

NOTICE OF PROPOSED RULEMAKING
TITLE 4. PROFESSIONS AND OCCUPATIONS
CHAPTER 16. ARIZONA MEDICAL BOARD

1.

<u>Sections Affected</u>	<u>Rulemaking Action</u>
R4-16-101	Amend
R4-16-603	Amend
Article 7	New article
R4-16-701	New section
R4-16-702	New section
R4-16-703	New section
R4-16-704	New section
R4-16-705	New section
R4-16-706	New section
R4-16-707	New section

2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):
Authorizing statute: A.R.S. §§ 32-1403 A)(8), 32-1404(D)
Implementing statute: A.R.S. §§ 32-1401(20), 32-1401(27)(tt)

3. A list of all previous notices appearing in the *Register* addressing the proposed rule:
Notice of Rulemaking Docket Opening: 12 A.A.R.

4. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:
Name: Timothy Miller, Executive Director
Address: 9545 E. Doubletree Ranch Road
Scottsdale, Arizona 85258
Telephone: (480) 551 2791
Fax: (480) 551 2828
E-mail: tmiller@azmd.gov

5. An explanation of the rule, including the agency's reasons for initiating the rule:
The Board is making rules to provide standards for office-based surgery conducted in a physician's office or other outpatient setting that is not part of a licensed hospital or licensed outpatient surgical center.

6. A reference to any study relevant to the rule that the agency reviewed and either proposes to rely on or not rely on in its evaluation of or justification for the rule, where the public may obtain or

review each study, all data underlying each study, and any analysis of each study and other supporting material:

The Board did not review or rely on any study.

7. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

8. The preliminary summary of the economic, small business, and consumer impact:

As used in this summary, minimal means less than \$1,000, moderate means between \$1,000 and \$10,000, and substantial means greater than \$10,000.

The rules affect the Board, a licensed physician who performs office-based surgery, a health care professional, staff member, and a patient. The Board should experience minimal to substantial costs to write and implement the rules. The Board believes that most licensed physicians who are currently performing office-based surgery using sedation follow the provisions stated in the rules. These physicians should experience minimal increases in costs because of the rules. Those physicians that are not currently following the rules' provisions could experience minimal to substantial increases in costs, depending on the rule(s) not being followed. By providing clear and understandable rules the rules protect physicians, staff members, health care professionals, and patients. The rules offer recourse to a patient who believes the physician who performed office-based surgery has committed an act of unprofessional conduct because the physician violated the statutes or rules governing office-based surgery.

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name: Timothy Miller, Executive Director

Address: 9545 E. Doubletree Ranch Road
Scottsdale, Arizona 85258

Telephone: (480) 551 2791

Fax: (480) 551 2828

E-mail: tmiller@azmd.gov

10. The time, place, and nature of the proceedings for the making, amendment, or repeal of the rule, or if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:

Date:

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Time:

Location:

A person may submit written comments about the proposed rules no later than 5:00 p.m., ??? to the individual listed in item 4 and 9. Persons with a disability may request reasonable accommodations by contacting the individual listed in item 4 and 9. Requests should be made as early as possible to allow sufficient time to arrange for the accommodations.

11. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

12. Incorporations by reference and their location in the rules:

None

13. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 16. ARIZONA MEDICAL BOARD

ARTICLE 1. GENERAL PROVISIONS

R4-16-101. Definitions

ARTICLE 6. DISCIPLINARY ACTIONS

R4-16-603. Acts of Unprofessional Conduct

ARTICLE 7. OFFICE-BASED SURGERY USING SEDATION

R4-16-701. Health Care Institution License

R4-16-702. Administrative Provisions

R4-16-703. Procedure and Patient Selection

R4-16-704. Sedation Monitoring Standards

R4-16-705. Perioperative Period; Patient Discharge

R4-16-706. Emergency Drugs; Equipment and Space Used for Office-Based Surgery Using Sedation

