

**BOARD OF HOMEOPATHIC AND
INTEGRATED MEDICINE EXAMINERS**

FIVE-YEAR-REVIEW REPORT

4 A.A.C. 38

March 2014

INTRODUCTION

Homeopathy originated in the late 1700s in Germany. Originally it referred to a system of medicine that treats symptoms in accordance with the principle that a substance that produces symptoms in a healthy person will cure those symptoms in a sick person. Under Arizona statutes, homeopathy is a much broader practice and includes acupuncture, chelation therapy, homeopathy, minor surgery, neuromuscular integration, nutrition, orthomolecular therapy, and pharmaceutical medicine. The Board was organized in 1981 after certain physicians regulated by the Arizona Medical Board (AMB) alleged that the AMB was antagonistic toward nontraditional medicine. To be a licensed homeopathic physician in Arizona, a person must have an active allopathic (MD) or osteopathic (DO) license in good standing, but is not required to maintain the MD or DO license after obtaining a homeopathic license. There are currently 84 licensees. Six individuals applied for licensure in FY13. Six of the current licensees do not have another active medical license.

Statute that generally authorizes the agency to make rules: A.R.S. § 32-2904(B)(1)

1. Specific statute authorizing the rule:

- R4-38-101. Definitions: A.R.S. § 32-2904(B)(1)
- R4-38-102. Additional Requirements for Applicants Graduated from an Unapproved School of Medicine: A.R.S. § 32-2912(A)(2)
- R4-38-103. Postgraduate Requirements for Licensure: A.R.S. § 32-2912(G)(3)
- R4-38-104. Approved Postgraduate Coursework: A.R.S. § 32-2912(G)(3)
- R4-38-105. Approval of Preceptorship: A.R.S. § 32-2912(G)(3)
- R4-38-106. Fees: A.R.S. §§ 32-2914 and 32-2916
- R4-38-107. Examination: A.R.S. § 32-2913
- R4-38-108. Application for Licensure: A.R.S. § 32-2912(A)(8) and (G)
- R4-38-109. License Renewal: A.R.S. § 32-2915
- R4-38-110. Notification of Change in Contact Information: A.R.S. § 32-2916(B)

- R4-38-111. Experimental Forms of Diagnosis and Treatment: A.R.S. § 32-2933(27)
- R4-38-112. Peer Review: A.R.S. § 32-2933(27)
- R4-38-113. Chelation Therapy Practice Requirements: A.R.S. § 32-2901(6)
- R4-38-114. Rehearing or Review of Decision: A.R.S. § 41-1092
- R4-38-115. Use of Title and Abbreviation: A.R.S. § 32-2932
- R4-38-116. Continuing Education Requirement: A.R.S. § 32-2915(F)
- R4-38-117. Application for Continuing Education Approval: A.R.S. § 32-2915(F)
- R4-38-118. Audit of Compliance and Sanction for Noncompliance with Continuing Education Requirement: A.R.S. § 32-2915(F)
- R4-38-201. Definitions: A.R.S. § 32-2951
- R4-38-202. General Provisions: A.R.S. § 32-2951
- R4-38-206. Packaging: A.R.S. § 32-2951
- R4-38-301. Definitions: A.R.S. §§ 32-2901(15), 32-2904(A)(9), 32-2933, and 32-2939
- R4-38-302. Requirements to Supervise a Medical Assistant; Standards for Supervision: A.R.S. §§ 32-2904(A)(9) and 32-2939
- R4-38-303. Board Standards for a Formal Education Program: A.R.S. § 32-2904(A)(9)
- R4-38-304. Approved Practical Education Program; Renewal: A.R.S. § 32-2904(A)(9)
- R4-38-305. Minimum Requirements for Registration of a Homeopathic Medical Assistant: A.R.S. § 32-2904(A)(9)
- R4-38-306. Application to Register a Medical Assistant: A.R.S. § 32-2904(A)(9)
- R4-38-307. Additional Requirements to Register a Previously Licensed Health Care Practitioner: A.R.S. § 32-2904(A)(9)
- R4-38-308. Renewal of Medical Assistant Registration: A.R.S. § 32-2904(A)(9)
- R4-38-309. Restrictions on Delegated Procedures: A.R.S. §§ 32-2904(A)(9) and 32-2939
- R4-38-310. Registration Not Transferable; Multiple Employers: A.R.S. §32-2904(A)(9)
- R4-38-311. Responsibilities of a Registered Medical Assistant: A.R.S. § 32-2904(A)(9)
- R4-38-312. Unprofessional Conduct: A.R.S. § 32-2904(A)(9)
- R4-38-401. Definitions: A.R.S. §§ 32-2912(A)(8) and (G) and 32-2915(G)

