2013 FIVE-YEAR-REVIEW REPORT
ARIZONA MEDICAL BOARD
TITLE 4, CHAPTER 16, ARTICLE 7

FIVE-YEAR-REVIEW REPORT

ARIZONA MEDICAL BOARD

TITLE 4, CHAPTER 16, ARTICLE 7

TABLE OF CONTENTS

Five-Year-Review Overview

The Arizona Medical Board's (Board) primary duty is "to protect the public from unlawful, incompetent, unqualified, impaired or unprofessional practitioners of allopathic medicine through licensure, regulation and rehabilitation of the profession in this state." A.R.S. § 32-1403(A). Legislation was passed in 2007 that required the Board to write rules for office-based surgery using sedation. The rules are contained in A.A.R. Title 4, Chapter 16, Article 7, were approved by the Governor's Regulatory Review Council, and became effective January 8, 2008. Article 7 consists of seven rules that set out requirements for physicians who perform office-based surgery, including provisions for policies and procedures; required equipment; staff education, training, and experience; informed consent; monitoring patients, patient discharge; and emergency and transfer of patients. All of the rules were written to protect the health and safety of patients who undergo office-based surgery using sedation. The Board has reviewed these rules and determined that the rules are effective as written and do not require to be amended or repealed.

Information that is identical for all of the rules

The following information is the same for all of the rules reviewed in this report:

1. **Authorization of the rule by existing statutes**

   All of the rules have general authority in A.R.S. § 32-1403(A)(8) and A.R.S. § 32-1404(D). The rules have specific authority in A.R.S. § 32-1401(20) and 32-1401(27)(tt).

2. **Objective of the rule**

   Each rule was written to protect the health and safety of patients who undergo office-based surgery using sedation. To that end, the analysis for each rule states what it does to achieve this protection.

3. **Analysis of effectiveness in achieving the objective**

   All of the rules are currently effective.

4. **Analysis of consistency with state and federal rules and statutes**

   All of the rules are consistent with state and federal rules and statutes.

5. **Status of enforcement of the rule**

   The Board currently enforces all of the rules.

6. **Analysis of clarity, understandability, and conciseness**

   All of the rules are clear, concise, and understandable.

7. **Written criticisms of the rules received in the last five years**

   The Board has not received any written criticisms of the rules in the last five years.

8. **Comparison of the current economic, small business, and consumer impact statement**

   In this comparison, minimal means less than $1,000, moderate means $1,000 to $10,000, and substantial means more than $10,000.

   The Board made new rules for office-based surgery using sedation in Article 7, which became effective on January 8, 2008. The economic impact statement (EIS) related to the rulemaking is attached. As anticipated by the Board, the rules have had minimal to moderate economic impact on the Board, physicians, other health care professionals, staff members, and patients. Most, if not all, physicians who provided office-based surgery at the time of rulemaking already met the standards provided in the rules. If a physician does not provide office based surgery using sedation and is contemplating performing such surgery, the rules offer standards of care that must be followed for patient safety. The Board has not received any comments from physicians stating that the rules are overly burdensome. The rules have effectively protected the health and safety of patients. The Board currently licenses 22, 219 physicians.

9. **Any analysis submitted to the agency by another person that compares the rule's impact on this state's business competitiveness to the impact on business in other states**

No one has submitted such an analysis to the Board.

10. If applicable, whether the agency completed the course of action indicated in the agency's previous five-year-review report

This is the first five-year-review performed on these rules.

11. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs necessary to achieve the underlying regulatory objective:

The Board has determined that the rules impose the least burden and costs to persons performing office-based surgery.

12. A determination 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:

There is no corresponding federal law so this provision does not apply.

13. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license, or agency authorization, whether the rule complies with A.R.S. § 41-1037 (relating to issuing general permits):

The rule was adopted January 8, 2008, so this provision does not apply.

14. Course of Action

The Board has reviewed these rules and determined that the rules are effective as written and do not require to be amended or repealed.

Article 7. Office-Based Surgery Using Sedation

R4-16-701. Health Care Institutions License

2. Objective of the rule

The objective of the rule is to state when a physician must obtain a health care institution license.

R4-16-702. Administrative Provisions

2. Objective of the rule

The objectives of the rule are to:

a. Establish and implement written policies and procedures;

b. Ensure staff members and health care professionals who assist or participate in office-based surgery using sedation meet educational, training, experience, scope of practice, and licensure requirements;

c. Establish equipment requirements;

d. Ensure informed consent is obtained; and

e. State other jurisdiction and statutory standards that must be met.

