

Significant Analysis
for Rule Concerning administration of sedation and anesthesia,
WAC 246-922-650 – Podiatric Physicians

Section 1. What is the scope of the rule?

RCW 18.22.015 (5) requires the Podiatric Medical Board (board) to adopt rules governing office based surgeries performed by podiatric physicians. The proposed rules identify the administration of sedation and anesthesia in the offices of podiatric physicians, including necessary training and equipment. Rules are needed to establish consistent standards for podiatric physicians who perform office-based surgery to reduce the risk of substandard care, inappropriate administration of anesthesia, infections, and other serious complications.

A podiatric physician shall not administer spinal anesthetic or any anesthetic that renders the patient unconscious under RCW 18.22.035. Podiatric physicians can perform office based surgeries using major conduction anesthesia, moderate sedation or analgesia or deep sedation or analgesia. This rule will require podiatric physicians who perform office-based surgery to:

- Obtain certification or accreditation from either the Joint Commission; the Accreditation Association for Ambulatory Health Care; the American Association for Accreditation of Ambulatory Facilities; or the Centers for Medicare and Medicaid Services;
- Have a physician authorized under chapter 18.71 RCW or chapter 18.57 RCW or a certified registered nurse anesthetist authorized under chapter 18.79 RCW administer the anesthesia for procedures requiring spinal or major conduction anesthesia above the ankle;
- Be competent and qualified to perform procedures in office-based surgery;
- Have at least one provider currently certified in advanced resuscitative techniques appropriate for the patient be present or immediately available with appropriate resuscitative equipment throughout the procedure and until the patient has met the criteria for discharge from the facility;
- Return patients who enter a deeper level of sedation than intended to the lighter level of sedation as quickly as possible;
- Separate surgical and monitoring procedures so the provider performing the surgery is not the provider monitoring the anesthesia;
- Create written emergency care and transfer protocols;

- Maintain legible, complete, and accurate medical and anesthesia records for each patient.

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

RCW 18.22.015 (5) allows the board to adopt rules governing the administration of sedation and anesthesia in the offices of podiatric physicians including necessary training and equipment. The rule will provide enforceable standards for office-based surgery that will reduce the risk of substandard care, inappropriate anesthesia, infections and serious complications by podiatric physicians when performing office-based surgery. The rule will also provide that patients who receive sedation and anesthesia in an office-based surgery setting are safe, monitored, and their physicians are maintaining legible, complete, comprehensive and accurate medical and anesthesia records.

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

RCW 18.22.015 (5) requires the board to adopt rules governing the administration of sedation and anesthesia when podiatric physicians perform office-based surgery. A rule is needed to set enforceable standards for practitioners conducting office-based surgery in a setting other than licensed hospitals; hospital associated surgical centers, and ambulatory surgical facilities.

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?

The Department of Health (department) has determined that the following subsections of the rule do not require a significant analysis: **Purpose** – this subsection only introduces what is to come later in the rule; **Definitions** – this subsection defines terms used later in the rule and does not set standards; **Exemptions** – this subsection clarifies what the rules do not apply to; **Application of rules** – this subsection only lists the levels of sedation or anesthesia.

The subsections of the rule that are significant are analyzed in the numbered list below.

1. Description: Accreditation or certification WAC 246-922-650 (5)

The proposed rule requires podiatric physicians to obtain accreditation or certification for the office where they perform surgeries.

Analysis:

Organizations, research, articles and other states speak to the benefits of accreditation as it related to patient safety.

On October 19, 2003 the American College of Surgeons' (ACS) Board of Regents approved a set of 10 fundamental patient safety principals that physicians should adhere to when performing office-based surgery that uses moderate or deep sedation or general anesthesia. One of the principals is physicians performing office-based surgery should have their facilities accredited by the Joint Commission (JC), or the American Association for Ambulatory Health Care (AAAHC).

According to the Federation of State Medical Boards, accreditation is an evaluation process that examines the quality of services provided in a particular surgical setting or facility compared to nationally established standards assumed to be indicative of quality care. Accreditation is for a specific period of time. Several nationally recognized organizations accredit ambulatory/outpatient surgery facilities; such accreditation certifies that the facility meets the organization's national standards. In requiring accreditation as a model, the state defers the setting of standards to accreditation organizations, thus avoiding the necessity for development of independent standards.

In an article entitled, "Preventing Errors In The Outpatient Setting: A Tale of Three States" by Elizabeth M. Lapentina and Elizabeth M. Armstrong policies to improve outpatient safety in New Jersey, New York and Florida were analyzed. The findings suggest that accreditation, combined with particular attention to ensuring anesthesia safety, can improve quality of care for outpatients.

