# **AMB Requesting Comments on Rules:**

**Article 6 – Disciplinary Actions** 

**Article 7 – Office Based Surgery** 

The Arizona Medical Board (AMB) is accepting comments on the rules in Article 6 & 7:

**Article 6 – Disciplinary Actions** 

**Article 7 – Office Based Surgery** 

Please email <u>communications@azmd.gov</u> with your comments.

# DEADLINE FOR COMMENT SUBMISSION IS: MARCH 15, 2021

A current version of the rules is attached or at the Secretary of State's website, azsos.gov

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#### **Historical Note**

New Section R4-16-506 recodified from R4-16-406 at 11 A.A.R. 1283, effective March 25, 2005 (Supp. 05-1). Amended by final rulemaking at 25 A.A.R. 3705, effective February 1, 2020 (Supp. 19-4).

#### R4-16-507. Dismissal of Complaint

A. The executive director, with concurrence of the investigative staff, shall dismiss a complaint if the review shows the complaint is whout merit and dismissal is appropriate.

B. The executive director shall provide to the Board at each regularly scheduled Board meeting a report that contains the information specified in A.R.S. § 32-1405(C)(21).

#### Historical Note

New Section R4-16-507 recodified from R4-16-407 at 11 A.A.R. 1283, effective March 25, 2005 (Supp. 05-1). Amended by final rulemaking at 25 A.A.R. 3705, effective February 1, 2020 (Supp. 19-4).

#### R4-16-508. Denial of License

A. The executive director shall deny a license to an applicant who does not meet statutory requirements for licensure if the executive director, investigative staff and supervising medical consultant concur after reviewing the application that the applicant does not meet the statutory requirements.

B. The executive director shall provide to the Board at each regularly scheduled Board meeting a list of the physicians whose applications were denied since the preceding Board meeting.

#### Historical Note

New Section R4-16-508 recodified from R4-16-408 at 11 A.A.R. 1283, effective March 25, 2005 (Supp. 05-1). Amended by final rulemaking at 25 A.A.R. 3705, effective February 1, 2020 (Supp. 19-4).

#### R4-16-509. Non-disciplinary Convent Agreement

The executive director may enter into a consent agreement under A.R.S. § 32-1451(F) with a physician to limit the physician's practice or rehabilitate the physician if there is evidence that a licensee is mentally or physically unable to engage safely in the practice of medicine and the investigative staff, supervising medical consultant, and lead Board member concur after leview of the case that a consent agreement is appropriate.

#### **Historical Note**

New Section R4-16-509 recodified from \$4-16-409 at 11 A.A.R. 1283, effective March 25, 2005 Supp. 05-1). Amended by final rulemaking at 25 A.A. 3705, effective February 1, 2020 (Supp. 19-4).

## R4-16-510. Appealing Executive Director Actions

- A. Any person aggrieved by an action taken by the executive director under the authority delegated in this Article may appeal that action to the Board. The aggrieved person shall file a written request with the Board no later than:
  - Thirty days after notification of the action, if personally served; or
  - Thirty-five days after the date on the notification, if mailed.
- B. The aggrieved person shall provide, in the written request, evidence showing:
  - An irregularity in the investigative process or the executive director's review deprived the party of a fail decision;
  - Misconduct by Board staff, a Board consultant, of the executive director that deprived the party of a fair decision; or

- Material evidence newly discovered that could have a bearing on the decision and that, with reasonable diligence, could not have been discovered and produced earlier.
- C. The fact that the aggrieved party does not agree with the executive director's action is not grounds for a review by the Board.
- D. If an aggreed person fails to submit a written request within the time specified in subsection (A), the Board is relieved of the requirement to review actions taken by the executive director. The executive director may, however, evaluate newly provided information that is material or substantial in content to determine whether the Board should review the case.
- E. If a written request is submitted that meets the requirements of subsection (B):
  - The Board shall consider the written request at its next regularly scheduled meeting.
  - If the written request provides new material or substantial evidence that requires additional investigation, the investigation shall be conducted as expeditiously as possible and the case shall be forwarded to the Board at the first possible regularly scheduled meeting.

#### Historical Note

New Section R4-16-510 recodified from R4-16 410 at 11 A.A.R. 1283, effective March 25, 2005 (Supp. 85-1). Amended by final rulemaking at 25 A.A.R. 3705, effective February 1, 2020 (Supp. 19-4).

