Interpretive Statement

WASHINGTON Medical Commission
Licensing. Accountability. Leadership.

Title:	Application of the Office-based Surgery Rule, WAC 246-919-601, to the Use of Nitrous Oxide	INS2023-0x
References:	WAC 246-919-601	
Contact:	Washington Medical Commission	
Phone:	(360) 236-2750	E-mail: medical.commission@wmc.wa.gov
Supersedes:	None	
Effective Date:		
Approved By:	Karen Domino, MD, Chair	

The Washington Medical Commission (WMC) interprets WAC 246-919-601, regulating the use of analgesia, anesthesia, and sedation in office-based settings, to exempt the use of nitrous oxide from the requirements of the rule if three requirements are met: (1) nitrous oxide is administered it at a concentration of 50% or less, (2) it is used without another inhaled anesthetic, a sedative, or an opioid drug, and (3) when the facility in which the procedure takes place has specific safeguards, listed below, in place. If a physician uses nitrous oxide with a concentration greater than 50%; uses it with another inhaled anesthetic, a sedative, or an opioid drug; or uses it in a facility that does not have the specific safeguards in place, the physician must comply with the requirements in WAC 246-919-601.

The WMC adopted WAC 246-919-601 in 2010 to promote patient safety by establishing consistent standards and competency for procedures requiring analgesia, anesthesia, or sedation performed in an office-based setting. The rule was designed to complement new legislation requiring the licensing of ambulatory surgical facilities.

The rule contains certain requirements to ensure that patients are safe when undergoing procedures in a physician's office. These requirements include accreditation or certification of the facility where the procedures take place; competency; separation of surgical and monitoring functions; written emergency care and transfer protocols; the ability to rescue a patient who enters a deeper level of sedation than intended; and having a licensed health care practitioner currently certified in advanced resuscitative techniques appropriate for the patient age group present or immediately available.

WAC 246-919-601 provides in relevant part:

> (2) Definitions. The following terms used in this subsection apply throughout this section unless the context clearly indicates otherwise:
> ...
> (e) "Minimal sedation" means a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be

impaired, ventilatory and cardiovascular functions are unaffected. Minimal sedation is limited to oral, intranasal, or intramuscular medications.

...

(g) "Office-based surgery" means any surgery or invasive medical procedure requiring analgesia or sedation, including, but not limited to, local infiltration for tumescent liposuction, performed in a location other than a hospital or hospital-associated surgical center licensed under chapter 70.41 RCW, or an ambulatory surgical facility licensed under chapter 70.230 RCW.

(3) Exemptions. This rule does not apply to physicians when:
(a) Performing surgery and medical procedures that require only minimal sedation (anxiolysis), or infiltration of local anesthetic around peripheral nerves. Infiltration around peripheral nerves does not include infiltration of local anesthetic agents in an amount that exceeds the manufacturer's published recommendations.

WAC 246-919-601(3)(a) specifically exempts from the rule requirements procedures that require only minimal sedation. WAC 246-919-601(2)(e) clarifies that minimal sedation is limited to oral, intranasal, or intramuscular medications. The WMC revised the rule in 2020 to add the term "intranasal" to the definition of minimal sedation to permit the use of midazolam when sprayed into the nose.

The WMC rule does not state whether the administration of nitrous oxide is considered to be minimal sedation, and, therefore, exempt from the rule.

Nitrous oxide, an inhaled anesthetic, has a dose-dependent sedating effect, and can be used for procedural sedation, general anesthesia, dental anesthesia, and to treat severe acute pain. When administered as a sole anesthetic agent at a concentration of 50% or less (combined with oxygen), nitrous oxide has minimal effects on respiration and has no muscle relaxation properties. Used in this way, nitrous oxide sedates a patient for a brief period of time and presents a low risk to the patient, provided that certain safeguards, set forth below, are in place.

Under these circumstances, the WMC considers the administration of nitrous oxide as minimal sedation and, therefore, is not subject to WAC 246-919-601. The facility in which the procedure takes place is not required to be accredited or certified by an entity approved by the WMC. If, however, nitrous oxide is administered in combination with another anesthetic agent or is administered at a concentration of greater than 50%, this is not minimal sedation and, therefore this is subject to the requirements of WAC 246-919-601, including the requirement for the facility to be credentialed or certified.

