

**NOTICE OF PROPOSED RULEMAKING**

**TITLE 4. PROFESSIONS AND OCCUPATIONS**

**CHAPTER 22. BOARD OF OSTEOPATHIC EXAMINERS IN MEDICINE AND SURGERY**

**PREAMBLE**

<b><u>1. Articles, Parts, and Sections Affected</u></b>	<b><u>Rulemaking Action</u></b>
R4-22-101	Amend
R4-22-102	Re-number
R4-22-102	Amend
R4-22-103	Re-number
R4-22-103	New Section
R4-22-104	Re-number
R4-22-104	Amend
R4-22-105	Re-number
R4-22-105	Amend
R4-22-106	Re-number
R4-22-106	Amend
R4-22-107	Repeal
R4-22-107	Re-number
R4-22-107	Amend
R4-22-108	Re-number
R4-22-108	Amend
R4-22-110	Re-number
R4-22-111	Re-number
R4-22-112	Re-number
R4-22-115	Re-number
Article 2	Amend
R4-22-201	New Section
R4-22-202	New Section
R4-22-203	Re-number
R4-22-203	Amend
R4-22-204	New Section

R4-22-205	New Section
R4-22-206	New Section
R4-22-207	Amend
R4-22-212	Re-number
R4-22-212	New Section
Article 3	New Article
R4-22-301	New Section
R4-22-302	New Section
R4-22-303	New Section
R4-22-304	New Section
R4-22-305	New Section
Article 4	New Article
R4-22-401	Re-number
R4-22-401	Amend
R4-22-402	Re-number
R4-22-402	Amend
R4-22-403	Re-number
R4-22-403	Amend
Article 5	New Article
R4-22-501	New Section
R4-22-502	New Section
R4-22-503	New Section
R4-22-504	New Section
R4-22-505	New Section
R4-22-506	New Section
R4-22-507	New Section
R4-22-508	New Section

**2. Citations to the agency's statutory rulemaking authority to include the authorizing statute (general) and the implementing statute (specific):**

Authorizing statute: A.R.S. § § 32-1803(A)(5) and 32-1803(C)(1)

Implementing statute: A.R.S. § § 32-1822, 32-1833, 32-1825, 32-1826, 32-1828, 32-1829, 32-1830, 32-1831, 32-1832, 32-1855, 32-1855.01, 32-1859, 32-1861, and 32-1871

**3. Citations to all related notices published in the *Register* as specified in R1-1-409(A) that pertain to the record of the proposed rule:**

Notice of Rulemaking Docket Opening: 19 A.A.R. 3988, December 6, 2013

**4. The agency's contact person who can answer questions about the rulemaking:**

Name: Jenna Jones, Executive Director

Address: Board of Examiners in Osteopathic Medicine and Surgery  
9535 E. Doubletree Ranch Road  
Scottsdale, AZ 85258

Telephone: (480) 657-7703

Fax: (480) 657-7715

E-mail: Jenna.Jones@azdo.gov

Web site: www.azdo.gov

**5. An agency's justification and reason why a rule should be made, amended, repealed, or renumbered, to include an explanation about the rulemaking:**

The Board is making the changes identified as needed in a five-year-review report approved by the Council on June 8, 2010, making new rules regarding dispensing drugs and office-based surgery, establishing standards for re-entering medical practice, and establishing a program for treatment and rehabilitation of impaired physicians. The Board is making the rules consistent with statute, agency practice, and current rule-writing standards.

**6. A reference to any study relevant to the rule that the agency reviewed and proposes either to rely on or not to 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 relevant to the rules.

**7. A showing of good cause why the rulemaking is necessary to promote a statewide interest if the rulemaking 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:**

The following rule changes will have minimal economic impact on applicants and licensees:

- Increasing the charge for verification of a license issued by the Board;
- Changing the examination required for licensure;
- Establishing minimum requirements for dispensing drugs;
- Expanding the procedures that a medical assistant is permitted to perform under direct supervision; and

- Establishing minimum standards for performing office-based surgery.

**9. The agency's contact person who can answer questions about the economic, small business, and consumer impact statement:**

Name: Jenna Jones, Executive Director

Address: Board of Examiners in Osteopathic Medicine and Surgery  
9535 E. Doubletree Ranch Road  
Scottsdale, AZ 85258

Telephone: (480) 657-7703

Fax: (480) 657-7715

E-mail: Jenna.Jones@azdo.gov

Web site: www.azdo.gov

**10. The time, place, and nature of the proceedings to make, amend, repeal, or renumber the rule, or if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:**

An oral proceeding regarding the proposed rules will be held as follows:

Date: Thursday, May 1, 2014

Time: 10:00 a.m.

Location: 9535 E. Doubletree Ranch Road  
Scottsdale, AZ 85258

**11. All agencies shall list other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:**

None

**a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:**

The licenses, registrations, and permits listed in R4-22-201 are general permits.

**b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:**

The rules are not more stringent than federal law. An osteopathic physician who dispenses a controlled substance is required under 21 CFR, Chapter 11, to register with the federal Drug Enforcement

Administration and to comply with provisions regarding labeling, packaging, and recordkeeping. The rules in Article 3 are consistent with federal law.

**c. Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:**

No analysis was submitted.

**12. A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rules:**

The following materials are incorporated by reference in R4-22-106:

*Handbook of the Bureau of Osteopathic Specialists*, revised August 2013, available from the AOA at 142 E. Ontario Street, Chicago, IL 60611, 800-621-1773, or [www.osteopathic.org](http://www.osteopathic.org)

*ABMS Guide to Medical Specialties*, 2013, available from the ABMS at 222 N. LaSalle Street, Suite 1500, Chicago, IL 60601, 312-436-2600, or [www.abms.org](http://www.abms.org)

The following material is incorporated by reference in R4-22-402:

*Standards and Guidelines for Medical Assisting Educational Programs*, revised 2008, available from CAAHEP, 1361 Park Street, Clearwater, FL 33756, 727-210-2350, or [www.caahep.org](http://www.caahep.org).

**13. The full text of the rules follows:**

## TITLE 4. PROFESSIONS AND OCCUPATIONS

### CHAPTER 22. BOARD OF OSTEOPATHIC EXAMINERS IN MEDICINE AND SURGERY

#### ARTICLE 1. GENERAL PROVISIONS

##### Section

R4-22-101. Definitions

~~R4-22-108.~~ R4-22-102. ~~Specialist Designation~~ Fees and Charges

R4-22-103. ~~Approved Internships and Residencies~~ Submitting Documents to the Board

~~R4-22-212.~~ R4-22-104. Licensing Time-frames

R4-22-105. ~~Repealed~~ Equivalents to an Approved Internships and Residencies Internship or Residency

~~R4-22-102.~~ R4-22-106. ~~Rehearing or Review of Decision~~ Specialist Designation

~~R4-22-115.~~ R4-22-107. ~~Labeling, Recordkeeping, Storage, and Packaging of Drugs~~ Petitions for Rulemaking

~~R4-22-106.~~ R4-22-108. ~~Fees and Charges~~ Rehearing or Review of Decision

R4-22-110. Renumbered

R4-22-111. Renumbered

R4-22-112. ~~Medical Assistant Training Requirement~~ Renumbered

R4-22-115. ~~Petitions for Rulemaking~~ Renumbered

#### ARTICLE 2. LICENSING AND TIME-FRAMES

##### Section

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R4-22-202. ~~Reserved~~ Determining Qualification for Licensure

~~R4-22-104.~~ R4-22-203. ~~Reserved~~ Examination; and Issuance of Licenses; Lapse of Application Practice  
Equivalency to an Examination