R4-38-402. Application; Initial License, Permit, or Registration: A.R.S. §32-2912(A)(8) and (G)

R4-38-403. Application; Renewal of License, Permit, or Registration: A.R.S. §32-2915(G)

2. Objective of the rule including the purpose for the existence of the rule:

R4-38-101. Definitions: The objective of the rule is to define terms used in the rules in a manner that is not explained adequately by a dictionary definition. The definitions are designed to facilitate understanding by those who use the rules.

R4-38-102. Additional Requirements for Applicants Graduated from an Unapproved School of Medicine: The objective of the rule is to specify the medical education that the Board has determined is of equivalent quality to that provided by an approved school of medicine. The purpose is to provide a means by which an individual who did not graduate from an approved school of medicine can become licensed.

R4-38-103. Postgraduate Requirements for Licensure: The objective of the rule is to specify postgraduate alternatives to having a degree in homeopathic medicine. The purpose is to provide a means by which an individual who did not obtain a degree in homeopathic medicine can become licensed.

R4-38-104. Approved Postgraduate Coursework: The objective of this rule is to specify postgraduate course work that the Board determined qualifies an individual for licensure even if the individual did not obtain a degree in homeopathic medicine. The purpose is to provide a means by which an individual who did not obtain a degree in homeopathic medicine can become licensed.

R4-38-105. Approval of Preceptorship: The objective is to specify the standards and procedure for obtaining the Board's approval of a preceptorship. The purpose is to provide a means by which an individual who did not obtain a degree in homeopathic medicine can become licensed.

R4-38-106. Fees: The objective of the rule is to specify the fees that the Board charges for its licensing activities. This enables an applicant to submit the correct amount.

R4-38-107. Examination: The objective of the rule is to prescribe the examination applicants are required to pass before being licensed, establish the passing criterion, and indicate materials that may be taken to the examination. This provides an applicant with necessary information regarding the examination qualification criteria.

R4-38-108. Application for Licensure: The objective of the rule is to specify information an applicant is required to submit to the Board and information the applicant is required to have others submit to the Board. This enables an applicant to ensure that all required information is submitted.

R4-38-109. License Renewal. The objective of the rule is to specify when a licensee is required to submit license renewal materials to the Board, the materials that must be submitted, and the consequences of failing to submit materials timely. This enables a licensee to renew timely and avoid having a license expire.

R4-38-110. Notification of Change in Contact Information. The objective of the rule is to provide notice that the Board communicates with a licensee using the information the licensee has provided. This ensures that a licensee knows it is important to keep the Board apprised of changes in contact information.

R4-38-111. Experimental Forms of Diagnosis and Treatment. The objective of the rule is to clarify what is and what is not an experimental form of diagnosis and treatment. This assists licensees to avoid engaging in unprofessional conduct.

R4-38-112. Peer Review. The objective of the rule is to establish minimum standards for peer review committees, which is one of the generally accepted criteria for use with an experimental form of diagnosis and treatment. This assists licensees to avoid engaging in unprofessional conduct.

R4-38-113. Chelation Therapy Practice Requirements. The objective of the rule is to establish minimum standards for the practice of chelation therapy for other than the treatment of metal poisoning. This assists licensees to avoid engaging in unprofessional conduct.

R4-38-114. Rehearing or Review of Decision. The objective of this rule is to specify the procedures and standards for requesting a rehearing or review of a Board decision. This enables a licensee to know how to exhaust the licensee's administrative remedies before making application for judicial review under A.R.S. § 12-901.

R4-38-115. Use of Title and Abbreviation. The objective of the rule is to specify the manner in which a homeopathic physician may designate the kind of physician he or she is. This assists licensees to avoid engaging in unprofessional conduct.

