

NOTICES OF FINAL RULEMAKING

The Administrative Procedure Act requires the publication of the final rules of the state's agencies. Final rules are those which have appeared in the *Register* first as proposed rules and have been through the formal rulemaking process including approval by the Governor's Regulatory Review Council or the Attorney General. The Secretary of State shall publish the notice along with the Preamble and the full text in the next available issue of the *Register* after the final rules have been submitted for filing and publication.

NOTICE OF FINAL RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

[R08-262]

PREAMBLE

- 1. Sections Affected**
R4-23-110
R4-23-404
- Rulemaking Action**
Amend
Amend
- 2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):**
Authorizing statutes: A.R.S. §§ 32-1901.01(B)(11), (12), (24), (25), (26), (27) and 32-1904(A)(1)
Implementing statutes: A.R.S. §§ 32-1904(B)(5) and 32-1968(D)
- 3. The effective date of the rules:**
October 4, 2008
- 4. A list of all previous notices appearing in the *Register* addressing the proposed rules:**
Notice of Rulemaking Docket Opening: 13 A.A.R. 1279, April 6, 2007
Notice of Proposed Rulemaking: 13 A.A.R. 4369, December 14, 2007
Notice of Termination of Rulemaking: 14 A.A.R. 459, February 15, 2008
Notice of Rulemaking Docket Opening: 14 A.A.R. 534, February 22, 2008
Notice of Proposed Rulemaking: 14 A.A.R. 562, February 29, 2008
- 5. The name and address of agency personnel with whom persons may communicate regarding the rules:**
Name: Dean Wright, Compliance Officer
Address: Board of Pharmacy
1700 W. Washington St., Suite 250
Phoenix, AZ 85007
Telephone: (602) 771-2727
Fax: (602) 771-2749
E-mail: dwright@azpharmacy.gov
- 6. An explanation of the rules, including the agency's reasons for initiating the rules:**
A.R.S. § 32-1968(D) specifies that any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail or the internet is misbranded. A.R.S. § 32-1965(1) states that selling any drug that is misbranded is prohibited. According to A.R.S. § 32-1996(A), a person who sells a misbranded drug is guilty of either a class 2 misdemeanor or a class 5 felony based on intent. A.R.S. § 32-1901.01(B)(12) states that a pharmacist or intern is guilty of unprofessional conduct for knowingly dispensing a drug on a prescription order that was issued in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail or the internet. The Board intends to amend R4-23-404 (Unethical Practices) by adding language to specifically address the issue of dispensing prescriptions received from a business conducted by mail or the internet, specifically prescription orders based on an internet-based questionnaire or internet-based consultation all without a valid preexisting medical practitioner-patient relationship. The Board published a Notice of Rulemaking Docket Opening regarding this issue on April 6, 2007 and published a Notice of Proposed Rulemaking on December 14, 2007. Subsequently on January 14, 2008, the Board

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held a public hearing regarding the proposed rulemaking. Based on comments from the public hearing, the Board decided to remove some language and add a new definition for “medical practitioner-patient relationship” to R4-23-110. Because Article 1 was not opened in the original Notice of Rulemaking Docket Opening, the Board decided to terminate the original docket and open a docket to include Article 1, (Administration) and specifically Section R4-23-110 (Definitions). The original docket was terminated on February 15, 2008. The rules include format, style, and grammar necessary to comply with the current rules of the Secretary of State and Governor’s Regulatory Review Council.

The Board believes that approval of this rulemaking benefits the public and the pharmacy community by clearly establishing the standards for professional conduct appropriate to the establishment and maintenance of a high standard of integrity and dignity in the profession of pharmacy.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The agency did not review or rely on any study relevant to the rules.

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

Not applicable

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

The amended rules will impact the Board, pharmacists, and the public. The rules’ impact on the Board will be the usual rulemaking-related costs, which are minimal. The Board estimates the amended rules will have no economic impact on pharmacies or pharmacists, because the rule’s changes clarify the statutory language that has been in place for over 12 years.

The public, Board, and pharmacists benefit from rules that are clear, concise, and understandable. The rules benefit the public and the pharmacy community by clearly establishing the standards for professional conduct appropriate to the establishment and maintenance of a high standard of integrity and dignity in the profession of pharmacy.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

There are no substantial changes in the final rules from the proposed rules. There are minor changes to style, format, grammar, and punctuation requested by G.R.R.C. staff.

11. A summary of the comments made regarding the rules and the agency response to them:

A public hearing was held March 31, 2008. Janet Elliott representing the Arizona Community Pharmacy Committee attended the public hearing. Ms. Elliott provided written comment from The Arizona Community Pharmacy Committee voicing support for the rulemaking. No other comments were received.