R4-22-204. ~~Reserved~~ License Issuance; Effective Date of License

R4-22-205. ~~Reserved~~ License Renewal

R4-22-206. ~~Reserved~~ Procedure for Application to Re-enter Practice

R4-22-207. Continuing Medical Education; Waiver; Extension of Time to Complete

R4-22-212. ~~Licensing Time frames~~      Confidential Program for Treatment and Rehabilitation of Impaired Osteopathic Physicians

**ARTICLE 3.    DISPENSING DRUGS**

Section

R4-22-301. Registration to Dispense Required

R4-22-302. Packaging and Inventory

R4-22-303. Prescribing and Dispensing Requirements

R4-22-304. Recordkeeping and Reporting Shortages

R4-22-305. Inspections; Denial and Revocation

**ARTICLE 4.    MEDICAL ASSISTANTS**

Section

~~R4-22-110.~~      R4-22-401.      Approval of Educational Programs for Medical Assistants

~~R4-22-111.~~      R4-22-402.      Medical Assistants – Authorized Procedures

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**ARTICLE 5.    OFFICE-BASED SURGERY**

Section

R4-22-501.      Definitions

R4-22-502.      Health Care Institution License

R4-22-503.      Administrative Provisions

R4-22-504.      Procedure and Patient Selection

R4-22-505.      Sedation Monitoring Standards

R4-22-506.      Perioperative Period; Patient Discharge

R4-22-507.      Emergency Drugs; Equipment and Space Used for Office-based Surgery

R4-22-508.      Emergency and Transfer Provisions

## ARTICLE 1. GENERAL PROVISIONS

### **R4-22-101. Definitions**

In addition to the definitions in A.R.S. § 32-1800, in this Chapter:

“ABHES” means Accrediting Bureau of Health Education Schools.

“ABMS” means American Board of Medical Specialties.

“ACCME” means the Accreditation Council for Continuing Medical Education.

"ACGME" means the Accreditation Council on Graduate Medical Education.

“AOA” means the American Osteopathic Association.

“AOIA” means the American Osteopathic Information Association.

"Approved internship," "Approved preceptorship," and "Approved residency" mean training accredited by the AOA or ACGME.

“CAAHEP” means Commission on Accreditation of Allied Health Education Programs.

“CME” means continuing medical education.

“COMLEX” means Comprehensive Osteopathic Medical Licensing Examination.

“Continuing medical education” means a course, program, or other training that the Board approves for license renewal.

“Controlled substance” means a drug, substance, or immediate precursor, identified, defined, or listed in A.R.S. Title 36, Chapter 27, Article 2.

“FCVS” means Federal Credentials Verification Service.

“Licensee” means an individual who holds a current license issued under A.R.S. Title 32, Chapter 17.

“MAP” means Monitored Aftercare Program.

“NBME” means the National Board of Medical Examiners.

“NBOME” means the National Board of Osteopathic Medical Examiners.

"Post-graduate training program" means an approved internship or residency.

“USMLE” means United States Medical Licensing Examination.

### **~~R4-22-108.~~ R4-22-102. Specialist Designation Fees and Charges**

A. Under the specific authority provided by A.R.S. §§ 32-1826(A) and 32-1871(A)(5), the Board establishes and shall collect the following fees for the Board’s licensing activities:

1. Application to practice osteopathic medicine, \$400;
2. Issuance of initial license, \$180 (pro-rated);
3. Biennial renewal of license, \$636 plus the penalty and reimbursement fees specified in A.R.S. §

32-1826(B), if applicable;

4. Locum tenens registration, \$300;
5. Annual registration for internship, residency, or clinical fellowship, \$50;
6. Teaching license, \$318;
7. Five-day educational teaching permit, \$106; and
8. Annual registration to dispense drugs and devices, \$240 (initial registration fee is pro-rated).

**B.** Under the specific authority provided by A.R.S. § 32-1826(C), the Board establishes and shall collect the following charges for services provided by the Board:

1. Verification of a license to practice osteopathic medicine issued by the Board and copy of licensee's complaint history, ~~\$5.00~~ \$10;
2. Issuance of a duplicate license, \$10;
3. List of physicians licensed by the Board, \$25.00 if for non-commercial use or \$100 if for commercial use;
4. Copying records, documents, letters, minutes, applications, and files, 25¢ per page.;
5. Copy of an audio tape, \$35.00; and
6. Digital medium not requiring programming, \$100.

**C.** Except as provided under A.R.S. § 41-1077, the fees listed in subsection (A) are not refundable.

**R4-22-103. Submitting Documents to the Board**

An individual who wants the Board to consider a document at a meeting or hearing shall submit the document to the Board at least 15 days before the meeting or hearing or at another time as directed by the Board.

**~~R4-22-212.~~ R4-22-104. Licensing Time-frames**

**A.** The overall time-frame described in A.R.S. § 41-1072(2) for each type of license issued by the Board is listed in Table 1. An applicant and the Executive Director of the Board may agree in writing to extend the substantive review and overall time-frames by no more than 25 percent of the overall time-frame listed in Table 1.

**B.** The administrative completeness review time-frame described in A.R.S. § 41-1072(1) for each type of license issued by the Board is listed in Table 1. The administrative completeness review time-frame for a particular license begins on the date the Board receives an application package for that license.

1. If the application package is incomplete, the Board shall send to the applicant a written notice specifying the missing document or incomplete information. The administrative completeness review and overall time-frames are suspended from the postmark date on the notice until the date the Board receives the missing document or incomplete information.

2. If the application package is complete, the Board shall send to the applicant a written notice of administrative completeness.
  3. If the Board grants or denies a license during the administrative completeness review time-frame, the Board shall not issue a separate written notice of administrative completeness.
- C.** The substantive review time-frame described in A.R.S. § 41-1072(3) for each type of license issued by the Board is listed in Table 1. The substantive review time-frame begins on the postmark date of the Board's notice of administrative completeness.
1. During the substantive review time-frame, the Board may make one comprehensive written request for additional information or documentation. The substantive review and overall time-frames are suspended from the postmark date on the comprehensive written request for additional information or documentation until the Board receives the additional information or documentation. The agency and applicant may agree in writing to allow the agency to submit supplemental requests for additional information.
  2. The Board shall send a written notice of approval to an applicant who meets the requirements of A.R.S. Title 32, Chapter 17 and this Chapter.
  3. The Board shall send a written notice of denial to an applicant who fails to meet the requirements of A.R.S. Title 32, Chapter 17 or this Chapter.
- D.** The Board shall administratively close an applicant's file if the applicant fails to submit the information or documentation required under subsection (B)(1) or (C)(1) within 360 days from the date on which the application package was originally submitted. If an individual whose file is administratively closed wishes to be licensed, the individual shall file another application package and pay the application fee.
- E.** ~~Under A.R.S. § 41-1073(E)(2), the Board is not establishing a time frame for issuance of the following licenses because the~~ The Board shall grant or deny each license the following licenses within seven days after receipt of an application:
1. Ninety-day extension of locum tenens registration ~~under A.R.S. § 32-1823(C);~~
  2. Waiver of continuing education requirements for a particular period ~~under A.R.S. § 32-1825(C);~~
  3. Extension of time to complete continuing education requirements ~~under A.R.S. § 32-1825(C);~~
  4. ~~Annual registration of an approved internship, residency, clinical fellowship program, or short term residency program under A.R.S. § 32-1826(A)(6);~~
  5. Five-day educational training permit ~~under A.R.S. § 32-1828; and~~
  6. ~~5. Extension of one-year renewable training permit under A.R.S. § 32-1829(B).~~
- F.** In computing any time-frame prescribed in this Section, the day of the act or event that begins the time-frame is not included. The computation includes intermediate Saturdays, Sundays, and official state holidays. If the last day of a time-frame falls on a Saturday, Sunday, or official state holiday, the next business day is the time-frame's last day.