An article entitled, "How States Regulate Office Surgery – A Primer" by Adrian Hochstadt states that the American Society of Plastic Surgeons and American Society for Anesthetic Plastic Surgery have gone as far as requiring their members who perform certain levels of office-based surgery to do so in facilities that are accredited by a nationally recognized entity.

The American Gastroenterological Association believes that patient safety is best protected if standards are adopted by sites that are certified as an ambulatory surgical center and/or are accredited by a nationally recognized accreditation program.

In 1994 California passed a law that requires that surgery performed under a certain specified level of anesthesia, if not performed in a licensed hospital or surgery center, be done in an accredited facility. The California Medical Board does not perform the accreditation, but instead delegates the accreditation to agencies that it approves; currently there are four viable accreditation agencies, American Association for Accreditation of Ambulatory Surgical Facilities (AAAASF), AAAHC, the JC and the Institute of Medical Quality.

The New York State Public Health Council and the New York State Department of Health endorse guidelines for office-base surgery practitioners that say they should

strongly consider the use of outside accrediting agencies to help assure the public that they are providing care and services in a safe environment and adhering to the highest standards of quality and professionalism. Accrediting organizations include the AAAHC, the AAAASF and the JC.

The proposed rule requires accreditation or certification within 180 days of the effective date of this rule. A podiatric physician who performs office-based surgery procedures covered by this rule must ensure that the facility in which the procedures are performed is appropriately equipped and maintained through certification or accreditation from one of the following accrediting entities. These entities are nationally known and accredit or certify office-based surgery settings in other states:

Name of Accreditation or Certification Agency	Cost of Accreditation or Certification
Joint Commission (JC)	<ul style="list-style-type: none"> • \$6,950 for three years of accreditation
Accrediting Association for Ambulatory Health Care (AAAHC)	<ul style="list-style-type: none"> • \$645 application fee • \$3,000 - \$6,000 maximum three years accreditation
American Association for Accreditation of Ambulatory Surgical Facilities (AAASF)	<ul style="list-style-type: none"> • \$1,100 annual fee • \$950.00 every three years, inspection fee for single physician office
The Centers for Medicare and Medicaid Services (CMS)	<p>These standards will apply to physician offices that perform office-based surgery. CMS currently does not offer accreditation for ambulatory surgery centers. CMS will accept an accreditation exam from JC, AAAHC or AAAASF to meet certification requirements.</p>

The benefit in obtaining accreditation or certification is that it promotes patient safety by requiring compliance with nationally recognized standards for the facility where office-based surgery is performed. The benefit of ensuring patient safety through compliance with national standards outweighs the cost of accreditation or certification.

2. *Description: Competency WAC 246-922-650 (6)*

The rule will require that office-based surgery physicians must be able to demonstrate qualifications and competency for the procedures being performed.

Analysis: The department assumes there are several mechanisms for a podiatric physician to obtain qualifications and competency to perform office-based surgeries including, but not limited to podiatry school and required continuing education (i.e., 50 hours of CE every two years). The department assumes, therefore, there are no compliance costs for this section. If the board initiates disciplinary action against a practitioner, the practitioner may have to prove competency to the board.

3. Description: Presence of an anesthesiologist or anesthetist WAC 246-922-650 (7)

The rule will require that for procedures requiring spinal or major conduction anesthesia above the ankle, a physician authorized under Chapter 18.71 RCW or Chapter 18.57 RCW or a certified registered nurse anesthetist authorized under Chapter 18.79 RCW must administer the anesthesia.

Analysis: The cost is approximately \$175 an hour for an anesthesiologist and approximately \$75 an hour for a certified nurse anesthetist to be present to monitor sedation. The length of time for a surgery is not being estimated due to unknown factors such as the type of surgery and the health of the patient. A podiatric physician shall not administer spinal anesthetic or any anesthetic that renders the patient unconscious under 18.22.035 (4) (b). Administering anesthesia at these levels require special training. The benefit of requiring an expert in anesthesia is that it will improve patient safety and it allows the primary physician to focus on the surgery.

4. Description: Qualifications for administration of sedation and analgesia WAC 246-922-650 (8)

A podiatric physician must be qualified to administer sedation by completing continuing medical education; obtaining relevant training in a residency training program or having privileges for conscious sedation granted by a hospital medical staff.