R4-16-703. Procedure and Patient Selection

2. Objective of the rule

The objectives of the rule are to require a physician to ensure the office-based surgery using sedation:

a. Can be performed safely because of adequate staff, equipment, and health care professionals;

b. Is of a duration and complexity that allows patient discharge within 24 hours;

c. Is within the education, training and experience of the physician and staff members and health care professionals; and

d. Is not performed under the conditions stated in the rule.

R4-16-704. Sedation Monitoring Standards

2. Objective of the rule

The objective of the rule is to state the requirements for monitoring sedation at different levels of administration.

R4-16-705. Perioperative Period; Patient Discharge

2. Objective of the rule

The objectives of the rule are to require the physician to be physically present in the room where office-based surgery using sedation is performed, state requirements for emergency procedures at different levels of sedation after the surgery is performed, and state discharge requirements.

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

2. Objective of the rule

The objectives of the rule are to require sedation and emergency equipment and drugs; state space requirements in the physician's office; require emergency backup power in the event of a power failure; and require the physician to maintain, test, and inspect all equipment used for office-based surgery using sedation; and maintain documentation of the maintenance.

R4-16-707. **Emergency and Transfer Provisions**

2. Objective of the rule

The objectives of the rule are to require that health care professionals and staff members who participate or assist in office-based surgery using sedation receive the instruction stated in the rule and that the physician does not use any drug or agent that triggers malignant hyperthermia.

2013 FIVE-YEAR-REVIEW REPORT
TITLE 4. PROFESSIONS AND OCCUPATIONS
CHAPTER 16. ARIZONA MEDICAL BOARD
ARTICLE 5. EXECUTIVE DIRECTOR DUTIES

FIVE-YEAR-REVIEW REPORT

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 16. ARIZONA MEDICAL BOARD

ARTICLE 5. EXECUTIVE DIRECTOR DUTIES

TABLE OF CONTENTS

Five-Year-Review Summary

Statutory authority

The Arizona Medical Board (Board) is statutorily vested with the "primary duty to protect the public from unlawful, incompetent, unqualified, impaired or unprofessional practitioners of allopathic medicine through licensure, regulation, and rehabilitation of the profession in this state." A.R.S. § 32-1403(A). A.R.S. § 32-1403(A)(10) allows the Board to delegate to the Board's executive director the Board's authority under A.R.S. § 32-1405 or A.R.S. § 32-1451. A.R.S. § 32-1405 requires the Board to appoint an executive director and sets forth the duties of the executive director. A.R.S. § 32-1451 states the executive director, if delegated by the Board, shall require any combination of mental, physical, or oral or written medical competency examinations of a physician and conduct investigations. A.R.S. § 32-1451 also states the executive director, if delegated by the Board, may require a doctor to undergo assessment by a Board-approved rehabilitative, retraining, or assessment program. The Board has authority to adopt rules pursuant to Title 41, Chapter 6 that are necessary and proper to carry out the purposes of Chapter 16. A.R.S. § 32-1404(D).

The rules

In A.A.C. R4-16-501 through R4-16-510, the Board has established rules clarifying the executive director's duties. On July 28, 1999, the Board voted to delegate the acts promulgated in current Article 5 to the executive director. R4-16-501 through R4-16-505 were made by exempt rulemaking effective August 12, 2003 and recodified to Article 5, effective March 25, 2005. R4-16-506 through R4-16-510 were recodified, effective March 25, 2005. R4-16-501 allows the executive director to require a physician who is under investigation by the Board to submit to a mental, physical, oral, or written medical competency examination under certain conditions and sets forth other investigational interview requirements. R4-16-502 provides the standards for the executive director to refer a case to a formal interview before the Board. R4-16-503 provides for the executive director's responsibilities for requests from physicians for inactive status and license cancellation. R4-16-504 sets forth the conditions under which the executive director may enter into an interim consent agreement with a physician. R4-16-505 sets forth the executive director's responsibilities relating to mediated cases. R4-16-506 contains the provisions and conditions for the executive director to directly refer a case to formal hearing. R4-16-507 contains the provisions and conditions for the executive director to dismiss a complaint.

R4-16-508 contains the provisions and conditions for the executive director to deny a license. R4-16-509 contains the conditions under which the executive director may enter into a non-disciplinary consent agreement. Finally, R4-16-510 contains the provisions for appealing the actions of the executive director.