**Table 1. Time-frames (in days)**

Type of License	Statutory Authority	Overall Time-frame	Administrative Completeness Time-frame	Substantive Review Time-frame
License	A.R.S. § 32-1822	120	30	90
License Renewal	A.R.S. § 32-1825	120	30	90
90-day Locum Tenens Registration	A.R.S. § 32-1823	60	30	30
One-year Renewable Training Permit	A.R.S. § 32-1829(A)	60	30	30
Short-term Training Permit	A.R.S. § 32-1829(C)	60	30	30
One-year Training Permit at Approved School or Hospital	A.R.S. § 32-1830	60	30	30
Two-year Teaching License	A.R.S. § 32-1831	60	30	30
Registration to Dispense Drugs and Devices	A.R.S. § 32-1871	90	30	60
Renewal of Registration to Dispense Drugs and Devices	A.R.S. §§ 32-1826(A)(11) and 32-1871	60	30	30
<del>Authorization to Read or Interpret Mammographic Images</del>	<del>A.R.S. § 32-2842</del>	<del>60</del>	<del>30</del>	<del>30</del>
<del>Renewal of Authorization to Read or Interpret Mammographic</del>	<del>A.R.S. § 32-2842</del>	<del>60</del>	<del>30</del>	<del>30</del>

Images				
Approval of Educational Program for Medical Assistants	A.R.S. § <del>32-1800(19)</del> <u>32-1800(17)</u>	60	30	30

**~~R4-22-103. R4-22-105. Repealed~~ Equivalentents to an Approved Internships and Residencies Internship or Residency**

For purposes of A.R.S. § 32-1822, the equivalent of an approved internship or approved residency is any of the following:

1. One or more years of a fellowship training program approved by the ~~American Osteopathic Association (AOA)~~ AOA or the ~~Accreditation Council on Graduate Medical Education (ACGME)~~ ACGME; ~~or~~
2. A current certification by the AOA in an osteopathic medical specialty; ~~or~~
3. ~~For those who were awarded a Doctor of Osteopathy degree in 1946 or earlier, a minimum of 10 years of continuous active practice of osteopathic medicine and surgery immediately before applying for licensure.~~

**~~R4-22-102. R4-22-106. Specialist Designation~~**

**A.** ~~A specialty board approved by the The Board includes only those~~ approves specialty boards recognized by the:

1. American Osteopathic Association Bureau of Osteopathic Specialties and listed in the ~~*Yearbook and Directory of the American Osteopathic Association, 1991, page 643*~~ *Handbook of the Bureau of Osteopathic Specialists (BOS), revised August 2013, available from the AOA at 142 E. Ontario Street, Chicago, IL 60611, 800-621-1773, or www.osteopathic.org;* ~~or the and~~
2. American Board of Medical Specialties (ABMS) and listed in the ~~*Annual Report and Reference Handbook of the American Board of Medical Specialties, June 1991, page 103, which are incorporated herein by reference and on file with the Office of the Secretary of State*~~ *ABMS Guide to Medical Specialties, 2013, available from the ABMS at 222 N. LaSalle Street, Suite 1500, Chicago, IL 60601, 312-436-2600, or www.abms.org.*

**B.** The Board incorporates the materials listed in subsection (A) by reference. The materials include no future editions or amendments. The Board shall make the materials available at the Board office and on its web site.

**~~R4-22-115. R4-22-107. Labeling, Recordkeeping, Storage, and Packaging of Drugs Petitions~~ Petition for**

## **Rulemaking or Review**

- A.** ~~Labeling. The following information shall be included on labels of medications being dispensed by licensed osteopathic physicians:~~
- ~~1. Serial number and date dispensed.~~
  - ~~2. Name of the patient for whom drug was issued.~~
  - ~~3. Name, strength and quantity of drug dispensed.~~
  - ~~4. Directions for use and cautionary statement if any is contained in the prescription order for the drug.~~
  - ~~5. Name of drug and manufacturer or distributor in case of generic substitution.~~
  - ~~6. Name, address and telephone number of the dispensing physician.~~
  - ~~7. In the case of controlled substances, the cautionary statement "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."~~
- B.** ~~Required information. A prescription order shall contain the following information:~~
- ~~1. Date of issuance.~~
  - ~~2. Name and address of the patient for which the prescription order has been issued.~~
  - ~~3. Name, strength and quantity of the drug prescribed and dispensed.~~
  - ~~4. Name and address of the physician dispensing the medication.~~
  - ~~5. Drug Enforcement Agency number of the physician dispensing for controlled substances.~~
- C.** ~~Prescription recordkeeping. Prescription orders for drugs dispensed by licensed osteopathic physicians shall be:~~
- ~~1. Sequentially numbered and dated on date of dispensing.~~
  - ~~2. Filed separately from the patient records.~~
  - ~~3. Filed separately for Class II controlled substances.~~
  - ~~4. Filed separately or marked with a prominent red "C" for Class III, IV, & V controlled substances.~~
  - ~~5. Listed in a log showing the name of patient, name of drug, number dispensed, and date of dispensation.~~
- D.** ~~Records, receipts, refilling prescriptions:~~
- ~~1. A record of refills shall be kept on the back of the prescription showing the date, name or initials of dispensing physician and quantity dispensed if that varies from the original amount ordered.~~
  - ~~2. Resale of medication to another licensed physician shall not exceed 5% of the seller's total annual sales of medications. A record of the sale shall be kept for a period of three years.~~
  - ~~3. Invoices of receipts and records of disbursement shall be maintained for all controlled substances for a period of three years.~~
  - ~~4. Annual inventories of all controlled substances shall be performed and available for review by Drug Enforcement Agency and other drug control agencies.~~
  - ~~5. Schedule II controlled substances prescription orders shall not be refilled.~~
  - ~~6. Schedule III, IV and V controlled substances prescription orders may be refilled a maximum of five times~~

~~within six months from date of prescription order.~~

~~**E. Storage.**~~

- ~~1. All medications shall be stored in a locked cabinet or room, with restricted access to the drug storage area.~~
- ~~2. Storage rooms should not exceed a high temperature of 85° Fahrenheit.~~
- ~~3. All medications shall be in current or unexpired dating or returned to source of supply.~~

~~**F. Packaging.** A medication dispensed by the physician shall be in light resistant container with a consumer safety cap (i.e., a container cap that does not screw directly on or off the container) unless the patient and physician agree otherwise and shall be labeled by a mechanically printed label.~~

~~**A.** A person may petition Petitions to the Board pursuant to under A.R.S. § 41-1033 for either a: shall be made in writing by delivering or mailing to the Board a letter requesting the adoption of the rule. The letter shall state the purpose for the proposed rule, the name and address of the person requesting the adoption of the rule, and be signed by that person.~~

- ~~1. Rulemaking action relating to a Board rule, including making a new rule or amending or repealing an existing rule; or~~
- ~~2. Review of an existing Board practice or substantive policy statement alleged to constitute a rule.~~

~~**B.** A person shall submit to the Board a written petition including the following information:~~