R4-16-707. Emergency and Transfer Provisions

TITLE 4. PROFESSIONS AND OCCUPATIONS
CHAPTER 16. ARIZONA MEDICAL BOARD
ARTICLE 1. GENERAL PROVISIONS

R4-16-101. Definitions

Unless the context otherwise requires, definitions prescribed under A.R.S. § 32-1401 and the following apply to this Chapter:

1. “ACLS” means advanced cardiac life support, which is performed according to certification standards of the American Heart Association.
2. “Agent” means an item or element that causes an effect.
3. "Approved medical assistant training program" means a program accredited ~~program~~ by any of the following:
 - a. ~~the~~ The Commission on Accreditation of Allied Health Education Programs (CAAHEP);
 - b. ~~the~~ The Accrediting Bureau of Health Education Schools (ABHES); or
 - c. a A medical assisting program accredited by any accrediting agency recognized by the United States Department of Education; or
 - d. a A training program designed and offered by a licensed allopathic physician; ~~that~~ which meets or exceeds any of the prescribed programs, and verifies the entry-level competencies of a medical assistant prescribed under R4-16-402(A).
4. "Deep sedation” means a drug-induced depression of consciousness during which a patient:
 - a. Cannot be easily aroused, but
 - b. Responds purposefully following repeated or painful stimulation.
5. "Discharge" means a written or electronic documented termination of office-based surgery to a patient.
6. “Drug” means the same as in A.R.S. § 32-1901.
7. "Emergency" means an immediate threat to the life or health of a patient.
8. “Emergency drug” means a drug that is administered to a patient in an emergency.
9. "General Anesthesia" means a drug-induced loss of consciousness during which a patient:
 - a. Is unarousable even with painful stimulus; and
 - b. May partially or completely lose the ability to maintain ventilatory, neuromuscular, or cardiovascular function or airway.

10. “Health care professional” means a registered nurse defined in A.R.S. § 32-1601, registered nurse practitioner defined in A.R.S. § 32-1601, physician assistant defined in A.R.S. § 32-2501, and any individual authorized to perform surgery according to A.R.S. Title 32 who participates in office-based surgery using sedation at a physician’s office.
11. "Informed consent" means advising a patient of:
 - a. Alternatives to the office-based surgery using sedation,
 - b. Associated risks of office-based surgery using sedation, and
 - c. Possible complications from the office-based surgery using sedation.
12. "Inpatient" has the same meaning as in A.A.C. R9-10-201.
13. “Minimal Sedation” means a drug-induced state during which:
 - a. A patient responds to verbal commands,
 - b. Cognitive function and coordination may be impaired, and
 - c. A patient's ventilatory and cardiovascular functions are unaffected.
14. “Moderate Sedation” means a drug-induced depression of consciousness during which:
 - a. A patient responds to verbal commands or light tactile stimulation, and
 - b. No interventions are required to maintain ventilatory or cardiovascular function.
15. "Monitor" means to assess the condition of a patient.
16. *“Office-based surgery” means a medical procedure conducted in a physician's office or other outpatient setting that is not part of a licensed hospital or licensed ambulatory surgical center. (A.R.S. § 32-1401(20))*
17. "PALS" means pediatric life support, which is performed according to certification standards of the American Academy of Pediatrics or the American Heart Association.
18. "Patient" means an individual receiving office-based surgery using sedation.
19. "Physician" has the same meaning as doctor of medicine as defined in A.R.S. § 32-1401.
20. "Sedation" means minimum sedation, moderate sedation, or deep sedation.
21. “Staff member” means an individual who:
 - a. Is not a health care professional, and
 - b. Assists with office-based surgery using sedation under the supervision of the physician performing the office-based surgery using sedation.
22. "Transfer" means a physical relocation of a patient from a physician's office to a licensed health care institution.

ARTICLE 6. DISCIPLINARY ACTIONS

R4-16-603. Acts of Unprofessional Conduct

A physician commits an act of unprofessional conduct when the physician violates one or more subparagraphs of A.R.S. § 32-1401(27). These statutory violations are referenced under the categories that follow.