## ARTICLE 6. DISCIPLINARY ACTIONS

### R4-16-601. Expired

#### Historical Note

New Section R4-16-601 recodified from R4-16-501 at 11 A.A.R. 1283, effective March 25, 2005 (Supp. 05-1). Section expired under A.R.S. § 41-1056(E) at 16 A.A.R. 2062, effective September 14, 2010 (Supp. 10-3).

#### R4-16-602. Expired

#### Historical Note

New Section R4-16-602 recodified from R4-16-502 at 11 A.A.R. 1283, effective March 25, 2005 (Supp. 05-1). Section expired under A.R.S. § 41-1056(E) at 16 A.A.R. 2062, effective September 14, 2010 (Supp. 10-3).

Editor's Note: To conform with the renumbering in A.R.S., the Arizona Medical Board requested (under A.R.S. § 41-1011 et seq.) a subsection reference update in R4-16-603 [R05-85]. Please refer to the historical notes for more details (Supp. 05-1).

#### R4-16-603. Expired

#### Historical Note

New Section R4-16-603 recodified from R4-16-503 at 11 A.A.R. 1283. effective March 25, 2005 (Supp. 05-1). A.R.S. § 32-1401(26) subsection corrected to A.R.S. § 32-1401(27) under a formal written request from the Board, March 22, 2005 (Supp. 05-1). Amended by final rulemaking at 14 A.A.R. 380, effective January 8, 2008 (Supp. 08-1). Section expired under A.R.S. § 41-1056(E) at 16 A.A.R. 2062, effective September 14, 2010 (Supp. 10-3).

#### R4-16-604. Aggravating Factors Considered in Disciplinary Actions

When determining the degree of discipline, the Board may consider certain factors including, but not limited to, the following:

- 1. Prior disciplinary offenses;
- Dishonest or selfish motive:

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- 3. Pattern of misconduct; multiple offenses:
- Bad faith obstruction of the disciplinary proceeding by intentionally failing to comply with rules or orders of the Board:
- Submission of false evidence, false statements, or other deceptive practices during the investigative or disciplinary process;
- 6. Refusal to acknowledge wrongful nature of conduct; and
- 7. Vulnerability of the victim.

#### Historical Note

New Section R4-16-604 recodified from R4-16-504 at 11 A.A.R. 1283, effective March 25, 2005 (Supp. 05-1).

## R4-16-605. Mitigating Factors Considered in Disciplinary

When determining the degree of discipline, the Board may consider certain factors including, but not limited to, the following:

- 1. Absence of prior disciplinary record;
- 2. Absence of dishonest or selfish motive;
- Timely good faith effort to rectify consequences of misconduct;
- 4. Interim rehabilitation;
- 5. Remoteness of prior offenses; and
- How much control the physician has of processes in the specific practice setting.

#### Historical Note

New Section R4-16-605 recodified from R4-16-504 at 11 A.A.R. 1283, effective March 25, 2005 (Supp. 05-1).

# 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.

## Historical Note

New Section made by final rulemaking at 14 A.A.R. 380, effective January 8, 2008 (Supp. 08-1).

#### 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:
  - 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:
  - Ensure that a staff member who assists with or a healthcare professional who participates in office-based surgery using sedation:
    - Has sufficient education, training, and experience to perform duties assigned;
    - If applicable, has a current license or certification to perform duties assigned; and
    - Performs only those acts that are within the scope of practice established in the staff member's or health care professional's governing statutes;
  - Ensure that the office where the office-based surgery using sedation is performed has all equipment necessary:

- For the physician to safely perform the office-based surgery using sedation,
- For the physician or health care professional to safely administer the sedation,
- For the physician or health care professional to monitor the use of sedation, and
- d. For the physician and health care professional administering the sedation to rescue a patient after the sedation is administered to the patient and the patient enters into a deeper state of sedation than what was intended by the physician.
- Ensure that a copy of the patient's rights policy is provided to each patient before performing office-based surgery using sedation:
- Obtain informed consent from the patient before performing an office-based surgery using sedation that:
  - a. Authorizes the office-based surgery, and
  - Authorizes the office-based surgery to be performed in the physician's office; and
- 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:
  - The local jurisdiction's fire code:
  - The local jurisdiction's building codes for construction and occupancy:
  - The biohazardous waste and hazardous waste standards in 18 A.A.C. 13, Article 14; and
  - The controlled drug administration, supply, and storage standards in 4 A.A.C. 23.