A physician administering nitrous oxide at a concentration of 50% or less, and without another inhaled anesthetic, a sedative, or an opioid drug, must employ the following safeguards for the administration of nitrous oxide to be considered minimal sedation:

Competence. The physician must be competent and qualified to perform the procedure and to oversee the administration of nitrous oxide. The physician should complete a continuing medical education course in the administration of nitrous oxide analgesia.

Certification in advanced resuscitative techniques. At least one licensed health care practitioner currently certified in advanced resuscitative techniques appropriate for the patient age group must be present or on site and immediately available with age-size-appropriate resuscitative equipment throughout the procedure and until the patient has met the criteria for discharge from the facility. Certification in advanced resuscitative techniques includes, but is not limited to, advanced cardiac life support (ACLS), pediatric advanced life support (PALS), or advanced pediatric life support (APLS).

Sedation assessment and management. If an anesthesiologist or certified registered nurse anesthetist is not present, a physician intending to produce a given level of sedation should be able to "rescue" a patient who enters a deeper level of sedation than intended. If a patient enters a deeper level of sedation than planned, the physician must return the patient to the lighter level of sedation as quickly as possible, while closely monitoring the patient to ensure the airway is patent, the patient is breathing, and that oxygenation, heart rate and blood pressure are within acceptable values.

Separation of surgical and monitoring functions. The physician performing the surgical procedure must not administer the nitrous oxide or monitor the patient.

Emergency care and transfer protocols. A physician performing office-based surgery must ensure that in the event of a complication or emergency:

(a) All office personnel are familiar with a written and documented plan to timely and safely transfer patients to an appropriate hospital.

(b) The plan must include arrangements for emergency medical services and appropriate escort of the patient to the hospital.

Medical record. The physician must maintain a legible, complete, comprehensive, and accurate medical record for each patient. The medical record must include all of the following:

(a) Identity of the patient;

(b) History and physical, diagnosis and plan;

(c) Appropriate lab, X-ray or other diagnostic reports;

(d) Appropriate pre-anesthesia evaluation;

(e) Narrative description of procedure;

(f) Documentation of vital signs during the nitrous oxide sedation, including respiratory rate, oxygen saturation, heart rate, and blood pressure;

(g) Pathology reports, if relevant;

(h) Documentation of which, if any, tissues and other specimens have been submitted for histopathologic diagnosis;

(i) Provision for continuity of postoperative care; and

(j) Documentation of the outcome and the follow-up plan.

Scavenging of nitrous oxide. To protect staff, the physician should use scavenging to remove excess nitrous oxide from the operating room.

The WMC interprets WAC 246-919-601, regulating the use of analgesia, anesthesia, and sedation in office-based settings, to exempt the use of nitrous oxide from the requirements of the rule if three requirements are met: (1) nitrous oxide is administered it at a concentration of 50% or less; (2) it is used without another inhaled anesthetic, a sedative, or an opioid drug; and (3) the facility in which the procedure takes place has specific safeguards, listed above, in place. If a physician uses nitrous oxide with a concentration greater than 50%; uses it with another inhaled anesthetic, sedative, or an opioid drug; or uses it in a facility that does not have the specific safeguards in place, the use of nitrous oxide is not minimal sedation, and the physician must comply with the requirements in WAC 246-919-601.

Washington State Medical Association
Physician Driven, Patient Focused

October 9, 2023

Amelia Boyd
Program Manager
Washington Medical Commission

RE: Application of the office-based surgery rule/use of nitrous oxide interpretive statement

Dear Ms. Boyd,

On behalf of the Washington State Medical Association (WSMA), thank you for the opportunity to provide comment on the draft updated interpretive statement regarding the use of nitrous oxide for office-based surgery. The WSMA is grateful to both leadership and staff at the Washington Medical Commission (WMC) for their willingness to collaborate on the update of this interpretive statement. These updates will move procedures previously exclusively performed in a hospital or ambulatory surgical center (ASC) to office-based settings – increasing efficiency for patients and practitioners – while ensuring patient safety remains the top priority. **The WSMA is proud to offer our support for the interpretive statement.**