R4-38-116. Continuing Education Requirement. The objective of the rule is to specify continuing education activities that are approved by the Board and the standards used to decide whether to approve additional continuing education activities. This enables a licensee to have confidence that a continuing education activity will be accepted for license-renewal purposes.

R4-38-117. Application for Continuing Education Approval: The objective of the rule is to specify the requirements and procedures for obtaining the Board's approval of a continuing education course. This enables licensees to know that a Board-approved course meets certain minimum standards and will be accepted for license-renewal purposes.

R4-38-118. Audit of Compliance and Sanction for Noncompliance with Continuing Education Requirement. The objective of the rule is to provide notice to licensees that the Board will audit compliance with the continuing education requirement and the manner in which an audited licensee is required to submit evidence of compliance. This enables a licensee to avoid being sanctioned for noncompliance.

R4-38-201. Definitions. The objective of the rule is to define terms used in the rules in a manner that is not explained adequately by a dictionary definition. The definitions are designed to facilitate understanding by those who use the rules.

R4-38-202. General Provisions. The objective of the rule is to provide notice to a licensee that a permit to dispense is required before the licensee dispenses a controlled substance, pharmaceutical drug, homeopathic medication, prescription-only drug, natural substance, non-prescription drug, or device. This protects the public from possible misuse of drugs.

R4-38-206. Packaging. The objective of the rule is to specify the manner in which a licensee is required to package dispensed drugs. This protects the public from possible misuse of drugs.

R4-38-301. Definitions: The objective of the rule is to define terms used in the rules in a manner that is not explained adequately by a dictionary definition. The definitions are designed to facilitate understanding by those who use the rules.

R4-38-302. Requirements to Supervise a Medical Assistant; Standards for Supervision. The objective of the rule is to specify the manner in which a licensee must be qualified before supervising a medical assistant and the minimum standards for supervision of a medical assistant. This is to protect the public from care that does not meet generally accepted community standards.

R4-38-303. Board Standards for a Formal Education Program. The objective of the rule is to establish minimum standards for a medical-assistant formal educational program in various homeopathic modalities. This is to protect the public by ensuring that medical assistants who complete a formal educational program are prepared to provide quality care.

R4-38-304. Approved Practical Education Program; Renewal. The objective of the rule is to establish minimum standards for a medical-assistant practical educational program and procedures for obtaining the Board's approval of a practical educational program. This is to protect the public by ensuring that medical assistants who complete a practical educational program are prepared to provide quality care.

R4-38-305. Minimum Requirements for Registration of a Homeopathic Medical Assistant. The objective of the rule is to establish minimum standards for registering a homeopathic medical assistant. This is to protect the public by ensuring that both the medical assistant and the supervising homeopathic physician are qualified.

R4-38-306. Application to Register a Medical Assistant. The objective of the rule is to list the information required to register a medical assistant and the procedure for amending the job description of a registered medical assistant. This is to protect the public by ensuring that both the medical assistant and the supervising homeopathic physician are qualified.

R4-38-307. Additional Requirements to Register a Previously Licensed Health Care Practitioner. The objective of the rule is to specify additional requirements that apply when a licensee wants to register a previously licensed health care practitioner as a medical assistant. This is to protect the public from the possibility that a registered medical assistant may practice health care outside the scope of the medical assistant's job description.

R4-38-308. Renewal of Medical Assistant Registration. The objective of the rule is to specify when the registration of a medical assistant expires and the procedure for renewing the registration. This is to protect the public by ensuring that only a properly registered medical assistant provides care.

R4-38-309. Restrictions on Delegated Procedures. The objective of the rule is to specify procedures that may not be delegated to a medical assistant. This is to protect the public by ensuring that procedures requiring the knowledge and skill of a physician are provided by a physician rather than a medical assistant.

R4-38-310. Registration Not Transferable; Multiple Employers. The objective of the rule is to clarify that registration of a medical assistant is specific to the medical assistant and the employing homeopathic physician. The rule also clarifies the manner in which multiple homeopathic physicians employing the same medical assistant are required to register the medical assistant. This protects the public by clearly identifying the homeopathic physician responsible for supervising a medical assistant.