- ~~1. Name, address, e-mail address, and telephone and fax numbers of the person submitting the petition;~~
- ~~2. Name of any person represented by the person submitting the petition;~~
- ~~3. If requesting a rulemaking action:~~
  - ~~a. Statement of the rulemaking action sought, including the A.A.C. citation of all existing rules, and the specific language of a new rule or rule amendment; and~~
  - ~~b. Reasons for the rulemaking action, including an explanation of why the existing rule is inadequate, unreasonable, unduly burdensome, or unlawful;~~
- ~~4. If requesting a review of an existing practice or a substantive policy statement:~~
  - ~~a. Subject matter of the existing practice or substantive policy statement, and~~
  - ~~b. Reasons why the existing practice or substantive policy statement constitutes a rule; and~~
- ~~5. Dated signature of the person submitting the petition.~~

~~**C.** A person may submit supporting information with a petition.~~

~~**D.** A person may submit a petition and any supporting information by e-mail, hand delivery, or the U.S. Postal Service.~~

~~**E.** The Board shall send the person submitting a petition a written response within 60 days of the date the Board receives the petition.~~

**~~R4-22-106.~~ R4-22-108. Fees and Charges Rehearing or Review of Decision**

- A. The Board shall provide for a rehearing and review of its decisions under A.R.S. Title 41, Chapter 6, Article 10 and rules established by the Office of Administrative Hearings.
- B. A Except as provided in subsection (I), a party is required to file a motion for rehearing or review of a decision of the Board to exhaust the party's administrative remedies.
- C. A party may amend a motion for rehearing or review at any time before the Board rules on the motion.
- D. The Board may grant a rehearing or review for any of the following reasons materially affecting a party's rights:
  - 1. Irregularity in the proceedings of the Board, or any order or abuse of discretion, that deprived the moving party of a fair hearing;
  - 2. Misconduct of the Board, its staff, an administrative law judge, or the prevailing party;
  - 3. Accident or surprise that could not have been prevented by ordinary prudence;
  - 4. Newly discovered material evidence that could not, with reasonable diligence, have been discovered and produced at the hearing;
  - 5. Excessive penalty;
  - 6. Error in the admission or rejection of evidence or other errors of law occurring at the hearing or during the progress of the proceedings;
  - 7. ~~That the~~ The Board's decision is a result of passion or prejudice; or
  - 8. ~~That the~~ The findings of fact or decision is not justified by the evidence or is contrary to law.
- E. The Board may affirm or modify a decision or grant a rehearing to all or any of the parties on all or part of the issues for any of the reasons in subsection (D). An order modifying a decision or granting a rehearing shall specify with particularity the grounds for the order.
- F. When a motion for rehearing or review is based upon affidavits, the affidavits shall be served with the motion. An opposing party may, within 15 days after service, serve opposing affidavits. ~~The Board may extend this period for a maximum of 20 days, for good cause as described in subsection (I).~~
- G. Not later ~~that~~ than 10 days after the date of a decision, after giving parties notice and an opportunity to be heard, the Board may grant a rehearing or review on its own initiative for any reason for which it might have granted relief on motion of a party. The Board may grant a motion for rehearing or review, timely served, for a reason not stated in the motion.
- H. If a rehearing is granted, the Board shall hold the rehearing within 60 days after the issue date on the order granting the rehearing.

- I. ~~The Board may extend all time limits listed in this Section upon a showing of good cause. A party demonstrates good cause by showing that the grounds for the party's motion or other action could not have been known in time, using reasonable diligence, and:~~
- ~~1. A ruling on the motion will further administrative convenience, expedition, or economy; or~~
  - ~~2. A ruling on the motion will avoid undue prejudice to any party. If the Board makes a specific finding that a particular decision needs to be effective immediately to preserve the public peace, health, or safety and that a review or rehearing of the decision is impracticable, unnecessary, or contrary to the public interest, the Board shall issue the decision as a final decision without an opportunity for rehearing or review.~~
- J. A party that has exhausted the party's administrative remedies may appeal a final order of the Board under A.R.S. Title 12, Chapter 7, Article 6.

**R4-22-110.     Renumbered**

**R4-22-111.     Renumbered**

**R4-22-112.     Renumbered**

**R4-22-115.     Renumbered**

## **~~ARTICLE 2. LICENSING AND TIME-FRAMES~~**

**R4-22-201.     **Reserved**     Application Required**

An individual or entity that seeks a license or other approval from the Board shall complete and submit an application form prescribed by the Board. The Board has prescribed the following application forms, which are available from the Board office or web site:

1. License,
2. License renewal,
3. Locum tenens registration,
4. Initial registration to dispense,
5. Registration to dispense renewal,
6. Renewable one-year post-graduate training permit,
7. Renewal of post-graduate training permit,
8. Short-term training permit,
9. Two-year teaching license, and

10. Approval of an educational program for medical assistants.

**R4-22-202. Reserved Determining Qualification for Licensure**

**A. To obtain a license, an applicant shall submit:**

1. The application form specified in R4-22-201;
2. The proof required under A.R.S. § 32-1822(A);
3. A list of all Board-certified specializations, the certifying entity, and a copy of each certification or letter verifying specialization;
4. A malpractice claim or suit questionnaire for each instance of medical malpractice in which there was an award, settlement, or payment;
5. A passport-size picture taken within the last 60 days; and
6. The application fee required under R4-22-102(A).

**B. In addition to the materials required under subsection (A), an applicant shall have the following information submitted directly to the Board by the specified entity:**

1. Professional Education Verification form or an official transcript submitted by the osteopathic college from which the applicant graduated;
2. Verification of Postgraduate Training form submitted by each postgraduate facility or program at which the applicant trained;
3. Practice Experience Verification form for at least seven of the last 10 years submitted by each health care facility or employer at which the applicant obtained experience;
4. Verification of passing the medical licensure examination if the examination was passed within the last seven years submitted by the examining entity; and
5. Verification of licensure form submitted by every state in which the applicant is or has been licensed as an osteopathic physician.

**C. If an applicant has established a credentials portfolio with the FCVS or AOIA, the applicant may request that the FCVS forward to the Board some or all of the materials required under subsection (B).**

**D. The Board shall conduct a substantive review of the information submitted under subsections (A) and (B) and determine whether the applicant is qualified for licensure by virtue of:**

1. Possessing the knowledge and skills necessary to practice medicine safely and skillfully;

2. Demonstrating a history of professional conduct; and
3. Possessing the physical, mental, and emotional fitness to practice medicine.

**E.** If the substantive review referenced in subsection (D) does not yield sufficient information for the Board to determine whether an applicant is qualified for licensure, the Board shall request that the applicant appear before the Board for an interview.

1. The Board shall conduct an application interview in the same manner as an informal hearing conducted under A.R.S. § 32-1855 and shall accord the applicant the same rights as a respondent.
2. In conjunction with an application interview, the Executive Director or Board may require that the applicant, at the applicant's expense:
  - a. Provide additional documentation,
  - b. Submit to a physical or psychological examination,
  - c. Submit to a practice assessment evaluation,
  - d. Pass an approved special purposes competency examination listed in R4-22-203(A), or
  - e. Fulfill any combination of the requirements listed in subsections (D)(2)(a) through(d).

**F.** If the substantive review referenced in subsection (D) reveals that an applicant has been subject to disciplinary action or criminal conviction, the Board shall consider the following factors to determine whether the applicant has been rehabilitated from the conduct underlying the disciplinary action or criminal conviction:

1. Nature of the disciplinary or criminal action including charges and final disposition;
2. Whether all terms of court-ordered sentencing or Board-issued order were satisfied;
3. Whether the disciplinary action or criminal conviction was set aside, dismissed with prejudice, or reduced;
4. Whether a diversion program was entered and completed;
5. Whether the circumstances, relationships, or personal attributes that caused or contributed to the underlying conduct changed;
6. Personal and professional references attesting to rehabilitation; and
7. Other information the Board determines demonstrates whether the applicant has been rehabilitated.

