities than on public entities. All entities with opioid prescribing authority will be held to the same performance requirements.

SECTION 9:

Determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, 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 10:

Demonstrate that the rule has been coordinated, to the maximum extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter.

There are no other applicable laws.