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

Not applicable

13. Any material incorporated by reference and its location in the rules:

None

14. Were these rules previously approved as emergency rules?

No

15. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 1. ADMINISTRATION

Section
R4-23-110. Definitions

ARTICLE 4. PROFESSIONAL PRACTICES

Section
R4-23-404. Unethical Practices

ARTICLE 1. ADMINISTRATION

R4-23-110. Definitions

In addition to definitions in A.R.S. § 32-1901, the following definitions apply to 4 A.A.C. 23:

- “Active ingredient” No change
- “Alternate physician” No change
- “Approved course in pharmacy law” No change
- “Approved Provider” No change
- “Authentication of product history” No change
- “Automated storage and distribution system” No change
- “Batch” No change
- “Beyond-use date” No change
- “Biological safety cabinet” No change
- “Care-giver” No change
- “Community pharmacy” No change
- “Component” No change
- “Compounding and dispensing counter” No change
- “Computer system” No change
- “Computer system audit” No change
- “Contact hour” No change
- “Container” No change
- “Continuing education” No change
- “Continuing education activity” No change
- “Continuing education unit” or “CEU” No change
- “Correctional facility” No change
- “CRT” No change
- “Current good compounding practices” No change
- “Current good manufacturing practice” No change
- “Cytotoxic” No change
- “Day” No change
- “DEA” No change
- “Delinquent license” No change
- “Dietary supplement” No change
- “Digital signature” No change
- “Dispensing pharmacist” No change
- “Drug sample” No change
- “Drug therapy management” No change
- “Drug therapy management agreement” No change
- “Electronic signature” No change
- “Eligible patient” No change
- “Extreme emergency” No change
- “FDA” No change
- “Immediate notice” No change
- “Inactive ingredient” No change
- “Internal test assessment” No change
- “ISO Class 5 environment” No change
- “ISO Class 7 environment” No change
- “Limited-service correctional pharmacy” No change

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- “Limited-service long-term care pharmacy” No change
- “Limited-service mail-order pharmacy” No change
- “Limited-service nuclear pharmacy” No change
- “Limited-service pharmacy permittee” No change
- “Limited-service sterile pharmaceutical products pharmacy” No change
- “Long-term care consultant pharmacist” No change
- “Long-term care facility” or “LTCF” No change
- “Lot” No change
- “Lot number” or “control number” No change
- “Materials approval unit” No change
- “Mechanical counting device for a drug in solid, oral dosage form” No change
- “Mechanical storage and counting device for a drug in solid, oral dosage form” No change
- “Mediated instruction” No change

“Medical practitioner-patient relationship” means that before prescribing, dispensing, or administering a prescription-only drug, prescription-only device, or controlled substance to a person, a medical practitioner, as defined in A.R.S. § 32-1901, shall first conduct a physical examination of that person or have previously conducted a physical examination. This subdivision does not apply to:

A medical practitioner who provides temporary patient supervision on behalf of the patient’s regular treating medical practitioner;

Emergency medical situations as defined in A.R.S. § 41-1831;

Prescriptions written to prepare a patient for a medical examination; or

Prescriptions written, prescription-only drugs, prescription-only devices, or controlled substances issued for use by a county or tribal public health department for immunization programs, emergency treatment, in response to an infectious disease investigation, public health emergency, infectious disease outbreak or act of bioterrorism. For purposes of this item, “bioterrorism” has the same meaning as in A.R.S. § 36-781.

- “MPJE” No change
- “NABP” No change
- “NABPLEX” No change
- “NAPLEX” No change
- “Order” No change
- “Other designated personnel” No change
- “Outpatient” No change
- “Outpatient setting” No change
- “Patient profile” No change
- “Pharmaceutical patient care services” No change
- “Pharmaceutical product” No change
- “Pharmacist-administered immunizations training program” No change
- “Pharmacy counter working area” No change
- “Pharmacy law continuing education” No change
- “Pharmacy permittee” No change
- “Precursor chemical” No change
- “Prepackaged drug” No change
- “Prep area” No change
- “Proprietor” No change
- “Provider pharmacy” No change
- “Radiopharmaceutical” No change
- “Radiopharmaceutical quality assurance” No change
- “Radiopharmaceutical services” No change

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- “Red C stamp” No change
- “Refill” No change
- “Regulated chemical” No change
- “Remodel” No change
- “Remote drug storage area” No change
- “Resident” No change
- “Responsible person” No change
- “Score transfer” No change
- “Security paper” No change
- “Shared order filling” No change
- “Shared order processing” No change
- “Shared services” No change
- “Sight-readable” No change
- “Single-drug audit” No change
- “Single-drug usage report” No change
- “Standard-risk sterile pharmaceutical product” No change
- “Sterile pharmaceutical product” No change
- “Strength” No change
- “Substantial-risk sterile pharmaceutical product” No change
- “Supervision” No change
- “Supervisory physician” No change
- “Supplying” No change
- “Support personnel” No change
- “Transfill” No change
- “Verified signature” or “signature verifying” No change
- “Wholesale distribution” No change
- “Wholesale distributor” No change

ARTICLE 4. PROFESSIONAL PRACTICES

R4-23-404. Unethical Practices

- A.** No change
 - 1. No change
 - 2. No change
 - a. No change
 - b. No change
- B.** No change
 - 1. No change
 - 2. No change
- C.** No change
- D.** No change
 - 1. No change
 - 2. No change
 - 3. No change
- E.** No change
 - 1. No change
 - 2. No change
 - 3. No change
- F.** Drugs dispensed in the course of the conduct of a business of dispensing drugs through diagnosis by mail or the internet.
 - 1. A pharmacist shall not dispense a drug from a prescription order if the pharmacist has knowledge, or reasonably should know under the circumstances, that the prescription order was issued on the basis of an internet-based questionnaire or an internet-based consultation without a medical practitioner-patient relationship as defined in R4-23-110.

2. A pharmacist who dispenses a prescription-only drug, prescription-only device, or controlled substance in violation of this Section is engaging in unethical conduct in violation of A.R.S. § 32-1901.01.