R4-38-311. Responsibilities of a Registered Medical Assistant. The objective of the rule is to specify the manner in which a registered medical assistant is required to communicate the medical assistant's status and the homeopathic modality in which the medical assistant is qualified. This protects the public from being confused regarding the qualification of the individual providing care.

R4-38-312. Unprofessional Conduct. The objective of the rule is to specify conduct relating to supervision of a medical assistant that is unprofessional. This enables a homeopathic physician to avoid conduct that might lead to disciplinary action.

R4-38-401. Definitions: The objective of the rule is to define terms used in the rules in a manner that is not explained adequately by a dictionary definition. The definitions are designed to facilitate understanding by those who use the rules.

R4-38-402. Application; Initial License, Permit, or Registration. The objective of the rule is to specify the procedure and time-frames used by the Board to evaluate an application for initial license, permit, or registration. This enables an applicant to know what can be expected from the Board after an application is submitted.

R4-38-403. Application; Renewal of License, Permit, or Registration. The objective of the rule is to specify the procedure and time-frames used by the Board to evaluate an application for renewal of a license, permit, or registration. This enables an applicant to know what can be expected from the Board after an application is submitted.

3. Effectiveness of the rules in achieving their objectives including a summary of any available data supporting the conclusion:

The Board concluded that the rules are effective in achieving their objectives. This conclusion was reached following meetings on September 25, 2013, and October 2, 2013, at which the Board reviewed all of the rules and identified needed changes. None of the needed changes interferes with the current effectiveness of the rules in achieving their objectives.

4. Consistency of the rules with state and federal statutes and other rules made by the agency, and a listing of the statutes or rules used in determining the consistency:

The rules are consistent with state and federal law. A homeopathic physician who dispenses a controlled substance is required under 21 CFR, Chapter 3, to register with the federal Drug Enforcement Administration and to comply with provisions regarding labeling, packaging, and recordkeeping. The rules in Article 2 reflect federal law.

The Board's statutes are changing on January 1, 2015 (See Laws 2011, Chap 186). At that time, the Board will have authority to license an individual who is not also licensed by the Arizona Medical Board or the Board of Osteopathic Examiners in Medicine and Surgery. This change will necessitate rule changes.

5. Agency enforcement policy including whether the rules are currently being enforced and, if so, whether there are any problems with enforcement:

The Board reports that it enforces the rules as written. The Board indicates there has been some confusion regarding whether individuals are required to be registered as a medical assistant. The rules, however, clearly indicate the minimum requirements that must be met by both the homeopathic physician and the individual before the individual may be considered for registration and further indicate that if the homeopathic physician intends that the individual will work as a medical assistant, the homeopathic physician is required to register the individual.

6. Clarity, conciseness, and understandability of the rules:

Although the Board identified minor ways in which the rules could be improved, the rules are generally clear, concise, and understandable and consistent with current rule writing standards.

R4-38-201 and R4-38-301 provide definitions applicable to the Article in which the Section appears. Both Sections cite to three statutes that provide definitions. It would be better if these two Sections clearly indicated the definitions provided apply only to the Article in which the Section appears and the citation to the three statutes that provide definitions was added to R4-38-101.

In both R4-38-103 and R4-38-401, the internal cross-references to A.R.S. § 32-2912 cite incorrect subsections.

R4-38-304(E), R4-38-306(C), and R4-38-308(B)(2) refer to fees in R4-38-105. This cross reference is incorrect. The fees are in R4-38-106.

In R4-38-402(C), the correct reference for the Section dealing with examination and interview requirements is R4-38-107. Also, the lead needs to clarify that the examination and interview applies only to application for an initial license and not to application for permit or registration.

Throughout the rules, reference to the Council of Homeopathic Education needs to be changed to the Accrediting Commission on Homeopathic Education in North American.

Comments from Dr. Hayle Aldren, which are discussed in item 7, indicate the language in R4-38-302(D) needs to be clarified.