Analysis – It is important that podiatric physicians be qualified to administer sedation and this section outlines ways a physician may become qualified. The department assumes there are several mechanisms for a podiatric physician to obtain qualifications and competency to administer analgesia including, but not limited to, their formal education (podiatric school), residency programs and required continuing education. The department, therefore, assumes there is no compliance cost for this section. The benefit is that podiatric physicians would receive the education and training to administer sedation safely to the public.

5. Description: Resuscitative preparedness WAC 246-922-650 (9)

At least one provider currently certified in resuscitative techniques, e.g. advance cardiac life support (ACLS), pediatric life support (PALS), or advance pediatric life support (APLS), must be present or immediately available with appropriate resuscitative equipment throughout the procedure and until the patient has met the criteria for discharge from the facility.

Analysis: - Requiring a provider certified in resuscitative techniques be on site will ensure that resuscitation begins immediately in the event of an emergency. If a provider does not have any of these certifications the cost for ACLS, PALS, or APLS ranges from \$199 to \$275. The certification is good for 2-3 years.

The requirement to have age-appropriate resuscitative equipment is essential and is a requirement of the certification standards in WAC 246-922-650 (5). The department's

assumption is that a podiatric physician performing these procedures in a certified or accredited office will already have appropriate training and resuscitative equipment necessary. Therefore no additional cost is required. The benefit is the public is assured that a physician working in a certified or accredited office will have appropriate training and necessary resuscitative equipment.

6. Description: Sedation assessment and management WAC 246-922-650 (10) - A podiatric physician must be able to rescue patients who enter a deeper level of sedation than intended. If a patient enters into a deeper level of sedation than planned, the physician must return the patient to the lighter level of sedation as quickly as possible while ensuring the patient is closely monitored, the airway is patent, the patient is breathing, and that their oxygenation, heart rate, and blood pressure are within acceptable values.

Analysis: The department assumes podiatric physicians learn how to rescue a patient that has entered a deeper level of sedation than intended in their training. The department assumes there are no costs associated with this as the physician would already have the necessary training and knowledge. The benefit is that the physician has the ability and knowledge to bring a patient back from any state of sedation.

7. Description: Separation of surgical and monitoring functions WAC 246-922-650 (11) - The provider performing the surgical procedure must not provide the anesthesia or monitoring.

Analysis: Information provided from other states and articles confirm that the trend is to promote patient safety by having the surgeon be separate from the practitioner who is monitoring the anesthesia. The article, "Preventing Errors In The Outpatient Setting: A Tale of Three States", gives an example of the reasoning for the trend, it says, "A 1997 survey by the American Society of Plastic and Reconstructive Surgeons identified five deaths in 24,245 liposuction cases, for a fatality rate of 20.6 per 100,000. Likewise, a census of 1,200 aesthetic plastic surgeons revealed that there were ninety-five deaths in 496,245 lipoplasties from 1994 to 1998, a mortality rate of 19.1 per 100,000. The majority (78 percent) of these ninety-five deaths occurred in the outpatient setting. At this rate, mortality from lipoplasty is higher than mortality from motor vehicle crashes (15.2 per 100,000) or homicides (5.9 per 100,000)".

A report by Dr. A Jay Burns regarding safety and efficacy in an Accredited Outpatient Plastic Surgery Facility states, "Between 1989 and 1990 office-based surgery increased threefold to 1.2 million procedures per year. Current estimates suggest four out of every five operative procedures will be performed in outpatient facilities by the year 2005, and that one-quarter will be performed in a doctor's office".

The American Society of Anesthesiologist states that anesthesiologists "are responsible for administering anesthesia to relieve pain and for managing vital life functions,

including breathing, heart rhythm and blood pressure, during surgery. After surgery, they maintain the patient in a comfortable state during the recovery....”

The American Association of Nurse Anesthetists states that nurse anesthetists “must stay with a patient for the entire procedure, constantly monitoring every important function of your body and individually modifying your anesthetic to ensure your maximum safety and comfort.”

Several states require separation of surgical and monitoring procedures.

Kentucky requires the individual administering conscious sedation and/or monitoring the patient cannot assist the surgeon in performing the surgical procedure.

Alabama requires that the individual administering moderate sedation/analgesia and/or monitoring the patient cannot assist the physician in performing the surgical procedure.

Rhode Island requires the person administering anesthesia shall not function in any other capacity during the surgical procedure.