NOTICE OF FINAL RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

[R08-259]

PREAMBLE

1. Sections Affected

R4-23-110
Article 5
R4-23-501
R4-23-502
R4-23-503
R4-23-504
R4-23-505

Rulemaking Action

Amend
New Article
New Section
New Section
New Section
New Section
New Section

2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rule is implementing (specific):

Authorizing statutes: A.R.S. §§ 32-1904(A)(1) and 36-2602

Implementing statutes: A.R.S. §§ 36-2603, 36-2604, 36-2605, 36-2606, 36-2607, 36-2608, 36-2609, and 36-2610

3. The effective date of the rules:

October 4, 2008

4. A list of all previous notices appearing in the Register addressing the proposed rule:

Notice of Rulemaking Docket Opening: 13 A.A.R. 3155, September 14, 2007

Notice of Proposed Rulemaking: 13 A.A.R. 4362, December 14, 2007

Notice of Supplemental Proposed Rulemaking: 14 A.A.R. 494, February 22, 2008

Notice of Supplemental Proposed Rulemaking: 14 A.A.R. 1233, April 18, 2008

5. The name and address of agency personnel with whom persons may communicate regarding the rule:

Name: Dean Wright, Compliance Officer

Address: Board of Pharmacy
1700 W. Washington St., Suite 250
Phoenix, AZ 85007

Telephone: (602) 771-2727

Fax: (602) 771-2749

E-mail: dwright@azpharmacy.gov

6. An explanation of the rule, including the agency's reasons for initiating the rule:

During the 48th Legislative Session, the Legislature passed H.B. 2136. The bill requires the Board to adopt rules establishing a controlled substances prescription monitoring program that includes a computerized central database tracking system to track the prescribing, dispensing, and consumption of Schedule II, III, and IV controlled substances that are dispensed by a medical practitioner or pharmacy that holds a valid license or permit issued under A.R.S. Title 32. Any necessary new definitions will be placed in R4-23-110 (Definitions). The new rules will be placed in a new Article 5 (Controlled Substances Prescription Monitoring Program) with new Sections for: program registration, requirements for data format and transmission, access to program data, computerized central database tracking system task force, and reports. The rules will include format, style, and grammar necessary to comply with the current rules of the Secretary of State and Governor's Regulatory Review Council.

The Board believes that approval of the rules benefits the public and the pharmacy and medical communities by establishing a central repository of all prescriptions dispensed for Schedule II, III, and IV controlled substances in Arizona. The program will improve the state's ability to identify controlled substance abusers or misusers and refer them to treatment, and to identify and stop diversion of prescription drugs in an efficient and cost effective manner that will not impede the appropriate medical utilization of controlled substances.

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7. A reference to any study relevant to the rule that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The agency did not review or rely on any study relevant to the rule.

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

Not applicable

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

The proposed rules will impact the Board, medical practitioners, pharmacies, pharmacists, and the public. The proposed rule's impact on the Board will be the usual rulemaking-related costs, which are minimal. The Board estimates the cost of the program will be from \$200,000 to \$400,000 per year. The costs of the program will be borne by the Board through an annual appropriation of \$395,795 from the Board's Pharmacy Fund. The Board will seek additional federal grants when available to help pay the costs of the program.

The Board estimates the proposed rules will have minimal to moderate economic impact on pharmacies or pharmacists. The cost to pharmacies will be to prepare and transmit the prescription data to the Board. The majority of pharmacies already transmit similar data in other states with monitoring programs. The few Arizona pharmacies that do not have a computer will be required to transmit the data through use of a universal claim form. There will be a cost in man-hours to manually prepare and transmit the data. The Board estimates this cost will be from \$0 to \$10 per day equaling an annual additional cost of from \$0 to \$2,600.

The Board estimates the proposed rules will have minimal to moderate economic impact on medical practitioners. Those medical practitioners who dispense Schedule II, III, and IV controlled substances to patients will be required to transmit prescription data to the Board. Those medical practitioners without computers will be required to manually transmit the data, which will require a staff person to complete a type of universal claim form. There will be a cost in man-hours to prepare and transmit the data. The Board estimates this additional cost may apply to approximately 2,000 of the estimated 24,000 medical practitioners licensed to practice medicine in Arizona. The Board estimates an average medical practice will need an additional one to two man-hours to process the prescription data at a cost of from \$0 to \$25 per day, equaling an additional annual cost of from \$0 to \$6,500.

The public, Board, and pharmacists benefit from rules that are clear, concise, and understandable. The Board rules benefit the public and the pharmacy and medical communities by establishing a central repository of all prescriptions dispensed for Schedule II, III, and IV controlled substances in Arizona. The program will improve the state's ability to identify controlled substance abusers or misusers and refer them to treatment, and to identify and stop diversion of prescription drugs in an efficient and cost effective manner that will not impede the appropriate medical utilization of licit controlled substances.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

A public hearing on the Notice of Proposed Rulemaking published on December 14, 2007 was held on January 14, 2008. As a result of that public hearing, Sections R4-23-502(A), R4-23-503(A), R4-23-503(C)(3), (4), and (5), and R4-23-505(C) were changed to add the words "or its designee" after the word "Board." These changes are necessary to make the language consistent with the language of the other Sections in the rulemaking, such as R4-23-502(B), (C), and (D) and R4-23-505(A). These changes are also necessary to be consistent with the Board's intent to have the program use a contracted vendor to collect, store, and manage the data and provide web-based services. These changes are also necessary to address a comment made by the public requesting language clarifying that the prescription information submitted or reports provided will go to or come from the Board or its designee. The Board feels that these final changes are not substantial nor do they change the intent from the proposed rulemaking.

