

Supplemental Significant Analysis
for Rule Concerning administration of sedation and anesthesia,
WAC 246-853-650 – Safe and effective analgesia and anesthesia administration in
office-based surgical settings (osteopathic physicians)

Section 1. What is the scope of the rule?

RCW 18.57.005(4) allows the Board of Osteopathic Medicine and Surgery (board) to adopt rules governing office-based surgeries performed by osteopathic physicians. The proposed rule identifies the administration of sedation and anesthesia in the offices of osteopathic physicians, including necessary training and equipment. Rules are needed to establish consistent standards for osteopathic physicians who perform office-based surgery to reduce the risk of substandard care, inappropriate administration of anesthesia, infections, and other serious complications.

The revised proposed rule will require osteopathic physicians who perform office-based surgery using major conduction anesthesia, moderate sedation or analgesia or deep sedation or analgesia to:

- Obtain certification or accreditation in good standing from one of the following: the Joint Commission, the Accreditation Association for Ambulatory Health Care, the American Association for Accreditation of Ambulatory Surgery Facilities, the Centers for Medicare and Medicaid Services, the Planned Parenthood Federation of America, or the National Abortion Federation;
- Be competent and qualified to perform procedures in office-based surgery;
- Have at least one licensed health care practitioner 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 osteopathic physician performing the surgery is not the provider monitoring the anesthesia. However, the health care practitioner who administers intravenous medications to a patient who is under minimal or moderate sedation, may assist the operating physician with minor, interruptible tasks for short durations;
- 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 18.57.005(4) allows the board to adopt rules governing the administration of sedation and anesthesia when osteopathic 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. The rule will also provide that patients who receive sedation and anesthesia in an office-based surgery setting are safe, monitored, and the osteopathic physicians are maintaining legible, complete, comprehensive and accurate medical and anesthesia records.

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

RCW 18.57.005(4) allows the board to adopt rules governing the administration of sedation and anesthesia when osteopathic physicians perform office-based surgery. A rule is needed to set enforceable standards for practitioners conducting office-based surgery in a setting other a hospital or a hospital-associated surgical center licensed under 70.41 RCW, or an ambulatory surgical facility licensed under 70.230 RCW.

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?

DOH has determined that no significant analysis is required for the following portions of the rule: **Purpose** – this only introduces what is to come later in the rule; **Definitions** – the definitions are self explanatory as to the meaning of the terms used later in the rule; **Exclusion** - this language is necessary for clarification purposes; **Application of rules** – this lists the levels of sedation or anesthesia.

The subsections of the rule that are significant are analyzed in the numbered list below. As discussed above, other portions of the rule are not significant and are therefore not included in this section by section analysis.

1. Description: Accreditation or certification WAC 246-853-650 (5)

The proposed rule requires osteopathic physicians to obtain accreditation or certification, within 365 days from the effective date of the rule, for the office(s) 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 principles 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 365 days of the effective date of this rule. An osteopathic 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 Entity	Cost of Accreditation or Certification
Joint Commission (JC)	<ul style="list-style-type: none"> • \$6950 for three years of accreditation
Accrediting Association for Ambulatory Health Care (AAAHC)	<ul style="list-style-type: none"> • \$650 application fee • \$4,350 – (4 doc or less and 2 or less OR and 1 site) three years or less depending on the accreditation decision in order to get 3 years accreditation, the office

	<p>must be substantially in compliance with accreditation standards. A new office opened 6 months or less will only be accredited for 1 year to be able to assure they are in compliance.</p> <ul style="list-style-type: none"> • \$6,000 maximum three years 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 (AAAASF)	<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 physicians conducting office-based surgery in a setting other than licensed hospitals; hospital associated surgical centers, and ambulatory surgical facilities 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>
Planned Parenthood Federation of America (PPFA)	<ul style="list-style-type: none"> • PPFA administers the accreditation process based on a three year cycle. • PPFA accreditation review in addition to the full clinical assessment also includes the review of IT, quality assurance, risk management and facilities. • The cost to accredit a center providing surgical and sedation services (based on number of providers) ranges from \$10,600 to \$16,000.
National Abortion Federation (NAF)	<ul style="list-style-type: none"> • Application Fee \$250 • Quality Assurance Inspections (QAI) Visit \$750 • Five year certification

The benefit of 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. Accreditation organizations have the goal of patient safety before, during and after performing office-based surgery. The benefit of ensuring patient safety through compliance with national standards outweighs the cost of accreditation or certification.

2. *Description: Competency WAC 246-853-650 (6)*

The rule will require that when an anesthesiologist or certified registered nurse anesthetist is not present, the osteopathic physicians performing the office-based surgery must be competent and qualified to operate and oversee the administration of sedation for the procedures being performed.