1. No change
 - a. No change
 - b. No change
2. No change
 - a. No change
 - b. No change
3. No change
 - a. No change
 - b. No change
4. No change
 - a. No change
 - b. No change
5. No change
 - a. No change
 - b. No change
6. No change
 - a. No change
 - b. No change
7. No change
 - a. No change
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8. No change
 - a. No change
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9. No change
 - a. No change
 - b. No change
10. No change
 - a. No change
 - b. No change

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- 11. No change
 - a. No change
 - b. No change
- 12. No change
 - a. No change
 - b. No change
- 13. No change
 - a. No change
 - b. No change.
- 14. No change
 - a. No change
 - b. No change
- 15. No change
 - a. No change
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- 16. No change
 - a. No change
 - b. No change
- 17. No change
 - a. No change
 - b. No change
- 18. No change
 - a. No change
 - i. No change
 - (1) No change
 - (2) No change
 - (3) No change
 - (4) No change
 - (5) No change
 - ii. No change
 - iii. No change
 - iv. No change
 - b. No change
 - i. No change

- ii. No change
 - c. No change
 - i. No change
 - ii. No change
 - d. No change
 - i. No change
 - ii. No change
- 19. No change
 - a. No change
 - b. No change
- 20. "Performing office-based surgery using sedation in violation of Board rules" includes those actions or omissions that violate A.R.S. § 32-1401(27)(tt) and Article 7 of this Chapter.
 - a. A one-time offense may be resolved with Probation. A violation with a departure from the standard of care may result in a minimum of a Letter of Reprimand and Probation.
 - b. Repetitive or egregious offenses may result in a minimum of Decree of Censure and Probation. Suspension or Revocation may be appropriate in some cases.

ARTICLE 7. OFFICE-BASED SURGERY USING SEDATION

R4-16-701. Health Care Institution License

A physician who uses general anesthesia in the physician's office or other outpatient setting that is not part of a licensed hospital or licensed ambulatory surgical center when performing office-based surgery using sedation shall obtain a health care institution license as required by the Arizona Department of Health Services under A.R.S. Title 36, Chapter 4 and 9 A.A.C. 10.

R4-16-702. Administrative Provisions

A. A physician who performs office-based surgery using sedation in the physician's office or other outpatient setting that is not part of a licensed hospital or licensed ambulatory surgical center shall:

- 1. Establish, document, and implement written policies and procedures that cover:
 - a. Patient's rights,
 - b. Informed consent,
 - c. Care of patients in an emergency, and
 - d. The transfer of patients;

2. Ensure that a staff member who assists with or a healthcare professional who participates in office-based surgery using sedation:
 - a. Has sufficient education, training, and experience to perform duties assigned; and
 - b. If applicable, has a current license or certification to perform duties assigned;
3. Ensure that a copy of the patient's rights policy is provided to each patient before performing office-based surgery using sedation;
4. Obtain informed consent from the patient before performing an office-based surgery using sedation that:
 - a. Authorizes the office-based surgery, and
 - b. Authorizes the office-based surgery to be performed in the physician's office;
5. Review all policies and procedures every 12 months and update as needed.

B. A physician who performs office-based surgery using sedation shall comply with:

1. The local jurisdiction's fire code;
2. The local jurisdiction's building codes for construction and occupancy;
3. The biohazardous waste and hazardous waste standards in A.A.C. Title 18, Chapter 13, Article 14;
4. The controlled drug administration, supply, and storage standards in A.A.C. Title 4, Chapter 23.

R4-16-703. Procedure and Patient Selection

A. A physician shall ensure that each office-based surgery using sedation performed:

1. Can be safely performed with the equipment, staff members, and health care professionals at in the physician's office;
2. Is of duration and degree of complexity that allows a patient to be discharged from the physician's office within 24 hours;
3. Is within the education, training, experience and skills of the physician; and
4. Is within the education, training, experience, and skills of the staff members and health care professionals at the physician's office.