Based on the public comments the Board changed R4-23-502(A)(3) by removing the words "name," "strength," and "dosage form." Based on the public comments, the Board changed R4-23-502(A)(7) by adding the words "identified as cash or third party" after the word "payment." The Board feels that these changes are not substantial, but rather provide a rule that is clear and understandable and not duplicative. During the public hearing, the Board staff realized that the terms "gender" and "telephone number" had been left out of R4-23-502(A)(2). Because "gender" and "telephone number" are required fields in the American Society of Automation in Pharmacy (ASAP) standard that is required in implementing statute, A.R.S. § 36-2608(B), it was determined that a Notice of Supplemental Proposed Rulemaking was required to add "gender" and "telephone number" to R4-23-502(A)(2).

Another public hearing on the first Notice of Supplemental Proposed Rulemaking published on February 22, 2008 was held on March 24, 2008. During the public hearing, the Arizona Veterinary Medical Association (AVMA) asked the Board to delay the start of data collection from veterinarians for one year to allow the veterinarians more time to prepare. The AVMA states that the majority of veterinarians do not have computer systems for patient records and they do not collect certain owner information (date of birth and gender) that will be required by the new rules. The AVMA also feels that having to report the data weekly is onerous, as the number of veterinary drugs and prescriptions is very small (only five or six drugs) compared to medical practitioners and pharmacies. The AVMA is asking that veterinarians be allowed to report on a monthly basis. Reporting on a monthly basis would reduce the economic

impact on veterinarians and their staff and still provide the small quantity of veterinarian prescription data in a reasonable time.

Based on the comments from the AVMA, the Board expressed its desire to work with the AVMA to help mitigate the program's impact on veterinarians by delaying the collection of data from veterinarians and other medical practitioners for a year. The Board agrees that since veterinarians use so few controlled drugs and dispense a limited quantity of prescriptions for those drugs, it is reasonable to have veterinarians report their dispensed prescription data on a monthly schedule instead of weekly. Section R4-23-502 is amended by adding the sentence: "The Board may approve a less frequent reporting period" to subsection (E). The Board will then be able to approve a request to report prescription monitoring program data using a less frequent reporting period on a case-by-case basis. The Board feels that this change will allow the Board to address specific issues from the regulated public regarding the collection of prescription monitoring program data without compromising the public health and safety. Because the changes requested by the AVMA are substantive, a second Notice of Supplemental Proposed Rulemaking was published on April 18, 2008.

Another public hearing on the second Notice of Supplemental Proposed Rulemaking published on April 18, 2008 was held May 19, 2008. Janet Elliott representing the Arizona Community Pharmacy Committee attended the public hearing. Ms. Elliott provided written comment from The Arizona Community Pharmacy Committee voicing support for the rulemaking. No other comments were received. During the public hearing, Board staff realized that the statutory requirement in A.R.S. § 36-2608(A)(3) requiring the reporting of "the name, address, telephone number, and DEA number of the prescribing medical practitioner" was inadvertently left out of the reporting requirements in R4-23-502(A). The final rules include the statutory reporting requirement at R4-23-502(A)(3) and the renumbering of subsections R4-23-502(A)(4) through (8) to R4-23-502(A)(5) through (9). The Board does not feel this is a substantial change as it is a statutory requirement. The Board feels it is better to have all the requirements delineated in one place within the rules. The Board made no other changes from the second Notice of Supplemental Proposed Rulemaking and the final rules. There are minor changes to style, format, grammar, and punctuation as requested by G.R.R.C. staff.

11. A summary of the comments made regarding the rules and the agency response to them:

A public hearing on the Notice of Proposed Rulemaking published on December 14, 2007 was held on January 14, 2008. No one attended the public hearing. The Board received written comment from the Arizona Community Pharmacy Committee voicing support for the rulemaking and the National Association of Chain Drug Stores (NACDS) voicing concerns with the rule. NACDS asked the Board to amend R4-23-502(A)(7) to clarify the method of payment by adding the words "identified as cash or third party." NACDS member pharmacies can easily provide information on a prescription as either cash or third-party payment, but it becomes more difficult and costly to provide a distinction for multiple types of third-party payments. The Board understands the difficulty and feels that just knowing whether the payment is either cash or third party is sufficient for the purposes of the monitoring program. NACDS asked the Board to amend the rules to clarify to whom the data will be submitted, NACDS understands that the Board intends to use a contract vendor to collect and store data. NACDS feels that the rules should use language similar to other Sections of the rules indicating the "Board or its designee." The Board agrees that the rules should be consistent and it is the Board's intent to have a contract vendor collect, store, and manage the database and provide web-based services. The Board identified Sections R4-23-502(A), R4-23-503(A), R4-23-503(C)(3), (4), and (5), and R4-23-505(C) as Sections where the words "or its designee" should be added to provide consistency with the other Sections of the rules and clarify who would be receiving data or providing reports. NACDS asked the Board to change the word "and" to "or" in R4-23-502(A)(3). NACDS feels that it is duplicative to ask for the drug name, strength, dosage form and the National Drug Code (NDC) number, because the NDC number by its definition provides the name, strength, dosage form, and manufacturer of a drug. The Board agrees that the NDC number does provide the drug name, strength, and dosage form, and is duplicative. Instead of changing the "and" to "or," the Board will change R4-23-502(A)(3) by removing the words "name," "strength," and "dosage form." NACDS asked the Board to clarify the implementation date of the program. The Board does not feel it is necessary to put the date of implementation in the rules, because we do not know the exact date and cannot know that date until we contract with a vendor. The Board will notify pharmacies and medical practitioners of the implementation date once that date is set.