**~~R4-22-104, R4-22-203. Reserved Examination; and Issuance of Licenses; Lapse of Application Practice~~**

## Equivalency to an Examination

- A. ~~Examination. Pursuant to A.R.S. § 32-1822(4), an applicant for licensure by examination must pass either the federal licensing examination (FLEX) with a grade of 75 or above in both components or the examination by the National Board of Osteopathic Examiners (NBOE) with a weighted average of 75% as determined by the NBOE. Approved examinations. For the purposes of licensing, the Board approves the following examinations:~~
1. All levels and parts of the COMLEX required by the NBOME with a passing score determined by the NBOME;
  2. All levels and parts of the USMLE required by the NBME with a passing score determined by the NBME; and
  3. A special purposes competency examination given by the NBOME or NBME to an applicant at the request of the Board, with a passing score established by the NBOME or NBME.
- B. ~~Waiver of examination. An applicant for licensure who is currently licensed to practice as an osteopathic physician and surgeon as specified in A.R.S. § 32-1822(4) need not take the examination referred to in subsection (A) if:~~ Practice equivalency to an examination. If an applicant has not passed an approved examination within the seven years before the date of application, the Board shall find that the applicant has practice experience equivalent to an approved examination if the applicant submits documentation of all of the following:
1. ~~The applicant has taken the FLEX or NBOE examination within the seven-year period preceding the date of application and passed with the grade level specified in subsection (A); or~~ On the date of application and continuously until the date the applicant is issued or denied a license, the applicant holds:
    - a. An active license to practice osteopathic medicine issued by another state, or
    - b. An active permit or temporary license to practice in an approved residency or fellowship;
  2. ~~The applicant has been continuously engaged in osteopathic practice and training since initial licensure. In determining whether an applicant has been continuously engaged in osteopathic practice and training, the Board will consider the following:~~ For at least seven of the 10 years immediately before the date of application, the applicant:
    - a. Total length of time the individual has been in the practice of medicine. Was in clinical practice providing direct patient care, or
    - b. Percentage of time the individual devoted to the practice of medicine while not in full-time practice. Was in the second or later year of an approved residency or fellowship; and
    - c. Type and amount of continuing medical education or professional training the individual obtained while not in full-time practice. Has completed a certification examination provided by a specialty board under R4-22-106; and

3. Within two years immediately before the date of application, the applicant completed at least 40 hours of approved CME, as defined and documented as specified in R4-22-207.

~~C. Personal interviews. The purpose of the personal interview required by A.R.S. § 32-1822(6) is to investigate the applicant's professional and personal background, to review the applicant's medical knowledge, to determine the applicant's ability to practice medicine in Arizona, and to clarify, explain, or amplify information obtained during the application process.~~

~~1. The personal interview may include questions relating to any or all of the following areas:~~

~~a. Substantive medical knowledge.~~

~~b. Arizona practice issues or problems.~~

~~c. Education qualifications.~~

~~d. Professional experience.~~

~~e. Applicant's moral character and fitness to practice medicine and surgery in Arizona.~~

~~2. An applicant must correctly answer 75% of the medical knowledge questions to be considered acceptable for licensure.~~

~~3. Any adverse information obtained by the Board during the personal interview may be grounds for further investigation or denial of licensure.~~

~~D. Time limitations. Each applicant for Arizona Osteopathic licensure must pass the written examination if required, and appear before the Board for the personal interview within one year from the date the application is filed. Failure to do so shall cause the application to lapse. Within six months from the date of successful completion of the personal interview, each applicant for Arizona Osteopathic licensure must complete all requirements for issuance of the license including payment of all fees and completion of an internship. Failure to do so shall cause the application to lapse.~~

**R4-22-204. Reserved License Issuance; Effective Date of License**

A. Within 90 days after an applicant for licensure receives notice from the Board that the applicant is approved, but no later than 360 days after the date on which the application was originally submitted, the approved applicant shall submit to the Board the license issuance fee required by A.R.S. § 32-1826(A) and the following information in writing:

1. Practice address and telephone number,

2. Residential address, and

3. A statement of whether the practice address or residential address should be used by the Board as the address of record.

B. The Board shall issue a license to an approved applicant that is effective on the date the information required

under subsection (A) is received.

- C.** A license application is considered withdrawn if an approved applicant fails to submit the information required within the time specified under subsection (A). If an applicant whose application is considered withdrawn wishes to be considered further for licensure, the applicant shall reapply by complying with R4-22-202.

**R4-22-205.    ~~Reserved~~    License Renewal**

To renew a license, the licensee shall submit to the Board the renewal application required under R4-22-201. Failure to receive notice of the need to renew does not excuse failure to renew timely.

**R4-22-206.    ~~Reserved~~    Procedure for Application to Re-enter Practice**

**A.** The procedures in this Section apply only to an osteopathic physician who:

1. Was licensed and practiced as an osteopathic physician in Arizona or another jurisdiction, and
2. Currently is not licensed and practicing as an osteopathic physician in Arizona or another jurisdiction.

**B.** All applicants to re-enter practice shall:

1. Submit the application required under R4-22-201, including all documents specified in the application; and
2. Pay the fee specified in R4-22-102(A).

**C.** In addition to complying with subsection (B), an applicant who has been out of practice for less than two years and has no disciplinary history shall submit documentation of completing at least 40 hours of Category 1-A or Category 1 CME in the applicant's intended field of practice within the two years before the date the application to re-enter practice is approved.

**D.** In addition to complying with subsection (B), an applicant who has been out of practice for more than two years and has no disciplinary history shall attend a Board meeting and:

1. Discuss with the Board evidence that the applicant remains competent to practice medicine; and
2. Develop a re-entry plan designed to ensure that the applicant is competent to practice medicine. The re-entry plan may include any or all of the following, at the discretion of the Board:
  - a. Taking a competency or specialty examination;
  - b. Taking continuing education;
  - c. Completing a practice assessment program;
  - d. Practicing under supervision or with restrictions; and
  - e. Submitting to a physical or psychological examination.

E. In addition to complying with subsection (B), an applicant who has been out of practice and has a history of disciplinary action shall attend a Board meeting and:

1. Establish to the Board's satisfaction that the applicant is rehabilitated from the underlying unprofessional conduct. In determining whether the applicant is rehabilitated, the Board shall consider the factors listed in R4-22-202(E); and
2. If the Board determines that the applicant is rehabilitated, take the actions listed in subsection (D) to ensure that the applicant is competent to practice medicine.

**R4-22-207. Continuing Medical Education; Waiver; Extension of Time to Complete**

A. Under A.R.S. § 32-1825(B), a licensee is required to obtain 20 hours of Board-approved CME in each of the two years ~~preceding~~ before license renewal. The Board shall approve the CME of a licensee if the CME complies with the following:

1. At least 12 hours are obtained annually by completing a CME classified by the AOA as Category 1A; and
2. No more than eight hours are obtained annually by completing a CME classified as AMA Category 1 approved by the an ACCME-accredited CME provider as Category 1.

B. ~~During the first year that a licensee is licensed, the~~ A licensee may fulfill 20 hours of the CME requirement for a particular year by participating in an approved residency, internship, fellowship, or preceptorship during that year.