B. A physician shall not perform office-based surgery using sedation if, the patient:

1. Has a medical condition or other condition that poses an undue risk of complications, or
3. Will require inpatient services at a hospital.

R4-16-704. Sedation Monitoring Standards

A physician who performs office-based surgery using sedation shall, from the time sedation is administered until post-sedation monitoring begins:

1. When administering minimum sedation, use a quantitative method of assessing the patient's oxygenation, such as pulse oximetry.
2. When administering moderate or deep sedation:
 - a. Use a quantitative method of assessing the patient's oxygenation, such as pulse oximetry;
 - b. Monitor the patient's circulatory function by the following:
 - i. Have a continuously displayed electrocardiogram,
 - ii. Document arterial blood pressure and heart rate at least every five minutes, and
 - iii. Evaluate the patient's cardiovascular function by pulse plethysmography or oximetry,
 - iv. Monitor the patient's temperature to maintain an appropriate temperature level; and
 - c. Ensure a licensed and qualified healthcare professional, other than the physician performing the office-based surgery, whose sole responsibility is attending to the patient, is present throughout the office-based surgery.

R4-16-705. Perioperative Period; Patient Discharge

A physician performing office-based surgery using sedation shall ensure that:

1. During office-based surgery using sedation, the physician is physically present in the room where office-based surgery is performed;
2. After the office-based surgery using sedation is performed, a physician is at the physician's office and sufficiently free of other duties to respond to an emergency until the patient's post-sedation monitoring is discontinued;
3. The physician, health care professional, or a staff member trained in ACLS or PALS is at the physician's office and sufficiently free of other duties to respond to an emergency until the patient is discharged;
4. A discharge is documented in the patient's medical record including:
 - a. The time and date of the patient's discharge, and
 - b. A description of the patient's medical condition at the time of discharge; and
5. A patient receives discharge instructions and documents in the patient's medical record that the patient received the discharge instructions.

R4-16-706. Emergency Drugs; Equipment and Space Used for Office-Based Surgery Using Sedation

A. A physician who performs office-based surgery using sedation shall ensure that the physician's office:

1. Has, at a minimum, the following:
 - a. A reliable oxygen source with a FiO2 monitor;
 - b. Suction;
 - c. Resuscitation equipment;
 - d. Emergency drugs; and
 - e. A cardiac monitor;
2. Has the sedation equipment for patient monitoring according to the standards in R4-16-704(B);
3. Has space large enough:
 - a. To allow for access to the patient during office-based surgery using sedation, recovery, and any emergency;
 - b. To accommodate all equipment necessary to perform the office-based surgery using sedation; and
 - c. To accommodate all equipment necessary for sedation monitoring;
4. Has a source of auxiliary electrical power available in the event of a power failure; and
5. Has equipment, emergency drugs, and resuscitative capabilities required under this section for patients less than 18 years of age, if office-based surgery using sedation is performed on these patients.
6. Is maintained to minimize the spread of infection.

B. A physician who performs office-based surgery using sedation shall:

1. Ensure that all equipment used for office-based surgery using sedation is maintained, tested, and inspected according to manufacturer specifications, and
2. Maintain documentation of manufacturer-recommended maintenance of all equipment used in office-based surgery using sedation.

R4-16-707. Emergency and Transfer Provisions

A. A physician who performs office-based surgery using sedation shall ensure that before a health care professional participates in or staff member assists with office-based surgery using sedation, the health care professional and staff member receive instruction in the following:

1. Policy and procedure in cases of emergency,
2. Policy and procedure for office evacuation, and
3. Safe and timely patient transfer.

- B.** A physician who performs office-based surgery using sedation shall ensure that before a health care professional participates in or staff member assists with office-based surgery using sedation, the health care professional or staff member receives instruction in the following:
1. Available equipment and medication for performing cardiopulmonary resuscitation, and
 2. Available equipment and medication for treating malignant hyperthermia when agents that trigger malignant hyperthermia are used.