Proposed course of action

The last five-year-review for the Article 5 rules was conducted by the Board and approved by the Governor's Regulatory Review Council (Council) on November 4, 2008. The Board determined that most of the rules were effective in their current state and determined it would make any changes by December 2011. However, the Board's priority was the physician's assistant rulemaking followed by the Title 4, Chapter 16, Articles 1 and 2 five-year-review-report, which was approved by the Council on May 3, 2011. The Board determined to make changes to the Articles 1 and 2 rules and adjusted priorities accordingly.

Based on this review, the Board believes that while most of the rules are effective in their current state, updating is important. The Arizona Ombudsman-Citizens Aide (ombudsman) conducted an investigation of the Arizona Medical Board beginning in 2012 and issued a lengthy report on October 9, 2013. This five-year-review report was almost entirely completed before the release of the ombudsman report and it must be noted that the ombudsman report does not specifically identify any of the rules contained in this five-year-review report as having been violated. Issues identified by the Board in the five-year-review report are mostly with its definitions and are non-substantive. However, as the Board makes changes to its statutes and rules, it will be giving appropriate consideration to the ombudsman report. The Board has identified its Article 1 (General Provisions) and Article 2 (Licensure) rules as their highest priority and is currently in the drafting stage of those rules. The Board expects to have the Article 1 and Article 2 rules through the rulemaking process by the end of 2014 and will begin working on the Article 5 rules and making changes it determines appropriate thereafter. The Board expects to submit a final rulemaking to the Governor's Regulatory Review Council for the Article 5 rules by December 2015.

Information That is Identical For All Rules

1. Authorization of the rule by existing statute

All of the rules have general authority in A.R.S. § 32-1404(D). Specific authority is stated in the individual rule.

4. Analysis of consistency with state and federal statutes and rules

Except as stated in R4-16-507, all of the rules are consistent with state and federal statutes and rules.

5. Status of enforcement of the rules

Except as stated in R4-16-510, all of the rules are being enforced.

6. Analysis of clarity, conciseness, and understandability

All of the rules are mostly clear, concise, and understandable. Specific analysis of clarity, conciseness, and understandability is stated in the individual rule.

7. Written criticism of the rules received in the last five years

The Board has not received any written criticisms of the rules in the last five years. Please see paragraph 14 for an explanation.

8. Comparison of the current economic, small business, and consumer impact statement

In this comparison, minimal means less than $1,000, moderate means between and $5,000 and substantial means greater than $5,000.

The rules were first made and codified in Article 4 and noticed by final rulemaking at 8 A.A.R. 830, which became effective February 7, 2002. They were later recodified to Article 5, effective March 25, 2004. The Board has attached the economic impact statement for its 2002 rulemaking.

In the economic impact statement, the Board determined the rules would affect the Board, Secretary of State, regulated community, and the public. The Board determined that it would bear minimal costs for writing the rules, fulfilling requirements imposed by the Governor's Regulatory Review Council and Secretary of State, and for notifying and answering questions from the regulated community and interested persons regarding the rulemaking. The Board believed that the costs would be offset by savings incurred by delegating duties to the executive director because the delegations facilitated workflow, improved disciplinary timeliness, and saved on duplicative efforts by the staff and the

Board. The Board determined the costs of the rulemaking would be borne by the Board, not the regulated community, which would benefit from the rules for the reasons stated above.

The economic impact remains as anticipated in the 2002 economic impact statement. The rules have not caused a change to state revenues. After reviewing the rules, the Board estimates that the actual economic impact of the rules is consistent with the economic impact statement submitted with the 2002 rulemaking. In FY 12 the executive director delegated actions consisting of 721 dismissals, 28 interim orders, 1 license denial, and 4 referrals to formal hearing.

9. Any analysis submitted to the agency by another person that compares the rule's impact on this state's business competitiveness to the impact on business in other states:

Such an analysis was not submitted to the Board.

10. If applicable, whether the agency completed the course of action indicated in the agency's previous five-year-review report

The last five-year-review report was approved by GRRC on November 4, 2008. In its report the Board had proposed to amend its rules by December 2011. The Board was unable to make rules because of the 2009 rulemaking moratorium.

11. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs necessary to achieve the underlying regulatory objective:

The Board has determined that the rules impose the least burden and costs.

12. A determination 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:

There is no corresponding federal law, so this provision does not apply.

13. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license, or agency authorization, whether the rule complies with A.R.S. § 41-1037 (relating to issuing general permits):

The rules were adopted before July 29, 2010, so this provision does not apply.