C. The Board shall accept the following documentation as evidence of compliance with the CME requirement:

1. For a CME under subsection (A)(1):
  - a. The AOA printout of the licensee's CME; or
  - b. A copy of the certificate of attendance from the provider of the CME showing:
    - i. Licensee's name,
    - ii. Title of the CME,
    - iii. Name of the provider of the CME,
    - iv. Category of the CME,
    - v. Number of hours in the CME, and
    - vi. Date of attendance;
2. For a CME under subsection (A)(2):
  - a. a A copy of the certificate of attendance from the provider of the CME showing the information listed in subsection (C)(1)(b); ~~and~~ or
  - b. A specialty board's printout showing a licensee's completion of CME.
3. For a CME under subsection (B), either a letter from the Director of Medical Education or a certificate of completion for the approved internship, residency, fellowship, or preceptorship.

- D.** Waiver of CME requirements. To obtain a waiver under A.R.S. § 32-1825(C) of the CME requirements, a licensee shall submit to the Board a written request that includes the following:
1. The period for which the waiver is requested,
  2. CME completed during the current license period and the documentation required under subsection (C), and
  3. Reason that a waiver is needed and the applicable documentation:
    - a. For military service. A copy of current orders or a letter on official letterhead from the licensee's commanding officer;
    - b. For absence from the United States. A copy of pages from the licensee's passport showing exit and reentry dates;
    - c. For disability. A letter from the licensee's treating physician stating the nature of the disability; or
    - d. For circumstances beyond the licensee's control:
      - i. A letter from the licensee stating the nature of the circumstances, and
      - ii. ~~any supporting documentation~~ Documentation that provides evidence of the circumstances.
- E.** The Board shall grant a request for waiver of CME requirements that:
1. Is based on a reason listed in subsection (D)(3),
  2. Is supported by the required documentation,
  3. Is filed no sooner than 60 days before and no later than 30 days after the license renewal date, and
  4. Will promote the safe and professional practice of osteopathy in this state.
- F.** Extension of time to complete CME requirements. To obtain an extension of time under A.R.S. § 32-1825(C) to complete the CME requirements, a licensee shall submit to the Board a written request that includes the following:
1. Ending date of the requested extension,
  2. CME completed during the current license period and the documentation required under subsection (C),
  3. Proof of registration for additional CME that is sufficient to enable the licensee to complete all CME required for license renewal before the end of the requested extension, and
  4. Licensee's attestation that the CME obtained under the extension will be reported only to fulfill the current license renewal requirement and will not be reported on a subsequent license renewal application.
- G.** The Board shall grant a request for an extension that:
1. Specifies an ending date no later than May 1,
  2. Includes the required documentation and attestation,
  3. Is submitted no sooner than 60 days before and no later than 30 days after the license renewal date, and
  4. Will promote the safe and professional practice of osteopathy in this state.

**R4-22-212. ~~Licensing Time-frames~~ Confidential Program for Treatment and Rehabilitation of Impaired Osteopathic Physicians**

- A.** To protect the public health and safety, a licensee is required by A.R.S. § 32-1822 to be physically, mentally, and emotionally able to practice medicine.
- B.** If the Board determines that a licensee may be impaired by substance abuse and there is evidence of an imminent danger to the public health and safety, the Board's Executive Director, with the concurrence of investigative staff, the medical consultant, or a Board member, may enter into:
1. A consent agreement with the licensee to restrict the licensee's practice if there is evidence that a restriction of the licensee's practice is needed to mitigate the danger to the public health and safety;
  2. A stipulated agreement with the licensee requiring the licensee to complete a Board-approved evaluation and treatment program for abuse or misuse of chemical substances if there is evidence the program would be successful in enabling the licensee to return to practice safely; and
  3. A stipulated agreement with the licensee to enter a Monitored Aftercare Program (MAP) if there is evidence the licensee intends to comply with a program for rehabilitation.

**ARTICLE 3. DISPENSING DRUGS**

**R4-22-301. Registration to Dispense Required**

- A.** An osteopathic physician shall register with the Board annually if the osteopathic physician:
1. Maintains a supply of controlled substances, as defined in A.R.S. § 32-1901(13), prescription-only drugs, as defined in A.R.S. § 32-1901(76), or prescription-only devices, as defined in A.R.S. § 32-1901(75), excluding manufacturers' samples;
  2. Prescribes the items listed in subsection (A)(1) to a patient of the osteopathic physician for use outside the office of the osteopathic physician; and
  3. Obtains payment for the items listed in subsection (A)(1) at a practice location in Arizona.
- B.** To register with the Board to dispense, an osteopathic physician shall:
1. Submit the form referenced in R4-22-201,
  2. Submit a copy of the osteopathic physician's current Drug Enforcement Administration certificate of registration for each location from which the osteopathic physician will dispense a controlled substance, and
  3. Pay the fee authorized by A.R.S. § 32-1826(A)(11).
- C.** An osteopathic physician who is registered with the Board to dispense shall renew the registration by

December 31 of each year by complying with subsection (B). If an osteopathic physician submits a timely and complete application to renew a registration to dispense, the osteopathic physician may continue to dispense until the Board approves or denies the renewal application.

- D.** If an osteopathic physician fails to submit a timely and complete application to renew a registration to dispense, the osteopathic physician shall immediately cease dispensing.
- a. If the osteopathic physician wishes to resume dispensing, the osteopathic physician shall register with the Board by complying with subsection (B) and shall not dispense until the osteopathic physician receives notice from the Board that the registration is approved.
  - b. If the osteopathic physician does not wish to resume dispensing, the osteopathic physician shall, as required by A.R.S. § 32-1871(F), submit to the Board an inventory disposal form, which is available from the Board office or on its web site.

**R4-22-302.     Packaging and Inventory**

- A.** An osteopathic physician shall dispense a controlled substance or prescription-only drug in a prepackaged or light-resistant container with a consumer safety cap that complies with standards specified in the official compendium, as defined at A.R.S. § 32-1901(55), and state and federal law, unless a patient or the patient's representative requests a non-safety cap.
- B.** An osteopathic physician shall ensure that a dispensed controlled substance or prescription-only drug is labeled with the following information:
1. The name, address, and telephone number of the dispensing osteopathic physician;
  2. The date the controlled substance or prescription-only drug is dispensed;
  3. The patient's name;
  4. The name of the controlled substance or prescription-only drug, strength, dosage, form, name of manufacturer, quantity dispensed, directions for use, and any cautionary statement necessary for the safe and effective used of the controlled substance or prescription-only drug; and
  5. A beyond-use date not to exceed one year from the date of dispensing or the manufacturer's expiration date if less than one year.
- C.** An osteopathic physician shall:
1. Secure all controlled substances in a locked cabinet or room;
  2. Control access to the locked cabinet or room by a written procedure that includes, at a minimum:
    - a. Designation of the persons who have access to the locked cabinet or room, and
    - b. Procedures for recording requests for access to the locked cabinet or room;
  3. Make the written procedure required under subsection (C)(2) available on demand by Board or its authorized representative for inspection or copying;
  4. Store prescription-only drugs so they are not accessible to patients; and

5. Store controlled substances and prescription-only drugs not requiring refrigeration in an area where the temperature does not exceed 85° F.
- D.** An osteopathic physician shall maintain a dispensing log for all controlled substances and the prescription-only drug nalbuphine hydrochloride (Nubain) dispensed. The osteopathic physician shall ensure that the dispensing log includes the following information on a separate inventory sheet for each controlled substance or prescription-only drug:
1. Date the drug is dispensed;
  2. Patient's name;
  3. Name of controlled substance or prescription-only drug, strength, dosage, form, and name of manufacturer;
  4. Number of dosage units dispensed;
  5. Running total of each controlled substance or prescription-only drug dispensed; and
  6. Written signature of the osteopathic physician next to each entry.
- E.** An osteopathic physician may use a computer to maintain the dispensing log required under subsection (D) if the log is quickly accessible through either on-screen viewing or printing a copy.
- F.** This Section does not apply to a prepackaged manufacturer sample of a controlled substance or prescription-only drug unless otherwise provided by federal law.