While we are supportive of the interpretive statement, we do offer one small technical correction to the draft in the section specific to scavenging of nitrous oxide. The new language references an "operating room" where it should cite a "procedure room":

> *Scavenging of nitrous oxide. To protect staff, the physician should use scavenging to remove excess nitrous oxide from the ~~operating room~~ procedure room.*

Our organization has appreciated the opportunity to work with Dr. Karen Domino and WMC staff on revisions to this interpretive statement. The update will ensure that physicians are able to utilize nitrous oxide in-office under regulations similar to dentists. This new interpretive statement will also relieve some pressure on hospitals and ASCs by providing care in the lowest cost settings while ensuring that patient safety is paramount.

Thank you for the opportunity to provide comment. Should you have follow-up questions, please contact WSMA Associate Policy Director Billie Dickinson.

Sincerely,

Billie Dickinson

Billie Dickinson
Associate Policy Director
Washington State Medical Association

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Interpretive Statement

WASHINGTON Medical Commission
Licensing. Accountability. Leadership.

Title:	"Qualified Physician" Under Optometry Law		IS2023-0x
References:	Chapter 18.53 RCW; Chapter 18.71 RCW		
Contact:	Washington Medical Commission		
Phone:	(360) 236-2750	E-mail:	medical.commission@wmc.wa.gov
Supersedes:	n/a		
Effective Date:			
Approved By:	Karen Domino, MD ,Chair		

The Washington Medical Commission (WMC) interprets the term "qualified physician" in Enrolled Substitute Senate Bill 5389, Chapter 400, Laws of 2023, to mean a physician who meets the following criteria:

1. Holds a current license to practice as a physician and surgeon with the WMC;
2. Is not currently under any disciplinary action by the WMC, including a stipulation to informal disposition;
3. Holds a current certification from the American Board of Ophthalmology; and
4. Has a surgical suite on site or holds privileges at a local hospital.

On May 9, 2023, Governor Inslee signed Enrolled Substitute Senate Bill 5389 modifying Chapter 18.53 RCW, an act regulating the practice of optometry in Washington. This new law expanded the scope of optometry to include certain advanced procedures:

> (2)(a) The practice of optometry may include the following advanced procedures:
> (i) Common complication of the lids, lashes, and lacrimal systems;
> (ii) Chalazion management, including injection and excision;
> (iii) Injections, including intramuscular injections of epinephrine and subconjunctival and subcutaneous injections of medications;
> (iv) Management of lid lesions, including intralesional injection of medications;
> (v) Preoperative and postoperative care related to these procedures;
> (vi) Use of topical and injectable anesthetics; and
> (vii) Eyelid surgery, excluding any cosmetic surgery or surgery 1 requiring the use of general anesthesia.

The new law provides that an optometrist cannot perform these advanced procedures until the Board of Optometry issued a license endorsement. The Board of Optometry will issue the

license endorsement after the optometrist meets "the educational, training, and competence criteria" set forth in the new law.

To receive a license endorsement, the optometrist must successfully complete postgraduate courses as designated by the Board, successfully complete a national examination for advanced procedures, and

> (iii) Enter into an agreement with a qualified physician licensed under chapter 18.71 RCW or an osteopathic physician licensed under chapter 18.57 RCW for rapid response if complications occur during an advanced procedure.

The new law does not define the term "qualified physician licensed under chapter 18.71 RCW." Since the WMC licenses allopathic physicians under chapter 18.71 RCW, the WMC is the proper entity to define the term "qualified physician."

Being able to respond rapidly to complications from the procedures listed in the new law requires a high level of competence. The WMC interprets the term "qualified physician under chapter 18.71 RCW" in Enrolled Substitute Senate Bill 5389, Chapter 400, Laws of 2023, to mean a physician who meets each of the following criteria:

1. Holds a current license to practice as a physician and surgeon with the WMC;
2. Is not currently under an order or a stipulation to informal disposition with the WMC;
3. Holds a current and unrestricted certification from the American Board of Ophthalmology; and
4. Has a surgical suite on site or holds privileges at a local hospital.

WASHINGTON ACADEMY OF EYE PHYSICIANS & SURGEONS

September 28, 2023

Members of the Washington Medical Commission:

Thank you for the opportunity to provide comments on the interpretive statement clarifying which specific providers may participate in such an agreement between optometrists and medical doctors as stipulated in SB 5389.