14. Proposed course of action

The last five-year-review for the Article 5 rules was conducted by the Board and approved by the Governor's Regulatory Review Council (Council) on November 4, 2008. The Board determined that most of the rules were effective in their current state and determined it would make any changes by December 2011. However, the Board's priority was the physician's assistant rulemaking followed by the Title 4, Chapter 16, Articles 1 and 2 five-year-review-report, which was approved by the Council on May 3, 2011. The Board determined to make changes to the Articles 1 and 2 rules and adjusted priorities accordingly.

Based on this review, the Board believes that while most of the rules are effective in their current state, updating is important. The Arizona Ombudsman-Citizens Aide (ombudsman) conducted an investigation of the Arizona Medical Board beginning in 2012 and issued a lengthy report on October 9, 2013. This five-year-review report was almost entirely completed before the release of the ombudsman report and it must be noted that the ombudsman report does not specifically identify any of the rules contained in this five-year-review report as having been violated. Issues identified by the Board in the five-year-review report are mostly with its definitions and are non-substantive. However, as the Board makes changes to its statutes and rules, it will be giving appropriate consideration to the ombudsman report. The Board has identified its Article 1 (General Provisions) and Article 2 (Licensure) rules as their highest priority and is currently in the drafting stage of those rules. The Board expects to have the Article 1 and Article 2 rules through the rulemaking process by the end of 2014 and will begin working on the Article 5 rules and making changes it determines appropriate thereafter. The Board expects to submit a final rulemaking to the Governor's Regulatory Review Council for the Article 5 rules by December 2015.

Information That is Identical Within Groups of Rules

3. Analysis of effectiveness in achieving the objective

The following rules are effective in achieving their objective:

R4-16-505

R4-16-507

The following rules are mostly effective in achieving their objective:

R4-16-501

R4-16-502

R4-16-503

R4-16-504

R4-16-506

R4-16-508

R4-16-509

The following rule is partially effective in achieving its objective:

R4-16-510

R4-16-501. Interim Evaluation and Investigational Interview

1. Authorization of the rule by existing statute

A.R.S. §§ 32-1405 (C)(12), 32-1451(C)

2. Objective of the rule

The objectives of the rule are the following for the purpose of determining whether a physician is mentally or physically competent to practice:

a. Allow the executive director to require a physician who is under investigation by the Board to submit to a mental, physical, oral, or written medical competency examination after following the directives in the rule;

b. Allow the executive director to request a physician to attend an investigational interview after following the directives in the rule; and

c. Require the executive director to report at each regularly scheduled Board meeting, a summary of the number and type of evaluations ordered and completed since the preceding Board meeting.

3. Analysis of effectiveness in achieving the objective

The rule is mostly effective but could be more effective for the reasons stated in paragraph 6.

6. Analysis of clarity, conciseness, and understandability

Most of the rule is clear, concise, and understandable. The label contains the phrase "interim evaluation" that is not used in the rule and the phrases "investigation supervisor" and "supervising medical consultant" are not defined.

14. Proposed course of action

The Board will delete the phrase "interim evaluation" and define terms when it amends the rule.

R4-16-502. Direct Referral to Formal Interview

1. Authorization of the rule by existing statute

A.R.S. § 32-1405(C)(27)

2. Objective of the rule

The objective of the rule is to require the executive director to refer a case to formal interview if the medical consultant, investigative staff, and lead Board member concur after review of the case that a formal interview is appropriate.

3. Analysis of effectiveness in achieving the objective

The rule is mostly effective but could be more effective for the reason stated in paragraph 6.

6. Analysis of clarity, conciseness, and understandability

Most of the rule is clear, concise, and understandable, but "case", "investigative staff", "medical consultant", and "lead board member" should be defined.

14. Proposed course of action

The Board will amend the rule to address the issues raised in paragraph 6.

R4-16-503. Request for Inactive Status and License Cancellation

1. Authorization of the rule by existing statute

A.R.S. § 32-1405(C)(26)

2. Objective of the rule

The objectives of the rule are to require the executive director to:

a. Grant a physician's request for inactive status or cancellation if the physician meets the requirements in A.R.S. § 32-1431 and 32-1433 and is not participating in a program defined in A.R.S. § 32-1452 (substance abuse treatment and rehabilitation program); and

b. Report at each regularly scheduled Board meeting a list of the individuals granted inactive or cancelled license status since the preceding Board meeting.

3. Analysis of effectiveness in achieving the objective

The rule is mostly effective but could be more effective for the reasons stated in paragraph 6.

