STATE OF WASHINGTON

DEPARTMENT OF HEALTH

Olympia, Washington 98504

NOTICE OF ADOPTION
INTERPRETIVE STATEMENT

Title of Interpretive Statement: Establishing the Use of Nitrous Oxide in Office-Based Settings Under WAC 246-919-601 | INS2023-02

Issuing Entity: Washington Medical Commission

Subject Matter: Regulating the use of analgesia, anesthesia, and sedation in office-based settings to exempt the use of nitrous oxide from the requirements of WAC 246-919-601.

Effective Date: October 20, 2023

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Interpretive Statement

WASHINGTON Medical Commission
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Title:	Establishing the Use of Nitrous Oxide in Office-Based Settings Under WAC 246-919-601	INS2023-02
References:	WAC 246-919-601	
Contact:	Washington Medical Commission	
Phone:	(360) 236-2750 E-mail: medical.commission@wmc.wa.gov	
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Approved By:	Karen Domino, MD, Chair (signature on file)	

The Washington Medical Commission (WMC) interprets WAC 246-919-601, Safe and effective analgesia and anesthesia administration in office based surgical settings, to exempt the use of nitrous oxide from the requirements of the rule if three requirements are met: (1) nitrous oxide is administered 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 procedure room.

Safe storage. The nitrous oxide must be stored in a secure room that is accessible only by authorized individuals and only during regular office hours. Policies and procedures should be established that limit access and opportunities for diversion and misuse of nitrous oxide.

The WMC interprets WAC 246-919-601, Safe and effective analgesia and anesthesia administration in office-based surgical 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.