**R4-22-303. Prescribing and Dispensing Requirements**

- A.** An osteopathic physician who dispenses a controlled substance, prescription-only drug, or prescription-only device shall record the following information on the patient's medical record:
1. Name, strength, dosage, and form of the controlled substance, prescription-only drug, or prescription-only device dispensed;
  2. Quantity or volume dispensed;
  3. Date of dispensing;
  4. Medical reasons for dispensing; and
  5. Number of refills authorized.
- B.** Before dispensing a controlled substance, prescription-only drug, or prescription-only device, an osteopathic physician shall review the prepared controlled substance, prescription-only drug, or prescription-only device to ensure that:
1. The container label and contents comply with the prescription; and
  2. The patient is informed of the name of the controlled substance, prescription-only drug, or prescription-only device, directions for use, precautions, and storage requirements.
- C.** An osteopathic physician shall purchase all controlled substance, prescription-only drugs, or prescription-only devices dispensed from a manufacturer or distributor approved by the United State Food and Drug

Administration or a pharmacy holding a current permit from the Arizona Board of Pharmacy.

- D.** The individual who prepares a controlled substance, prescription-only drug, or prescription-only device for dispensing shall countersign and date the original prescription form.

**R4-22-304. Recordkeeping and Reporting Shortages**

- A.** An osteopathic physician who dispenses a controlled substance or prescription-only drug shall ensure that an original prescription order, as defined in A.R.S. § 32-1901(77), for the controlled substance or prescription-only drug dispensed is dated, consecutively numbered in the order in which originally dispensed, and filed separately from patient medical records. The osteopathic physician shall ensure that original prescription orders are maintained in three separate files, as follows:

1. Schedule II controlled substances, which are listed at A.R.S. § 36-2513;
2. Schedule III, IV, and V controlled substances, which are defined or listed at A.R.S. §§ 36-2514 through 36-2516, and
3. Prescription-only drugs.

- B.** An osteopathic physician shall ensure that purchase orders and invoices for all dispensed controlled substances and prescription-only drugs are maintained for three years from the date on the purchase order or invoice in three separate files as follows:

1. Schedule II controlled substances;
2. Schedule III, IV, and V controlled substances and nalbuphine; and
3. All other prescription-only drugs.

- C.** An osteopathic physician who discovers a theft or loss of a controlled substance or dangerous drug, as defined in A.R.S. Title 36, Chapter 27, Article 2, from the physician's office shall:

1. Immediately notify the local law enforcement agency,
2. Provide the local law enforcement agency with a written report, and
3. Send a copy of the report to the U.S. Drug Enforcement Administration and the Board within seven days of the discovery of the theft or loss.

**R4-22-305. Inspections; Denial and Revocation**

- A.** An osteopathic physician shall allow the Board or its representative access to the physician's office and the records required under this Article for inspection of compliance with A.R.S. § 32-1871 and this Article.

- B.** Failure to comply with A.R.S. § 32-1871 and this Article is unprofessional conduct and grounds for revocation of the physician's registration to dispense or denial of renewal of registration to dispense.

- C.** The Board shall revoke an osteopathic physician's registration to dispense upon the occurrence of the following:

1. Suspending, revoking, surrendering, or canceling the physician's license;

2. Failing to timely renew the physician's license; or
3. Restricting the physician's ability to prescribe or administer medication, including loss or expiration of the physician's Drug Enforcement Administration Certificate of Registration.

**D.** If the Board denies a registration to dispense to an osteopathic physician, the physician may appeal the decision by filing a written request with the Board no later than 30 days after service of the notice of denial.

#### **ARTICLE 4. MEDICAL ASSISTANTS**

**~~R4-22-110.~~ R4-22-401. Approval of Educational Programs for Medical Assistants**

- A.** For purposes of this Section, a Board-approved medical assistant training program is a program:
1. Accredited by the ~~Commission on Accreditation of Allied Health Education Programs (CAAHEP)~~ CAAHEP;
  2. Accredited by the ~~Accrediting Bureau of Health Education Schools (ABHES)~~ ABHES;
  3. Accredited by any accrediting agency recognized by the United States Department of Education; or
  4. Designed and offered by a licensed osteopathic physician, meets or exceeds the standards of one of the accrediting programs listed in subsections (A)(1) through (A)(3), and the licensed osteopathic physician verifies that those who complete the program have the entry level competencies referenced in ~~R4-22-111~~ R4-22-402.
- B.** A person seeking approval of a training program for medical assistants shall submit to the Board the application required under R4-22-201 and verification to the Board that the program meets the requirements in subsection (A).

**~~R4-22-111.~~ R4-22-402. Medical Assistants – Authorized Procedures**

- A.** A medical assistant may, under the direct supervision of ~~an~~ a licensed osteopathic physician ~~or a physician assistant~~, perform the medical procedures listed in the Commission on Accreditation of Allied Health Education Programs' *Standards and Guidelines for Medical Assisting Educational Programs*, revised 2003 2008, ~~Section III(C)(3)(a) through (e)~~. This material is incorporated by reference, does not include any later revisions, amendments or editions, is on file with the Board, and may be obtained from the Commission on Accreditation of Allied Health Education Programs, 1361 Park Street, Clearwater, FL 33756, 727-210-2350, or at www.caahep.org.
- B.** Additionally, a medical assistant working under the direct supervision of ~~an~~ a licensed osteopathic physician ~~or physician assistant~~ may:
1. Perform physical medicine modalities, including administering whirlpool treatments, diathermy treatments, electronic galvanic stimulation treatments, ultrasound therapy, massage therapy, and traction

treatments;

2. Apply Transcutaneous Nerve Stimulation units and hot and cold packs; ~~and~~
3. Administer small volume nebulizers;
4. Draw blood;
5. Prepare proper dosages of medication and administer the medication as directed by the physician;
6. Assist in minor surgical procedures;
7. Perform urine analyses, strep screens, and urine pregnancy tests;
8. Perform EKGs; and
9. Take vital signs.

**~~R4-22-112.~~ R4-22-403. Medical Assistant Training Requirement**

- A. The ~~supervising licensed osteopathic physician or physician assistant~~ who will provide direct supervision to a medical assistant shall ensure that ~~a~~ the medical assistant satisfies one of the following training requirements before the medical assistant is employed:
1. Completes an approved medical assistant training program,
  2. Completes an unapproved medical assistant training program and passes a medical assistant examination administered by either the American Association of Medical Assistants or the American Medical Technologists, or
  3. Completes a medical services training program of the Armed Forces of the United States.
- B. This Section does not apply to a person who completed a medical assistant training program before ~~the effective date of this Section~~ August 7, 2004, and was employed continuously as a medical assistant since completing the program.

**ARTICLE 5. OFFICE-BASED SURGERY**

**R4-22-501. Definitions**

In this Article,

"ACLS" means advanced cardiac life support performed according to certification standards of the American Heart Association.

"Auscultation" means the act of listening to sounds within the human body either directly or through use of a stethoscope or other means.

BLS" means basic life support performed according to certification standards of the American Heart Association.

"Capnography" means monitoring the concentration of exhaled carbon dioxide of a sedated patient to

determine adequacy of the patient's ventilatory function.

"Deep sedation" means a drug-induced depression of consciousness during which a patient:

Cannot be easily aroused, but

Responds purposefully following repeated or painful stimulation, and

May partially lose the ability to maintain ventilatory function.