7. Summary of written criticisms of the rules received by the agency within the past five years, including letters, memoranda, reports, written analyses submitted to the agency questioning whether the rules are based on valid scientific or reliable principles or methods, and, written allegations made in litigation or administrative proceedings in which the agency was a party that the rules are discriminatory, unfair, unclear, inconsistent with statute or beyond the authority of the agency to enact, and the result of the litigation of administrative proceedings:

On March 28, 2012, Dr. Hayle Aldren asked for an interpretation of R4-38-302(D)(6), which requires that the physician supervising a medical assistant place a written order in the patient record on the day that the medical assistant performs a delegated procedure. Dr. Aldren's concern is that it is common practice to place an order for a future procedure in a patient record during an appointment or in anticipation of an appointment. The Board concluded that, as written, the rule is inconsistent with its intent and general medical practice. When the rule is amended, this will be corrected.

On April 9, 2013, Dr. Aldren asked whether an electronic signature is acceptable under R4-38-302(D)(8), which requires the physician supervising a medical assistant to review, initial, and date the medical assistant notes placed in patient records. The Board indicated the substantive intent of the rule is to ensure that medical assistants are properly supervised. The nature of the signature is not an issue. The Board recognized that digital signatures are commonly used in medical practice and encouraged Dr. Aldren to adopt a procedure consistent with the requirement that medical assistants be supervised.

8. A comparison of the estimated economic, small business, and consumer impact of the rules with the economic, small business, and consumer impact statement prepared on the last making of the rules or, if no economic, small business, and consumer impact statement was prepared on the last making of the rules, an assessment of the actual economic, small business, and consumer impact of the rules:

1998 Rulemaking

The rules in Article 4, which deals with the application and renewal process and licensing time-frames, were made in 1998. The primary economic impact of these rules is on the Board, which is required to comply with its licensing time-frames. The rules simply explain to an applicant what can be expected from the Board regarding application processing and action. The Board reports that it complies with its time-frames.

2003 Rulemaking

The rules in Article 2, which deal with Dispensing of Drugs by Homeopathic Physicians, were amended in this rulemaking. The primary objective of the amendments was to eliminate repetitive language. At the time the rules were amended, the Board anticipated the changes would have very little economic impact. The Board reports that the economic impact has been minimal.

2005 Rulemaking

R4-38-101, Definitions; R4-38-102, Additional Requirements for Applicants Graduated from an Unapproved School of Medicine; and R4-38-114, Rehearing or Review of Decision, were last amended in this rulemaking. At the time the rules were amended, the Board anticipated the changes would have very little economic impact. The Board reports that the economic impact has been minimal.

2010 Rulemaking

The rules in Article 3, which deal with medical assistants, were made in this rulemaking. At the time, The Board recognized that the rules would have some economic impact. For example, a homeopathic physician who wished to register a medical assistant would incur the cost of complying with the registration procedures and supervision standards but would receive the benefit of being able to make homeopathic services available to more customers. An individual who wanted to be registered as a medical assistant would incur the cost of completing either a formal or practical educational program but would receive the benefit of becoming eligible for registration and employment. The Board believes the anticipated impact occurred. There are currently 16 registered medical assistants. Almost all medical assistants become qualified by participating in a formal education program rather than a practical education program. No practical education program was approved in 2013.

2011 Rulemaking

In this rulemaking, the Board amended all of the rules in Article 1, General, that were not amended in the 2005 rulemaking. Many of the rule changes resulted from statutory changes that the legislature made in response to a Sunset Review of the Board. The Board believes the actual impact of the rules has been as anticipated.

The Board concluded that most of the economic impact on applicants and licensees resulted from legislative action rather than the rulemaking. The cost associated with obtaining 20 hours of Board-approved continuing education was estimated to be minimal because most licensees already participate in continuing education. It was expected there would be economic cost associated with passing an examination, especially if an applicant does not pass. However, this is a necessary requirement to enable the Board to fulfill its obligation to protect public health and safety. The Board expected administrative costs associated with applying for and renewing licensure. However, the benefits of being licensed outweigh the costs of making application. As a result of the clarification regarding the manner in which a title must be written, it was expected that a homeopathic physician might incur the expense of having letterhead and business cards made that are in compliance. This is a necessary cost of doing business and provides the benefit of helping the homeopathic physician avoid any charge of false advertising.