New York clinical guidelines for office-base surgery require that the minimum number of available personnel during conscious sedation should be two: the practitioner performing the surgery and the individual monitoring the patient

This proposed rule does not allow podiatric physicians who perform office-based surgery using major conduction anesthesia, moderate sedation or analgesia or deep sedation or analgesia to be responsible for administering the anesthesia or monitoring the patient during and after the surgery.

To gauge the potential impact of the requirement to separate surgical and monitoring functions, the department surveyed parties on its list serv. The Department also requested the association of podiatrists to survey its members. The survey asked physicians to indicate the level of anesthesia they use when they perform office-based surgery. The survey also asked if practitioners are currently using dedicated staff to administer and monitor anesthesia. The Department received 16 survey responses. Eight out of the 16 indicated they only use local or minimal anesthesia when performing office-based surgery and therefore this procedure would not apply to this practice. Of the respondents that indicated they perform surgeries that require moderate sedation or deep sedation 2 out of 8 indicated that they do not currently use dedicated practitioners to administer and monitor anesthesia.

For those practitioners who will need to hire a dedicated practitioner to administer anesthesia the department estimates it could cost approximately \$175 an hour for an anesthesiologist and approximately \$75 an hour for a certified nurse anesthetist (CRNA) to be present to administer and monitor sedation.

The benefit of separating the monitoring procedure and the surgical procedure greatly outweighs the cost because it allows the primary physician to focus on the surgery. In an

emergency, the primary physician can focus solely on the surgery while the anesthesiologist will focus on the sedation level.

8. Description: Emergency care and transfer protocols WAC 246-922-650 (12)

The rule requires a physician performing office-based surgery must be certain that in the event of a complication or emergency all office personnel are familiar with a written documented plan for the timely and safe transfer of patients to an appropriate hospital. The plan must include arrangements for emergency medical services and appropriate transfer of the patient to the hospital.

Analysis: The cost to develop and implement an emergency care and transfer protocol would be minimal as it would only be the initial time it would take for the physician to create a plan and train staff. The board assumes that it will take approximately four hours for a physician to develop the protocol. The board assumes the physician will train staff during routine office staff meetings and therefore other than time, there will be no other cost.

The benefit of an emergency care and transfer protocol is that patients will be transferred to an appropriate hospital in a timely manner, thereby improving patient safety. The benefit of getting patient faster emergent care greatly outweighs the minimal cost incurred by the physician.

9. Description: Medical record and anesthesia record, WAC 246-922-650 (13)

The rule will require physicians performing office-based surgery to maintain legible, complete, and accurate medical and anesthesia records for each patient.

Analysis: The rule requires a physician to put specific information regarding the surgery and anesthesia into the medical record. The department's assumption is that this is already considered the standard of care for physicians to maintain complete medical and anesthesia records for all patients. Therefore, there is no additional cost of maintaining medical and anesthesia records.

Cost Benefit Conclusion

As described above, the proposed rule requires practitioners that perform office-based surgery using moderate sedation, deep sedation or analgesia or major conduction anesthesia to satisfy several requirements (i.e., obtain accreditation or certification; have the presence of an anesthesiologist or anesthesiologist; demonstrate qualification and competency; have a provider certified in resuscitative techniques; be able to rescue a patient that experiences complications from anesthesia; have a designated licensed health care practitioner to administer sedation and monitor the patient; create and implement an emergency care and transfer protocol; and maintain legible, complete, and accurate medical and anesthesia records for each patient.) Although individual practitioners may

incur costs associated with these requirements, the overall benefit of increased patient safety outweighs these costs.

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

The board worked on draft language through multiple meetings. Draft rule language was sent out to multiple interested party lists and they also worked with members from the Medical Quality Assurance Commission, the Board of Osteopathic Medicine and Surgery and department policy staff to minimize the burden of this rule. In the course of these and other efforts, the following alternative version(s) of the rule were rejected:

- The language regarding reporting of a death or significant complication. This was duplicative of information regarding mandatory reporting already established in chapter 246-16 WAC and was removed.
- Some language and words were revised for clarification purposes.
- Establishing certification or accreditation standards from an accrediting agency is not burdensome. Conducting procedures in an office-based surgery center is optional for a physician. The board believes if a surgeon chooses to practice in this manner then they must also take on the responsibility of being competent, trained and having the necessary equipment when practicing in an office-based surgery setting. Setting certification standards or accreditation is not burdensome but setting a level that will help to keep patients safe.
- Separating surgical and monitory functions should not be viewed as burdensome but of a common sense way of conducting business so the primary physician can focus on the surgery being conducted.

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 Department of Health determined that the rule does 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.