The Washington Academy of Eye Physicians and Surgeons (ophthalmologists) actively participated in the Department of Health's Sunrise Review of a proposal from the optometrists to substantially increase their scope of practice. We also engaged with the Legislature as that proposal (SB 5389) was considered during the 2023 Session.

We have serious concerns about optometrists being given the authority to perform "advanced procedures" for which we contend they are very inadequately trained, and hence want to ensure the few patient safety measures included in SB 5389 are carefully implemented.

One of those provisions mandates that optometrists must establish an agreement with a "qualified physician" licensed as a medical doctor (MD) or a doctor of osteopathic medicine (DO) before any advanced procedures may be undertaken. Such an agreement would be utilized "if a rapid response is needed if complications occur during a procedure".

As the WMC has requested stakeholder input on this topic, we respectfully offer the following. (We are not aware of any specific proposed language to that effect so our comments are presented to the WMC in a general manner.) We concur with the DOH Sunrise Review recommendation as well as the legislative mandate for such an agreement, but would also strongly advise that <u>such agreements ONLY be signed between an</u>

optometrist and a board-certified ophthalmologist. Patient safety is not protected if the agreement for complications is with a primary care physician or non-ophthalmic physician specialty. Additionally, while most ophthalmologists are board-certified, not all are, so this further clarifying protection is important.

We also recommend the WMC clarify that "rapid response during a procedure" also pertains to complications discovered subsequent to a procedure. On a related matter, it is important for the WMC to consider defining what constitutes a complication since a MD or DO will be required to respond. This is particularly important due to ambiguities in additional sections of SB 5389, specifically in section 4, concerning the reporting of "adverse events". Notably, the bill lacks a definition of adverse events (in addition to a lack of a definition for complications). Does the agreement with a MD/DO for a rapid response not occur if there is an adverse event? What is the difference between a complication and an adverse event? We feel that the WMC would be an appropriate body to weigh in on those matters as the board of optometry undertakes its rule-writing process and we would welcome a discussion with you on these and related points.

It is our intention for WAEPS to make comments virtually on Friday, but we are also submitting these written comments per your invitation. Please let us know if you have questions or if we may assist you in any other way.

We are grateful for your ongoing attention to assuring that Washington's patient population is protected in all ways possible.

Sincerely,

Stephanie Cramer, MD
President, WAEPS

From: Farrell, Michael (WMC)
To: Bell, Kristina L (DOH)
Cc: Matthews, Micah T (WMC)
Subject: RE: WMC Interpretive Statement
Date: Monday, October 9, 2023 8:51:00 AM
Attachments: image001.png
image002.png
image003.png
image004.png
image005.png
image006.png
image007.png
image008.jpg
image009.png
image010.png

Hi Kristina,

Sorry for the delay in responding. I was attending a Commission meeting last week. Thank you for your feedback.

The intent of the current draft of the proposed Interpretive Statement is to ensure that patients who suffer complications from eye procedures, which can be very serious, are treated with the highest level of care by a physician who has the training, skill, and experience to rapidly treat the complication. The draft proposes that the physician who agrees to treat complications be a board-certified ophthalmologist who is not under disciplinary action and who has a surgical suite or holds privileges at a local hospital. The intent is to ensure that safeguards are in place to ensure that serious complications are handled by a qualified physician. Although SB 5389 does not specify that an ophthalmologist handle complications, it requires a "qualified physician" licensed by the Medical Commission or the Board of Osteopathy. This provision allows the Medical Commission and the Board of Osteopathy to determine the qualifications a physician needs to competently treat serious complications.

The Medical Commission's Policy Committee is meeting this Friday at 10 am to discuss the current draft. The meeting will be held via Microsoft Teams. We invite you and your board to attend the meeting to provide feedback on the draft.

The Policy Committee may send the draft to the full Commission for discussion at its next business meeting, which is scheduled for Friday, October 20, at 8:30 am. It will be virtual as well.

The Medical Commission appreciates feedback from the Board of Optometry and hopes that your board members can attend one or both meetings to discuss the proposed draft.