The rulemaking established standards for approval of a preceptorship. However, since 1999, only two preceptorships have been approved. Applicants for licensure are required to pass a written examination. During FY13, all who took the examination passed. All those who were audited for compliance with the continuing education requirement were in compliance.

In FY13, the Board received complaints regarding six licensees. Four of the complaints related to patient care and two related to administrative matters. One of the complaints has led to a scheduled hearing. Two others resulted in continuing probation.

2012 Rulemaking

In this rulemaking, the Board increased the fee to renew a license from \$975 to \$1,000. The Board expected the fee increase to generate approximately \$2,100 from the 85 licensees that existed in FY11. The Board's expectation was accurate. The Board collected \$89,400 in FY11 and \$91,000 in FY13. In FY13, the Board was appropriated \$107,600. The Board operates with one half-time employee.

9. Any analysis submitted to the agency by another person regarding the rule's impact on this state's business competitiveness as compared to the competitiveness of businesses in other states:

No analysis was submitted.

10. How the agency completed the course of action indicated in the agency's previous 5YRR:

The Board's previous 5YRR was approved by Council on July 7, 2009. The Board indicated in the report that it had submitted a rulemaking addressing all the rules in Articles 3 and 4 to the Council on December 8, 2008. However, Council was unable to act on the rulemaking because Governor Brewer imposed a moratorium on all rulemaking activity on January 22, 2009. The Board anticipated that Council would act on the submitted rulemaking when the Board was granted an exemption from the moratorium. However, for reasons that are not entirely clear, an exemption from the moratorium was provided for only Article 3. As previously indicated, the rulemaking on Article 3 went into effect in 2010.

The Board also indicated it would amend R4-38-103, R4-38-105, R4-38-106, R4-38-107, and R4-38-113, and Article 2. As previously indicated, the Board amended the rules in Article 1. It has not completed the work necessary on Article 2. The Article 4 rulemaking that was omitted from the exemption provided in 2009 has not been completed.

11. A determination after analysis that the probable benefits of the rules outweigh within this state the probable costs of the rules and the rules impose the least burden and costs to persons regulated by the rules, including paperwork and other compliance costs necessary to achieve the underlying regulatory objective:

The Board believes the rules impose the least burden on persons regulated by them. By making application and complying with the rules, those who obtain licensure as a homeopathic physician indicate they have personally determined that the benefits of being licensed outweigh the costs associated with the licensure and regulatory process. The rules establish minimum standards for being licensed as a homeopathic physician and require that an application be submitted, fees paid, continuing education obtained, and supervision provided to a medical assistant. All of these requirements impose economic burdens on those who wish to practice homeopathic medicine. However, the requirements are necessary to achieve the underlying regulatory objective, which is to protect the health and safety of the public that receives homeopathic treatment.

12. A determination after analysis that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law:

The rules are not more stringent than federal law. A homeopathic physician who dispenses a controlled substance is required under 21 CFR, Chapter 3, to register with the federal Drug Enforcement Administration and to comply with provisions regarding labeling, packaging, and recordkeeping. The rules in Article 2, which deal with dispensing drugs, are consistent with federal law.

13. For a rule made after July 29, 2010, that require issuance of a regulatory permit, license, or agency authorization, whether the rule complies with A.R.S. § 41-1037:

The following rules were made after July 29, 2010, and deal, at least tangentially, with issuance of a regulatory permit, license, or agency authorization: R4-28-103, R4-28-104, R4-28-105, R4-28-107, R4-28-108, R4-28-109, and R4-28-117. The rules deal with a regulatory permit, license, or agency authorization issued to qualified individuals to conduct activities that are substantially similar in nature. The rules comply with A.R.S. § 41-1037.

14. Course of action the agency proposes to take regarding each rule, including the month and year in which the agency anticipates submitting the rules to the Council if the agency determines it is necessary to amend or repeal an existing rule or to make a new rule. If no issues are identified for a rule in the report, the agency may indicate that no action is necessary for the rule:

The Board has drafted rules necessary to implement the statutory changes that go into effect on January 1, 2015. The Board will use this rulemaking to address the issues identified in items 6, 7, and 10. The Board intends to submit the rulemaking to Council by December 2014.