A public hearing on the first Notice of Supplemental Proposed Rulemaking published on February 22, 2008 was held on March 24, 2008. Brian Serbin, Emily Kane, Joe Abate, Wayne Anderson, Michael Ames, and Nancy Bradley representing the Arizona Veterinary Medical Association and Janet Elliott representing the Arizona Community Pharmacy Committee attended the hearing. The Arizona Veterinary Medical Association (AVMA) asked the Board to delay the start of data collection from veterinarians for one year to allow the veterinarians more time to prepare. The AVMA states that the majority of veterinarians do not have computer systems for patient records and they do not collect certain owner information (date of birth and gender) that will be required by the new rules. The AVMA also feels that having to report the data weekly is onerous, as the number of veterinary drugs and prescriptions is very small (only five or six drugs) compared to medical practitioners and pharmacies. The AVMA is asking that veterinarians be allowed to report on a monthly basis. Reporting on a monthly basis would reduce the economic impact on veterinarians and their staff and still provide the small quantity of veterinarian prescription data in a reasonable time.

Based on the comments from the AVMA, the Board expressed its desire to work with the AVMA to help mitigate the program's impact on veterinarians by delaying the collection of data from veterinarians and other medical practitioners for a year. The Board agrees that since veterinarians use so few controlled drugs and dispense a limited quantity

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of prescriptions for those drugs, it is reasonable to have veterinarians report their dispensed prescription data on a monthly schedule instead of weekly. Section R4-23-502 is amended by adding the sentence: "The Board may approve a less frequent reporting period" to subsection (E). The Board will then be able to approve a request to report prescription monitoring program data using a less frequent reporting period on a case-by-case basis. The Board feels that this change will allow the Board to address specific issues from the regulated public regarding the collection of prescription monitoring program data without compromising the public health and safety. Because the changes requested by the AVMA were substantive, a second Notice of Supplemental Proposed Rulemaking was published on April 18, 2008.

A public hearing on the second Notice of Supplemental Proposed Rulemaking published on April 18, 2008 was held May 19, 2008. Janet Elliott representing the Arizona Community Pharmacy Committee attended the public hearing. Ms. Elliott provided written comment from The Arizona Community Pharmacy Committee voicing support for the rulemaking. No other comments were received.

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

Not applicable

13. Any material incorporated by reference and its location in the rules:

None

14. Were these rules previously made as emergency rules?

No

15. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 1. ADMINISTRATION

Section

R4-23-110. Definitions

ARTICLE 5. ~~RECORDED~~ CONTROLLED SUBSTANCES PRESCRIPTION MONITORING PROGRAM

Section

R4-23-501. ~~Repealed~~ Controlled Substances Prescription Monitoring Program Registration

R4-23-502. ~~Repealed~~ Requirements for Data Format and Transmission

R4-23-503. ~~Repealed~~ Access to Controlled Substances Prescription Monitoring Program Data

R4-23-504. ~~Repealed~~ Computerized Central Database Tracking System Task Force

R4-23-505. ~~Repealed~~ Reports

ARTICLE 1. ADMINISTRATION

R4-23-110. Definitions

In addition to definitions in A.R.S. § 32-1901, the following definitions apply to 4 A.A.C. 23:

"Active ingredient" No change

"Alternate physician" No change

"Approved course in pharmacy law" No change

"Approved Provider" No change

"Authentication of product history" No change

"Automated storage and distribution system" No change

"Batch" No change

"Beyond-use date" No change

"Biological safety cabinet" No change

"Care-giver" No change

"Community pharmacy" No change

"Component" No change

"Computer system" No change

- “Computer system audit” No change
- “Contact hour” No change
- “Container” No change
- “Continuing education” No change
- “Continuing education activity” No change
- “Continuing education unit” or “CEU” No change
- “Correctional facility” No change
- “CRT” No change
- “CSPMP” means the Controlled Substances Prescription Monitoring Program established under A.R.S. Title 36, Chapter 28.
- “Current good compounding practices” No change
- “Current good manufacturing practice” No change
- “Cytotoxic” No change
- “Day” No change
- “DEA” No change
- “Delinquent license” No change
- “Dietary supplement” No change
- “Digital signature” No change
- “Dispensing pharmacist” No change
- “Drug sample” No change
- “Drug therapy management” No change
- “Electronic signature” No change
- “Eligible patient” No change
- “Extreme emergency” No change
- “FDA” No change
- “Immediate notice” No change
- “Inactive ingredient” No change
- “Internal test assessment” No change
- “ISO Class 5 environment” No change
- “ISO Class 7 environment” No change
- “Limited-service correctional pharmacy” No change
- “Limited-service long-term care pharmacy” No change
- “Limited-service mail-order pharmacy” No change
- “Limited-service nuclear pharmacy” No change
- “Limited-service pharmacy permittee” No change
- “Limited-service sterile pharmaceutical products pharmacy” No change
- “Long-term care consultant pharmacist” No change
- “Long-term care facility” or “LTCF” No change
- “Lot” No change
- “Lot number” or “control number” No change
- “Materials approval unit” No change
- “Mechanical counting device for a drug in solid, oral dosage form” No change
- “Mechanical storage and counting device for a drug in solid, oral dosage form” No change
- “Mediated instruction” No change
- “MPJE” No change
- “NABP” No change
- “NABPLEX” No change