Analysis: The department assumes there are several mechanisms for an osteopathic physician to obtain qualifications and competency to perform office-based surgeries including, but not limited to the formal education they received to become an osteopathic physician and the required continuing

education they must complete to remain licensed. The board requires one-hundred fifty hours of continuing education every three years at an estimated cost of \$30 per credit hour. If the board initiates disciplinary action against a practitioner, the practitioner may have to prove competency to the board. The department assumes there are no new compliance costs for this section.

3. Description: Qualifications for administration of sedation and analgesia WAC 246-853-650 (7)

An osteopathic physician must be qualified to administer sedation. Qualification may be shown by completing continuing medical education, obtaining relevant training in a residency training program or having privileges for conscious sedation granted by a hospital.

Analysis – It is important that osteopathic physicians be qualified to administer sedation and this section outlines ways a physician may become qualified. The department assumes there are several mechanisms for an osteopathic physician to obtain qualifications and competency to administer analgesia including, but not limited to, courses on administering analgesia in their osteopathic school, experience gained by completing their residency programs and course work completed in satisfying their continuing education requirement. The department assumes, therefore, there is no compliance cost for this section. The benefit is that osteopathic physicians would receive the education and training to administer sedation safely to the public.

4. Description: Resuscitative preparedness WAC 246-853-650 (8)

At least one licensed health care practitioner 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: - The board requires at least one licensed health care practitioner be currently certified in advanced or resuscitative techniques be present or immediately available during an office-based surgery procedure. This ensures resuscitation will begin without delay. 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 246-853-650 (5). The department's assumption is an osteopathic physician working in a certified or accredited office will have necessary resuscitative equipment or at least one licensed health care practitioner available who has had appropriate training. The benefit is the public is assured that an osteopathic physician working in a certified or accredited office will have appropriate training and necessary resuscitative equipment.

5. Description: Sedation assessment and Management WAC 246-853-650 (9) – If an anesthesiologist or certified registered nurse anesthetist is not present, an osteopathic 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 oxygenation, heart rate and blood pressure are within acceptable values.

Analysis: The department assumes osteopathic physicians learn how to rescue a patient that has entered a deeper level of sedation than intended in their osteopathic school, residency programs and required continuing education. The department assumes there is no compliance cost for this section. The benefit is that the physician has the ability and knowledge to bring a patient back from any state of sedation.

6. *Description: Separation of surgical and monitoring functions WAC 246-853-650 (10)*

The physician performing the surgical procedure must not administer the intravenous sedation, or monitor the patient.

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 osteopathic 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 interested parties list. The department also requested the Washington Osteopathic Medical Association 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 results showed that a large majority of practitioners used local anesthesia or minimal anesthesia when performing office-based surgeries. There were only a few respondents (5 out of 52) that indicated that they perform surgeries that require moderate sedation or deep sedation. Furthermore, of these respondents only one 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 \$85 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 surgeries involving moderate sedation while the licensed health care practitioner, designated by the physician will administer intravenous medications, monitor the patient and assist with minor, interruptible tasks of short duration. If deep sedation is being given, then the licensed health care practitioner who administers intravenous medications and monitors a patient must not perform or assist in the surgical procedure to ensure patient safety.

7. Description: Emergency care and transfer protocols WAC 246-853-650 (11)

The rule requires that an osteopathic physician performing office-based surgery to 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.

8. *Description: Medical Record and Anesthesia Record, WAC 246-853-650 (12)*

The rule will require osteopathic 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 requirement 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: obtain accreditation or certification; demonstrate qualification and competency; be able to rescue a patient that experiences complications from anesthesia; have a licensed health care practitioner certified in resuscitative techniques; 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 their interested party list and they also worked with members from the Medical Quality Assurance Commission, the Podiatric Medical Board 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 changed, added or rejected:

- The length of time to obtain accreditation or certification was changed from 180 calendar days to 365 calendar days of the effective date of this rule to ensure that physicians have enough time to obtain accreditation or certification.
- In lieu of accreditation or certification, facilities limiting office-based surgery to abortions or abortion-related services may be accredited or certified by either the Planned Parenthood Federation of American or the National Abortion Federation. The language was added to accommodate physicians practicing in this area.
- Language was added that a licensed health care practitioner providing sedations may assist the physician with minor, interruptible tasks when a patient is under minimal or moderate sedation.

- The language regarding reporting of a death or significant complication was removed because the board felt it was a duplication of information regarding mandatory reporting already established in Chapter 246-16 WAC and that it would be duplicative and confusing to the practitioner to also include in these rules.
- Not requiring certification or accreditation from a national organization. Conducting procedures in an OBS 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 OBS setting. Setting certification standards or accreditation in CMS, AAAHC, AAASF or JC is not burdensome but setting a level that will help to keep patients safe.

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 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?

This rule does not differ from any federal regulation or state 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. The Medical Quality Assurance Commission and the Podiatric Medical Board is in the process of developing a similar rule. The board worked with MQAC and the Podiatric Medical Board throughout the process to ensure, as much as possible, that the three rules are consistent.