6. Analysis of clarity, conciseness, and understandability

Most of the rule is clear, concise, and understandable, but the rule should state that the physician is required to meet the requirements in A.R.S. § 32-1431 "or" 32-1433 rather than the requirements in A.R.S. § 32-1431 "and" 1433.

14. Proposed course of action

The Board will amend the rule to address the issue raised in paragraph 6.

R4-16-504. Interim Consent Agreement

1. Authorization of the rule by existing statute

A.R.S. § 32-1405(C)(25)

2. Objective of the rule

The objective of the rule is to allow the executive director to enter into an interim consent agreement with a physician if there is evidence that a restriction is needed to mitigate imminent danger to the public health and safety and the investigative staff, the medical consultant, and lead board member agree that a consent agreement is appropriate.

3. Analysis of effectiveness in achieving the objective

The rule is mostly effective but could be more effective for the reasons stated in 6.

6. Analysis of clarity, conciseness, and understandability

Most of the rule is clear, concise, and understandable but the word "interim" should either be deleted or defined and the phrase "lead board member" should be defined. The rule could clarify the meaning of "investigative staff" and "medical consultant".

14. Proposed course of action

The Board will amend the rule to address the issues raised in paragraph 6.

R4-16-505. Mediated Case

1. Authorization of the rule by existing statute

A.R.S. § 32-1405(C)(23)

2. Objective of the rule

The objectives of the rule are to require the executive director to:

a. Close a case resolved through mediation; and

b. Report at each regularly scheduled Board meeting a list of the physicians whose cases are resolved through mediation since the preceding Board meeting.

3. Analysis of effectiveness in achieving the objective

The rule is mostly effective but could be more effective for the reason stated in paragraph 6.

6. Analysis of clarity, conciseness, and understandability

Most of the rule is clear, concise, and understandable, but the word "case" should be defined.

14. Proposed course of action

The Board will amend the rule to address the issue in paragraph 6.

R4-16-506. Referral to Formal Hearing

1. Authorization of the rule by existing statute

A.R.S. § 32-1405(C)(22)

2. Objective of the rule

The objectives of the rule are to:

a. Allow the executive director to directly refer a case to a formal hearing if the investigative staff, medical consultant, and lead board member concur that a hearing is appropriate after review of the physician's case; and

b. Provide at each regularly scheduled Board meeting a list of the physicians whose cases were referred to formal hearing since the preceding Board meeting and whether the referral is for revocation, suspension, a result of an out-of-state disciplinary action, or due to complexity of the case.

3. Analysis of effectiveness in achieving the objective

The rule is mostly effective but could be more effective for the reason stated in paragraph 6.

6. Analysis of clarity, conciseness, and understandability

Most of the rule is clear, concise, and understandable, but: "case", "investigative staff", and "medical consultant", and "lead board member" should be defined.

14. Proposed course of action

The Board will amend the rule to address the issues raised in paragraph 6.

R4-16-507. Dismissal of Complaint

1. Authorization of the rule by existing statute

A.R.S. § 32-1405(C)(21)

2. Objective of the rule

The objectives of the rule are to require the executive director:

a. With concurrence of the investigative staff, to dismiss a case if the review shows the case is without merit and dismissal is appropriate; and

b. Provide to the Board at each regularly scheduled Board meeting, a list of the physicians about whom complaints were dismissed since the preceding Board meeting.

3. Analysis of effectiveness in achieving the objective

The rule is mostly effective but could be more effective for the reasons stated in paragraphs 4 and 6.

4. Analysis of consistency with state and federal statutes and rules

Although the rule is consistent with A.R.S. § 32-1405(C)(21), it should be noted that the statute also requires the executive director to submit a report of the cases dismissed, including the complaint numbers and investigative time line. The Board follows both the statute and the rule.

6. Analysis of clarity, conciseness, and understandability

Most of the rule is clear, concise, and understandable, but "case" and "investigative staff" could be defined.

14. Proposed course of action

The Board will amend the rule to address the issues raised in paragraphs 4 and 6.

R4-16-508. Denial of License

1. Authorization of the rule by existing statute

A.R.S. §§ 32-1405(C)(5), 32-1405(C)(28)

2. Objective of the rule

The objectives of the rule are to require the executive director to:

a. Deny a license to an applicant who does not meet the statutory requirements for licensure if the executive director in consultation with the investigative staff and medical consultant concur after reviewing the application that the applicant does not meet the statutory requirements; and

b. Provide to the Board at each regularly scheduled Board meeting a list of the physicians whose applications were denied since the preceding Board meeting.