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- “NAPLEX” No change
- “Order” No change
- “Other designated personnel” No change
- “Outpatient” No change
- “Outpatient setting” No change
- “Patient profile” No change
- “Pharmaceutical patient care services” No change
- “Pharmaceutical product” No change
- “Pharmacist-administered immunizations training program” No change
- “Pharmacy counter working area” No change
- “Pharmacy law continuing education” No change
- “Pharmacy permittee” No change
- “Prepackaged drug” No change
- “Prep area” No change
- “Proprietor” No change
- “Provider pharmacy” No change
- “Radiopharmaceutical” No change
- “Radiopharmaceutical quality assurance” No change
- “Radiopharmaceutical services” No change
- “Red C stamp” No change
- “Refill” No change
- “Remodel” No change
- “Remote drug storage area” No change
- “Resident” No change
- “Responsible person” No change
- “Score transfer” No change
- “Security paper features” means the attributes incorporated into the paper of a prescription order, referenced in A.R.S. § 32-1968(A)(4), that ~~is~~ are approved by the Board or its staff and that includes one or more of the following features that attempt to prevent duplication or aid the authentication of a paper document: laid lines, enhanced laid lines, thermochromic ink, artificial watermark, fluorescent ink, chemical void, persistent void, penetrating numbers, high-resolution border, high-resolution latent images, micro-printing, prismatic printing, embossed images, abrasion ink, holograms, and foil stamping.
- “Shared order filling” No change
- “Shared order processing” No change
- “Shared services” No change
- “Sight-readable” No change
- “Single-drug audit” No change
- “Single-drug usage report” No change
- “Standard-risk sterile pharmaceutical product” No change
- “Sterile pharmaceutical product” No change
- “Strength” No change
- “Substantial-risk sterile pharmaceutical product” No change
- “Supervision” No change
- “Supervisory physician” No change
- “Supplying” No change
- “Support personnel” No change
- “Transfill” No change
- “Verified signature” or “signature verifying” No change

“Wholesale distribution” No change

“Wholesale distributor” No change

ARTICLE 5. ~~RECODIFIED~~ CONTROLLED SUBSTANCES PRESCRIPTION MONITORING PROGRAM

R4-23-501. ~~Recodified~~ Controlled Substances Prescription Monitoring Program Registration

- A.** Under A.R.S. § 36-2606, a medical practitioner who is issued a license under A.R.S. Title 32, Chapter 7, 11, 13, 14, 15, 16, 17, 21, 25, or 29 and possesses a current DEA registration under the Federal Controlled Substances Act shall have a current CSPMP registration issued by the Board.
- B.** Application. To obtain a CSPMP registration, a person shall submit a completed application on a form furnished by the Board that includes:
1. Applicant's name, address, mailing address, if different, e-mail address, telephone number, facsimile number, license number issued under A.R.S. Title 32, Chapter 7, 11, 13, 14, 15, 16, 17, 21, 25, or 29, and DEA registration number;
 2. Whether the applicant's license and DEA registration listed in subsection (B)(1) are current and in good standing, and if not, the status of the license and registration; and
 3. Date signed and applicant's verified signature.
- C.** Registration. Within seven business days of receipt of a completed application specified in subsection (B), the Board office shall determine whether an application is complete. If the application is complete, the Board office shall issue a registration number and mail a current renewal receipt to the applicant. If the application is incomplete, the Board office shall issue a notice of incompleteness. An applicant with an incomplete application shall comply with the requirements of R4-23-202(F)(2) and (3).
- D.** Registration renewal. As specified in A.R.S. § 36-2606(C), the Board shall automatically suspend the registration of any registrant that fails to renew the registration on or before May 1 of the year in which the renewal is due. The Board shall vacate a suspension if the registrant submits a renewal application. A suspended registrant is prohibited from accessing information in the prescription monitoring program database.
- E.** Pharmacy registration and renewal. Each pharmacy with a current Board-issued pharmacy permit and a current DEA registration is automatically registered in the CSPMP. Existing pharmacy permittees who possess a current DEA registration will receive a registration receipt before the implementation date of the CSPMP. For pharmacy permits issued on or after the CSPMP implementation date, the Board will issue a registration receipt when issuing the pharmacy's permit. Each pharmacy shall renew the CSPMP registration on or before May 1 of the year in which the renewal is due. The Board shall automatically suspend the registration of any registrant that fails to renew the registration on or before the date on which the renewal is due. The Board shall vacate a suspension if the registrant submits a renewal application. A suspended registrant is prohibited from accessing information in the prescription monitoring program database.
- F.** CSPMP database access. A medical practitioner or pharmacy that chooses to use the CSPMP database shall request a user name and password in writing from the CSPMP Director. Upon receipt of the request, the CSPMP Director or designee shall issue a user name and password provided the medical practitioner or pharmacy is in compliance with the registration requirements of this Section.