"Discharge" means a written or electronic documented termination of office-based surgery to a patient.

"Emergency" means an immediate threat to the life or health of a patient.

"General anesthesia" means a drug-induced loss of consciousness during which a patient:

Can not be aroused even with painful stimulus; and

May partially or completely lose the ability to maintain ventilatory, neuromuscular, or cardiovascular function or airway.

"Health-care professional" means a registered nurse or a registered nurse practitioner, as defined in A.R.S. § 32-1601, physician assistant, as defined in A.R.S. § 32-2501, and any individual authorized to perform surgery under A.R.S. Title 32 who participates in office-based surgery.

"Informed consent" means advising a patient of the:

Purpose for and alternatives to office-based surgery,

Risks associated with office-based surgery, and

Possible benefits and complications from office-based surgery.

"Malignant hyperthermia" means a life-threatening condition in an individual who has a genetic sensitivity to inhalant anesthetics and depolarizing neuromuscular blocking drugs that occurs during or after the administration of an inhalant anesthetic or depolarizing neuromuscular blocking drug.

"Minimal sedation" means a drug-induced state during which:

A patient responds to verbal commands,

Cognitive function and coordination may be impaired, and

A patient's ventilatory and cardiovascular functions are unaffected.

"Moderate sedation" means a drug-induced depression of consciousness during which:

A patient responds to verbal commands or light tactile stimulations, and

No interventions are required to maintain ventilatory or cardiovascular function.

"Monitor" means to assess the condition of a patient.

"Office-based surgery" means a medical procedure performed by an osteopathic physician in the physician's office or other practice location that is not part of a licensed hospital or licensed ambulatory surgical center while using sedation.

"PALS" means pediatric life support performed according to certification standards of the American Academy of Pediatrics or the American Heart Association.

"Rescue" means to correct adverse physiologic consequences of deeper than intended level of sedation and

return the patient to the intended level of sedation.

"Staff member" means an individual who:

Is not a health-care professional, and

Assists with office-based surgery under the supervision of the osteopathic physician performing the office-based surgery.

"Transfer" means a physical relocation of a patient from the office or other practice location of an osteopathic physician to a licensed health-care institution.

#### **R4-22-502. Health Care Institution License**

An osteopathic physician who performs office-based surgery 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.

#### **R4-22-503. Administrative Provisions**

**A.** An osteopathic physician who performs office-based surgery shall:

1. Establish, document, and implement written policies and procedures that cover:
  - a. Patients' rights,
  - b. Informed consent,
  - c. Care of patients in an emergency, and
  - d. Transfer of patients to a local accredited or licensed acute-care hospital;
2. Ensure that a staff member who assists with or a health-care professional who participates in office-based surgery:
  - a. Has sufficient education, training, and experience to perform assigned duties;
  - b. If applicable, has a current license or certification required to perform assigned duties; and
  - c. Performs only those acts that are within the scope of practice established in the staff member's or health-care professional's governing statutes;
3. Ensure that the office or other practice location where office-based surgery is performed has all equipment necessary for:
  - a. The physician to perform the office-based surgery safely,
  - b. The physician or health-care professional to administer the sedation safely,
  - c. The physician or health-care professional to monitor the use of sedation, and
  - d. The physician and health-care professional administering the sedation to rescue a patient after the sedation is administered if the patient enters into a deeper state of sedation than was intended by the physician;
4. Ensure that a copy of the patients' rights policy is provided to each patient before performing office-based surgery;

5. Obtain informed consent from the patient before performing office-based surgery that:
  - a. Authorizes the office-based surgery, and
  - b. Authorizes the office-based surgery to be performed at the specific practice location; and
6. Review all policies and procedures at least every 12 months and update as needed.

**B.** An osteopathic physician who performs office-based surgery shall comply with:

1. The local jurisdiction's fire code;
2. The local jurisdiction's building codes for construction and occupancy;
3. The bio-hazardous waste and hazardous waste standards in 18 A.A.C. 13, Article 14; and
4. The controlled drug administration, supply, and storage standards in 4 A.A.C. 23, Article 5.

**R4-22-504.**     **Procedure and Patient Selection**

**A.** An osteopathic physician shall ensure that each office-based surgery performed:

1. Can be performed safely with the equipment, staff members, and health-care professionals at 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, skills, and licensure of the physician; and
4. Is within the education, training, experience, skills, and licensure of the staff members and health-care professionals at the physician's office.

**B.** An osteopathic physician shall not perform office-based surgery if the patient:

1. 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.

**R4-22-505.**     **Sedation Monitoring Standards**

**A.** An osteopathic physician who performs office-based surgery when minimal sedation is administered to a patient shall ensure from the time sedation is administered until post-sedation monitoring begins that a quantitative method of assessing the patient's oxygenation, such as pulse oximetry, is used.

**B.** An osteopathic physician who performs office-based surgery when moderate or deep sedation is administered to a patient shall ensure from the time sedation is administered until post-sedation monitoring begins that:

1. A quantitative method of assessing the patient's oxygenation, such as pulse oximetry, is used;
2. The patient's ventilatory function is monitored by any of the following:
  - a. Direct observation,
  - b. Auscultation, or
  - c. Capnography;

3. The patient's circulatory function is monitored by:
  - a. Having a continuously displayed electrocardiogram,
  - b. Documenting arterial blood pressure and heart rate at least every five minutes, and
  - c. Evaluating the patient's cardiovascular function by pulse plethysmography;
4. The patient's temperature is monitored if the physician expects the patient's temperature to fluctuate; and
5. A licensed and qualified health-care professional, other than the physician performing the office-based surgery, is:
  - a. Present throughout the office-based surgery, and
  - b. Has the sole responsibility of attending to the patient.

**R4-22-506. Perioperative Period; Patient Discharge**

An osteopathic physician performing office-based surgery shall ensure all of the following:

1. The physician is physically present in the room where office-based surgery is performed while the office-based surgery is performed;
2. After the office-based surgery is performed and until the patient's post-sedation monitoring is discontinued, a physician is at the physician's office and sufficiently free of other duties to respond to an emergency;
3. 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;
4. If using moderate or deep 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;
5. A discharge is documented in the patient's medical record including:
  - a. The date and time of the patient's discharge, and
  - b. A description of the patient's medical condition at the time of discharge; and
6. The patient receives discharge instructions and receipt of the discharge instructions is documented in the patient's medical record.

**R4-22-507. Emergency Drugs; Equipment and Space Used for Office-based Surgery**

A. In addition to the requirements in R4-22-503(A)(3) and R4-22-504(A)(1), an osteopathic physician who performs office-based surgery 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;
- 2. The equipment for patient monitoring according to the standards in R4-22-505;
- 3. Space large enough to:
  - a. Allow access to the patient during office-based surgery, recovery, and any emergency;
  - b. Accommodate all equipment necessary to perform the office-based surgery; and
  - c. Accommodate all equipment necessary for sedation monitoring;
- 4. A source of auxiliary electrical power available in the event of a power failure;
- 5. Equipment, emergency drugs, and resuscitative capabilities required under this Section for patients less than 18 years of age, if office-based surgery is performed on these patients; and
- 6. Procedures to minimize the spread of infection.
- B.** An osteopathic physician who performs office-based surgery shall:
  - 1. Ensure that all equipment used for office-based surgery 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.

**R4-22-508. Emergency and Transfer Provisions**

- A.** An osteopathic physician who performs office-based surgery shall ensure that a health-care professional who participates in or a staff member who assists with office-based surgery receives 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.** When performing office-based surgery, an osteopathic physician shall not use any drug or agent that may trigger malignant hyperthermia.