Best regards,

Mike

Michael L. Farrell, JD
Washington Medical Commission

Were you satisfied with the service you received today? Yes or No

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From: Bell, Kristina L (DOH) <Kristina.Bell@doh.wa.gov>
Sent: Wednesday, October 4, 2023 12:00 PM
To: Farrell, Michael (WMC) <michael.farrell@wmc.wa.gov>
Subject: RE: WMC Interpretive Statement

Good Afternoon,
The Board of Optometry (board) would like to know the intent of drafting the interpretive statement? Currently the board believes the statement is restricting the care for patients if any complications may occur during procedures. Any complications that may occur should be performed by any class of practitioner not just an ophthalmologist. SB5389 does not require an ophthalmologist to manage complications that may occur due to the advanced procedures authorized. At this time, the Board feels the interpretive statement does not accurately represent all of the advanced procedures outlined by SB 53289.

I look forward to hearing from you have a wonderful day.

Kristina Bell
Program Manager
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Deaf or hard of hearing call 711

From: Farrell, Michael (WMC) <michael.farrell@wmc.wa.gov>
Sent: Wednesday, October 4, 2023 9:02 AM
To: Bell, Kristina L (DOH) <Kristina.Bell@doh.wa.gov>
Subject: RE: WMC Interpretive Statement

Kristina,

Nice to meet you via email. I look forward to getting feedback from the Board of Optometry.

From:	McElhiney, Becky A (DOH)
To:	Farrell, Michael (WMC)
Cc:	Chaney, James (DOH)
Subject:	RE: WMC Interpretive Statement
Date:	Tuesday, October 10, 2023 4:51:25 PM
Attachments:	image001.png image002.png image003.png image004.jpg image005.png image006.png

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Hello,

Below are the comments I received from the board regarding WMC's interpretive statement. Please let me know if you have further questions.

From Dr. Sobel:

> Questions:
> What sort of surgical suite? A WA State accredited ASF?
> Level of sedation should be better defined. Moderate or deep sedation can easily become general anesthesia. Perhaps anxiolysis via oral route is appropriate. Can Optometrists prescribe such medications? Manage opiod and benzodiazepine reversals? Airway management? ACLS training? What if the patient has an oculocardiac event?
>
> The procedural competence part is up to those who know this specialty best, but this seems at some odds with WA state laws governing ASF's and depth of anesthesia.
>
> This seems hard.
>
> Good luck!

From Dr. Morrissette:

> 1. I would ask a board certified opthomologist their interpretation as I am not an expert on the qualifications and scope of practice of an optometrist other than my emergency physician and patient knowledge.
> 2. A 'qualified physician" to provide surgery to eyelids etc should not include an optometrist. A Qualified physician should be an MD or DO.
> 3. Optometrist while a 'doctor' is not a medical doctor and should not be confused with an MD or a DO.

Thank you,

Becky McElhiney
Gender Pronouns: She/Her
Program Manager
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Medical Assistant Program

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Please consider the environment before printing this email

From: Chaney, James (DOH) <ulysses.chaney@doh.wa.gov>
Sent: Tuesday, October 3, 2023 4:37 PM
To: Farrell, Michael (WMC) <michael.farrell@wmc.wa.gov>
Cc: McElhiney, Becky A (DOH) <Becky.McElhiney@DOH.WA.GOV>
Subject: RE: WMC Interpretive Statement

Thank you so much Mike.

I will ask Becky (cc'd) to bcc board members and ask for comments.

Once we have response (s), if needed I will reach out and ask for a meeting.

Thank you again,

U. James Chaney
Executive Director
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From: Farrell, Michael (WMC) <michael.farrell@wmc.wa.gov>
Sent: Tuesday, October 3, 2023 4:24 PM
To: Chaney, James (DOH) <ulysses.chaney@doh.wa.gov>
Subject: WMC Interpretive Statement

Hi James,

I wanted you to know that the Medical Commission is considering an interpretive statement defining the term "qualified physician" in SSB 5389. This is the new law expanding the scope of practice for optometrists.

The WMC would like to get feedback from BOMS.

I attach the draft. The WMC policy committee will review the draft at its meeting next Friday, October 13.

Please let me know if you want to discuss.

Thanks!

Mike

Michael L. Farrell, JD
Washington Medical Commission