3. Analysis of effectiveness in achieving the objective

The rule is mostly effective but could be more effective for the reason stated in paragraph 6.

6. Analysis of clarity, conciseness, and understandability

Most of the rule is clear, concise, and understandable, but "investigative staff" and "medical consultant" should be defined.

14. Proposed course of action

The Board will amend the rule to address the issues raised in paragraph 6.

R4-16-509. Non-disciplinary Consent Agreement

1. Authorization of the rule by existing statute

A.R.S. § 32-1451(F)

2. Objective of the rule

The objective of the rule is to allow the executive director to enter into a consent agreement according to A.R.S. § 32-1451(F) and the investigative staff, the medical consultant, and the lead Board member concur that a consent agreement is appropriate.

3. Analysis of effectiveness in achieving the objective

The rule is mostly effective but could be more effective for the reason stated in paragraph 6.

6. Analysis of clarity, conciseness, and understandability

Most of the rule is clear, concise, and understandable, but "investigative staff", and "medical consultant" and "lead board member" should be defined.

14. Proposed course of action

The Board will amend the rule to address the issues raised in paragraph 6.

R4-16-510. Appealing Executive Director Actions

1. Authorization of the rule by existing statute

A.R.S. § 32-1405(E)

2. Objective of the rule

The objective of the rule is to set forth the process for an aggrieved person to appeal an action taken by the executive director.

3. Analysis of effectiveness in achieving the objective

The rule is partially effective for the reasons stated in paragraph 6 and the following: It is unclear whether the Board reviews an appeal of the executive director's decision as a prerequisite to filing an appeal with the Office of Administrative Hearings (OAH). Additionally, the grounds for review are narrower in this rule as opposed to the grounds for review in R4-16-103 or the grounds for review if the decision was appealed to OAH. The Board will determine which direction it will take when it amends the rule.

5. Status of enforcement of the rule

Most of the rule is enforced according to the rule as written. The Board should clarify the issues raised in paragraphs 3 and 6 when it amends the rule.

6. Analysis of clarity, conciseness, and understandability

Most of the rule is clear, concise, and understandable, but the second sentence in subsection (D) is confusing because it is unclear whether the provision for filing a written request in subsection (A) applies after the 30 or 35 day period has passed.

14. <u>Proposed course of action</u>

The Board will amend the rule to address the issues raised in paragraphs 3, 5, and 6.

ARIZONA MEDICAL BOARD

FIVE-YEAR-REVIEW REPORT
4 A.A.C. 16, ARTICLES 3 AND 6

JUNE 2015

INTRODUCTION

The Arizona Medical Board's (Agency) mission is to protect public safety through the judicious licensing, regulation and education of all allopathic physicians. A.R.S. § 32-1403(A) indicates the primary duty of the Agency is to protect the public from unlawful, incompetent, unqualified, impaired, or unprofessional practitioners of allopathic medicine through licensure, regulation, and rehabilitation.

Allopathic medicine is the system of medical practice that treats disease by using remedies that produce effects different from or incompatible with those produced by the disease under treatment.

The Agency shares an executive director and staff with the Regulatory Board of Physician Assistants (See A.R.S. § 32-2505). For FY 2015, the Agency is authorized to have 58.5 FTE staff members but due to budget constraints, currently has only 40.

In response to a 2013 report issued by the Arizona Office of the Ombudsman-Citizens' Aide (See item 7 of this report), the Agency reformed its licensing process. Key aspects of the reforms include fingerprinting and investigating an applicant's credentials. With a more stringent licensing process, the average time to approve a license increased from 13.5 days to 26.5 days in FY 2014 over FY 2013. Additionally, the number of complaints opened increased by 37%, nearly doubling the number of open investigations by the end of FY 2014. Throughout the first four months of FY 2015, the agency opened 609 complaints, 58% higher than the previous year. The Agency collected $5,621,239 in licensing fees during the current fiscal year and was appropriated $5,741,000. The Agency was appropriated an additional $684,000 for personnel funding during the next fiscal year. By supplementing staff to proper levels, these funds will enable the Agency to reduce the response time to license applications and address complaints and investigative matters in a timely manner.