R4-23-502. ~~Recodified~~ Requirements for Data Format and Transmission

- A.** Each dispenser shall submit to the Board or its designee by electronic means information regarding each prescription dispensed for a controlled substance listed in Schedules II, III, and IV of A.R.S. Title 36, Chapter 27, the Arizona Uniform Controlled Substances Act. The information reported shall conform to the August 31, 2005 Version 003, Release 000 *ASAP Rules-based Standard Implementation Guide for Prescription Monitoring Programs* published by the American Society for Automation in Pharmacy as specified in A.R.S. § 36-2608(B). The information submitted for each prescription shall include:
1. The name, address, telephone number, prescription number, and DEA registration number of the dispenser;
 2. The name, address, gender, date of birth, and telephone number of the person or, if for an animal, the owner of the animal for whom the prescription is written;
 3. The name, address, telephone number, and DEA registration number of the prescribing medical practitioner;
 4. The quantity and National Drug Code (NDC) number of the Schedule II, III, or IV controlled substance dispensed;
 5. The date the prescription was dispensed;
 6. The number of refills, if any, authorized by the medical practitioner;
 7. The date the prescription was issued;
 8. The method of payment identified as cash or third party; and
 9. Whether the prescription is new or a refill.
- B.** A dispenser shall submit the required information electronically unless the Board approves a waiver as specified in subsection (D).
- C.** A dispenser's electronic data transfer equipment including hardware, software, and internet connections shall meet the privacy and security standards of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and A.R.S. § 12-2292, in addition to common internet industry standards for privacy and security. A dispenser shall ensure that each

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electronic transmission meets the following data protection requirements:

1. Data shall be at least 128-bit encryption in transmission and at rest; and
2. Data shall be transmitted via secure e-mail, telephone modem, diskette, CD-ROM, tape, secure File Transfer Protocol (FTP), Virtual Private Network (VPN), or other Board-approved media.

- D.** A dispenser who does not have an automated recordkeeping system capable of producing an electronic report in the Board established format may request a waiver from electronic reporting by submitting a written request to the Board. The Board shall grant the request if the dispenser agrees in writing to report the data by submitting a completed universal claim form supplied by the Board or its designee.
- E.** Unless otherwise approved by the Board, a dispenser shall report by the close of business on each Friday the required information for the previous week, Sunday through Saturday. If a Friday falls on a state holiday, the dispenser shall report the information on the following business day. The Board may approve a less frequent reporting period if a dispenser makes a showing that a less frequent reporting period will not reduce the effectiveness of the system or jeopardize the public health.

R4-23-503. ~~Repealed~~ Access to Controlled Substances Prescription Monitoring Program Data

- A.** Except as provided in A.R.S. §§ 36-2604(B) and (C) and this Section, prescription information submitted to the Board or its designee is confidential and is not subject to public inspection.
- B.** The Board or its designee shall review the prescription information collected under A.R.S. Title 36, Chapter 28 and R4-23-502. If the Board or its designee has reason to believe an act of unprofessional or illegal conduct has occurred, the Board or its designee shall notify the appropriate professional licensing board or law enforcement or criminal justice agency and provide the prescription information required for an investigation.
- C.** The Board or its designee is authorized to release data collected by the program to the following:
1. A person who is authorized to prescribe or dispense a controlled substance to assist that person to provide medical or pharmaceutical care to a patient or to evaluate a patient;
 2. An individual who requests the individual's own controlled substance prescription information under A.R.S. § 12-2293;
 3. A professional licensing board established under A.R.S. Title 32, Chapter 7, 11, 13, 14, 15, 16, 17, 18, 21, 25, or 26. Except as required under subsection (B), the Board or its designee shall provide this information only if the requesting board states in writing that the information is necessary for an open investigation or complaint;
 4. A local, state, or federal law enforcement or criminal justice agency. Except as required under subsection (B), the Board or its designee shall provide this information only if the requesting agency states in writing that the information is necessary for an open investigation or complaint;
 5. The Arizona Health Care Cost Containment System Administration regarding individuals who are receiving services under A.R.S. Title 36, Chapter 29. Except as required under subsection (B), the Board or its designee shall provide this information only if the Administration states in writing that the information is necessary for an open investigation or complaint;
 6. A person serving a lawful order of a court of competent jurisdiction; and
 7. The Board staff for purposes of administration and enforcement of A.R.S. Title 36, Chapter 28 and this Article.
- D.** The Board or its designee may provide data to public or private entities for statistical, research, or educational purposes after removing information that could be used to identify individual patients or persons who received prescriptions from dispensers.

R4-23-504. ~~Repealed~~ Computerized Central Database Tracking System Task Force

- A.** The Board shall appoint a task force to help it administer the computerized central database tracking system as specified in A.R.S. § 36-2603.
- B.** The Task Force shall meet at least once each year and at the call of the chairperson to establish the procedures and conditions relating to the release of prescription information specified in A.R.S. § 36-2604 and R4-23-503.
- C.** The Task Force shall determine:
1. The information to be screened;
 2. The frequency and thresholds for screening; and
 3. The parameters for using the information to notify medical practitioners, patients, and pharmacies to educate and provide for patient management and treatment options.
- D.** The Board shall review and approve the procedures and conditions established by the Task Force as needed but at least once every calendar year.