#### Historical Note

New Section made by final rulemaking at 14 A.A.R. 380, effective January 8, 2008 (Supp. 08-1).

#### R4-16-703. Procedure and Patient Selection

- A. A physician shall ensure that each office-based surgery using sedation performed:
  - Can be safely performed with the equipment, staff members, and health care professionals at the physician's office:
  - Is of duration and degree of complexity that allows a patient to be discharged from the physician's office within 24 hours;
  - Is within the education, training, experience skills, and licensure of the physician; and
  - Is within the education, training, experience, skills, and licensure 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:
  - Has a medical condition or other condition that indicates the procedure should not be performed in the physician's office, or
  - 2. Will require inpatient services at a hospital.

#### **Historical Note**

New Section made by final rulemaking at 14 A.A.R. 380. effective January 8, 2008 (Supp. 08-1).

#### R4-16-704. Sedation Monitoring Standards

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

 A quantitative method of assessing a patient's oxygenation, such as pulse oximetry, is used when minimal sedation is administered to the patient, and

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- When moderate or deep sedation is administered to a patient:
  - A quantitative method of assessing the patient's oxygenation, such as pulse oximetry, is used:
  - The patient's ventilatory function is monitored by any of the following:
    - Direct observation,
    - ii. Auscultation, or
    - iii. Capnography;
  - The patient's circulatory function is monitored during the surgery by:
    - Having a continuously displayed electrocardiogram.
    - Documenting arterial blood pressure and heart rate at least every five minutes, and
    - Evaluating the patient's cardiovascular function by pulse plethysmography.
  - d. The patient's temperature is monitored if the physician expects the patient's temperature to fluctuate; and
  - e. That 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.

#### **Historical Note**

New Section made by final rulemaking at 14 A.A.R. 380, effective January 8, 2008 (Supp. 08-1).

#### R4-16-705. Perioperative Period; Patient Discharge

A physician performing office-based surgery using sedation shall ensure all of the following:

- During office-based surgery using sedation, the physician is physically present in the room where office-based surgery is performed:
- 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:
- If using minimal sedation, the physician or a health care
  professional certified in ACLS, PALS, or BLS is at the
  physician's office and sufficiently free of other duties to
  respond to an emergency until the patient is discharged:
- If using deep or moderate sedation, the physician or a health care professional certified 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;
- A discharge is documented in the patient's medical record including:
  - a. The time and date of the patient's discharge, and
  - A description of the patient's medical condition at the time of discharge; and
- A patient receives discharge instructions and documents in the patient's medical record that the patient received the discharge instructions.

#### Historical Note

New Section made by final rulemaking at 14 A.A.R. 380, effective January 8, 2008 (Supp. 08-1).

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

- A. In addition to the requirements in R4-16-702(A)(3) and R4-16-703(A)(1), a physician who performs office-based surgery using sedation shall ensure that the physician's office has at a minimum:
  - 1. The following:
    - a. A reliable oxygen source with a SaO<sub>2</sub> monitor:
    - b. Suction:
    - c. Resuscitation equipment, including a defibrillator;
    - d. Emergency drugs; and
    - e. A cardiac monitor;
  - The equipment for patient monitoring according to the standards in R4-16-704;
  - 3. Space large enough to:
    - Allow for access to the patient during office-based surgery using sedation, recovery, and any emergency:
    - Accommodate all equipment necessary to perform the office-based surgery using sedation; and
    - Accommodate all equipment necessary for sedation monitoring:
  - A source of auxiliary electrical power available in the event of a power failure; and
  - 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; and
  - 6. Procedures to minimize the spread of infection.
- B. A physician who performs office-based surgery using sedation shall:
  - Ensure that all equipment used for office-based surgery using sedation is maintained, tested, and inspected according to manufacturer specifications, and
  - Maintain documentation of manufacturer-recommended maintenance of all equipment used in office-based surgery using sedation.

#### **Historical Note**

New Section made by final rulemaking at 14 A.A.R. 380. effective January 8, 2008 (Supp. 08-1).

#### 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:
  - Policy and procedure in cases of emergency.
  - 2. Policy and procedure for office evacuation, and
  - 3. Safe and timely patient transfer.
- B. When performing office-based surgery using sedation, a physician shall not use any drug or agent that trigger malignant hyperthermia.

#### **Historical Note**

New Section made by final rulemaking at 14 A.A.R. 380. effective January 8, 2008 (Supp. 08-1).