Statute that generally authorizes the agency to make rules: A.R.S. § 32-1404(D)

1. Specific statute authorizing the rule:

   Article 3

   R4-16-301. A.R.S. § 32-1491(A)(4)

   R4-16-302. A.R.S. § 32-1491(A)(3) and (E)

   R4-16-303. A.R.S. § 32-1491(C) and (D)

   R4-16-304. A.R.S. § 32-1491(E)

   R4-16-305. A.R.S. § 32-1491(E)

   Article 6

   R4-16-604. A.R.S. §§ 32-1401(27) and 32-1403(A)(2) and (A)(5)

   R4-16-605. A.R.S. §§ 32-1401(27) and 32-1403(A)(2) and (A)(5)

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

   Article 3

   R4-16-301. Registration and Renewal: The objective of this rule is to specify the procedure to apply to register to dispense controlled substances and prescription-only drugs and devices and to renew a registration. This increases efficiency by enabling a physician to submit an administratively complete registration form and avoid having the registration expire.

   R4-16-302. Packaging and Inventory; Exception: The objective of this rule is to specify the secure manner in which controlled substances and prescription-only drugs must be stored, the information that must be on the label of a dispensed controlled substance or prescription-only drug, and the information required in an ongoing dispensing log. These provisions protect the public by minimizing the possibility that controlled substances or prescription-only drugs are available without medical supervision. The provisions also protect the physician from potential liability.

   R4-16-303. Prescribing and Dispensing Requirements: The objective of this rule is to specify the information that must be recorded in a patient's record when a physician dispenses a controlled substance or prescription-only drug or device to the patient and steps

required to ensure that the dispensed controlled substance or prescription-only drug or device is the medication or device intended. These provisions protect the public by ensuring the medication or device dispensed is the medication or device prescribed. The provisions also protect the physician from potential liability.

R4-16-304. Recordkeeping and Reporting Shortages: The objective of this rule is to specify records that must be maintained regarding purchase and dispensing of controlled substances and prescription-only drugs. The rule also specifies the entities a physician is required to notify when the physician discovers loss or theft of a controlled substance or dangerous drug. These provisions protect the public by minimizing the possibility that controlled substances and prescription-only drugs are available without medical supervision.

R4-16-305. Inspections; Denial and Revocation: The objective of this rule is to specify the possible disciplinary consequences for a physician who fails to cooperate with the Agency or allow access to the physician's office and records. These provisions enable a physician to avoid having the physician's dispensing registration denied or revoked.

Article 6

R4-16-604. Aggravating Factors Considered in Disciplinary Actions: The objective of this rule is to specify the key aggravating factors considered by the Agency when determining the degree of discipline to impose on a physician. This information enables a physician to prepare to address the factors at a disciplinary hearing and enables members of the Agency to act consistently from one disciplinary hearing to another.

R4-16-605. Mitigating Factors Considered in Disciplinary Actions: The objective of this rule is to specify the key mitigating factors considered by the Agency when determining the degree of discipline to impose on a physician. This information enables a physician to prepare to address the factors at a disciplinary hearing and enables members of the Agency to act consistently from one disciplinary hearing to another.

3. Effectiveness of the rule in achieving the objective including a summary of any available data supporting the conclusion:

   Although there are some issues with consistency and enforcement, which are discussed in items 4 and 5, the Agency believes the rules are generally effective in achieving their objectives. It bases this conclusion of the fact it is able to issue dispensing registrations as required under statute and protect the public from unlawful, incompetent, unqualified, impaired, or unprofessional practitioners of allopathic medicine.

4. Consistency of the rule 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 Agency identified the following issues regarding consistency of the rules with statute or other rules:

   Article 3: The American Recovery and Reinvestment Act of 2009 requires all public and private health care providers to make meaningful use of electronic medical records. The use of electronic medical records needs to be incorporated into Article 3.

   R4-16-301(A)(3): This subsection refers to a fee required in A.R.S. § 32-1436. Statute does not require a fee. Rather, it authorizes the Agency to establish fees. The correct citation for a required fee is R4-16-205.

   A.R.S. § 32-1921(E) provides that a licensed physician who dispenses medication and devices only at a public health facility or qualifying community health center is exempt from paying a fee to register with the Agency. The Agency needs to amend R4-16-301(A)(3) to indicate this exemption.

   R4-16-301(A) and R4-16-302(A): All internal cross references to the Board of Pharmacy statutes are incorrect.

   R4-16-303(E): The definition of “dispensing” contained in this subsection is different from that contained in A.R.S. §§ 32-1401(19) and 32-1491(F).

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

   The Agency enforces the rules in Articles 3 and 6 as written. The Agency experiences some difficulty enforcing R4-16-604 and R4-16-605 because of the subjective nature of the terms "dishonest or selfish motive."

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

   Although the rules are generally clear, concise, and understandable and consistent with current rule writing standards, they can be improved. In R4-16-604 and R4-16-605, the terms "dishonest or selfish motive," are subjective making them difficult to use in a consistent manner and the phrase "but not limited to" is redundant because "including" is not a term of exclusion.

7. Summary of written criticisms of the rule received by the agency with the past five years, including letters, memoranda, reports, written analyses submitted to the agency questioning whether the rule is 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 rule is discriminatory, unfair, unclear, inconsistent with statute or beyond the authority of the agency to enact, and the result of the litigation of administrative proceedings:

   In 2013, the Arizona Office of the Ombudsman-Citizens' Aide conducted an investigation in response to allegations that the Agency may have inappropriately approved or processed applications for initial or renewal licenses, locum tenens registrations, and dispensing registrations and concluded the Agency needed to ascertain which applicants, if any, the Agency approved in error and initiate processes to correct the errors. The legislature appropriated monies to hire a vendor to conduct a review of license applications received by the Agency from October 1, 2011 through February 5, 2014. The Office of the Auditor General also conducted an in-depth review of the Agency's licensing policies and procedures. In a report issued in April 2015, the Auditor General indicated the Agency has addressed identified deficiencies in it licensing processes including inadequate application forms, inadequate policies for obtaining necessary application documentation, and

inadequate policies and procedures to guide Agency staff when reviewing and processing applications.

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

   The rules in Article 3 were last substantively amended in a rulemaking that took effect on May 9, 2002. The rules were re-codified from Article 2 on March 25, 2005. The Agency believes that its conclusion that the 2002 rulemaking would have minimal economic impact on licensees who register to dispense drugs was generally correct. As of April 2015, there are 22,431 licensed physicians in Arizona. During 2014, only 109 of these licensees (.5%) registered to dispense drugs. None of the physicians registered to dispense drugs reports loss or theft of controlled or dangerous drugs in 2014.

   The rules in Article 6, which went into effect on August 12, 2003, were made under an exemption from the Administrative Procedure Act (See Laws 2002, Chapter 37, § 6) so no economic, small business, and consumer impact statement was prepared. However, when the rules were made, the Agency concluded the economic impact would be positive for both physicians and the public because the rules establish guidelines for the Agency to use when imposing sanctions on licensees. The Agency believes its conclusion regarding the economic impact of the rules was accurate. The rules were re-codified from Article 5 to Article 6 on March 25, 2005. During FY2014, 1,292 complaints were opened alleging some form of unprofessional conduct, which includes questionable care (See A.R.S. § 32-1401(27)) by licensed physicians. Disciplinary action was taken against 34 physicians in FY2014. The discipline generally was a letter of reprimand with probation. The Agency revoked the licenses of two physicians and six surrendered a license.

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 has been submitted.

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

    Council approved a 5YRR of Articles 3 and 6 on September 14, 2010. In the report, the Agency indicated it would amend R4-16-301, R4-16-303, R4-16-604, and R4-16-605 by June 2012. The Agency, which has had to deal with staff turn-over and high priority matters resulting from the 2013 report by the Arizona Office of the Ombudsman-Citizens' Aide, has yet to make the necessary changes. Current Agency leadership is committed to updating the rules specified in item 14.

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

    Many of the costs associated with registering with the Agency to dispense drugs and devices result from statute rather than rule. A.R.S. § 32-1491 requires the Agency to make rules regarding labeling, recordkeeping, storage, and packaging of drugs. The Agency made the rules in Article 3 in response to this statutory directive. The Agency determined that the burdens imposed on applicants and licensees by the requirements in Article 3 are outweighed by their benefits. The requirements are necessary to protect the public from incorrect use of controlled and dangerous substances and to protect licensees from potential liability.

    The minimal costs associated with the rules in Article 6 are imposed on only the Agency. The rules are not applicable to a licensee who is not alleged to have engaged in unprofessional conduct.

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:

None of the rules is more stringent than federal law. There are numerous federal laws relating to the provision of health care, including those regarding prescribing controlled substances, but the laws are not applicable to the Agency's rules. A licensed physician who registers with the Agency to dispense controlled substances is required to be registered also with the U.S. Drug Enforcement Administration.

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:

    This item is not applicable because none of the reviewed rules was made after July 29, 2010.

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 Agency intends to seek an exception to Executive Order 2015-01 so it can amend both rules in Article 6 and R4-16-301 through R4-16-303 to address issues identified in this report. The Agency intends to complete the required rule amendments by December 2016.