R4-23-505. ~~Repealed~~ Reports

- A.** Before releasing prescription monitoring program data, the Board or its designee shall receive a written request for controlled substance prescription information.
- B.** A person authorized to access CSPMP data under R4-23-503(C)(1) through (6) shall submit a written request that:
1. Specifies the information requested for the report;
 2. For a medical practitioner, provides a statement that the report's purpose is to provide medical or pharmaceutical care

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- to a patient or to evaluate a patient:
3. For an individual obtaining the individual's own controlled substance prescription information, provides a form of non-expired government-issued identification;
 4. For a professional licensing board, states that the information is necessary for an open investigation or complaint;
 5. For a local, state, or federal law enforcement or criminal justice agency, states that the information is necessary for an open investigation or complaint;
 6. For the AHCCCS Administration, states that the information is necessary for an open investigation or complaint; and
 7. For a person serving a lawful order of a court of competent jurisdiction, provides a copy of the court order.
- C. The Board or its designee may provide reports through U.S. mail, other common carrier, facsimile, or secured electronic media or may allow reports to be picked up in-person at the Board office.

NOTICE OF FINAL RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 24. BOARD OF PHYSICAL THERAPY

[R08-261]

PREAMBLE

1. Sections Affected

	<u>Rulemaking Action</u>
R4-24-201	Amend
R4-24-203	Amend
R4-24-204	Amend
R4-24-207	Amend
R4-24-208	Amend
Article 3	Amend
R4-24-302	Amend
R4-24-304	Renumber
R4-24-304	New Section
R4-24-305	Renumber
R4-24-305	Amend
R4-24-306	Renumber
R4-24-306	Amend
R4-24-307	Renumber
R4-24-307	Amend
R4-24-308	Renumber
R4-24-308	Amend
R4-24-309	Renumber
R4-24-309	Amend
R4-24-310	Renumber
R4-24-310	Amend
R4-24-311	Amend
R4-24-312	New Section

2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statute: A.R.S. § 32-2003(5)

Implementing statutes: A.R.S. §§ 32-2003(4) and (7), 32-2041(B), 32-2042, 32-2044, 32-2045, 32-2046, and 32-2051

3. The effective date of the rules:

October 4, 2008

4. List of all previous notices appearing in the Register addressing the final rules:

Notice of Rulemaking Docket Opening: 14 A.A.R. 894, March 28, 2008

Notice of Proposed Rulemaking: 14 A.A.R. 948, April 4, 2008

5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name: Heidi Herbst Paakkonen, Executive Director

Address: Board of Physical Therapy

Notices of Final Rulemaking

4205 N. 7th Ave., Suite 208
Phoenix, AZ 85013

Telephone: (602) 274-0236
Fax: (602) 274-1378
E-mail: Heidi.herbst-paakkonen@ptboard.state.az.us

6. An explanation of the rules, including the agency’s reasons for initiating the rulemaking:

This rulemaking relates, in part, to a five-year-review report approved by the Council in October 2004. The Board is amending its rules to make them more clear, concise, and understandable and consistent with statute and current agency practice. It is adding a rule regarding standards for adequate patient records and is amending rules to address the requirement that the Board determine that an individual is qualified to receive a public benefit before issuing a license to the individual. The Board is adding the requirement that an applicant whose first language is not English pass an English-proficiency examination within 18 months before the date on which the application is administratively complete.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

None

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

Not applicable

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

The costs associated with determining whether an individual is qualified to receive a public benefit arise from legislative action rather than this rulemaking. Licensees and certificate holders have always been required to maintain patient records. The new standards for patient records may impose minimal costs on licensees and certificate holders. However, the new standards will provide protections for both patients and licensees and certificate holders. An applicant for whom English is not a first language has always been required to pass an English-proficiency examination. The cost of ensuring that the examination is passed within 18 months of having the application determined to be administratively complete will be minimal.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

As a result of public comment, the Board removed R4-24-301, dealing with Lawful Practice, from this rulemaking. Within the next two months, the Board will further amend R4-24-301 consistent with the public comment and file a Notice of Supplemental Proposed Rulemaking with the Office of the Secretary of State.

Additionally, as indicated in item 11, the following non-substantive changes were made:

1. R4-24-304(A)(3)(b), as it appeared in the Notice of Proposed Rulemaking, was deleted.
2. The information required under R4-24-304(B)(2) was moved to R4-24-304(A)(3)(f).
3. In R4-24-304(C), the phrase “each time” was changed to “for each date.”
4. Clarifying language was added to several subsections.

11. A summary of the comments made regarding the rules and the agency response to them:

The Board received comments regarding the rules from five individuals. The comments and the Board’s analysis of and response to the comments follow:

COMMENT	ANALYSIS	RESPONSE
R4-24-302: Allow use of titles without periods.	The periods are required by law (See A.R.S. § 32-2042).	No change
R4-24-304: The clear, direct statements in this rule are superior to the documentation guidelines of APTA.	Thank you	No change
R4-24-304(A)(2): It doesn’t make sense to require that an electronic signature be secure and not require that the entire patient record be secure.	It is correct that a secure signature makes the entire record secure so the Board believes it is unnecessary to change the rule.	No change

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R4-24-304(A)(3)(b): Change the word “support” to “identify” because it is difficult for a physical therapist to assemble evidence that supports a diagnosis.	The Board decided to delete this requirement.	R4-24-304(A)(3)(b), as it appeared in the Notice of Proposed Rulemaking, was deleted.
R4-24-304(A)(6): Are signed billing records acceptable as a record of services provided and billed?	The Board is not in position to tell a licensee whether a particular record is acceptable. The Board simply requires that records of services provided and billed be accurate.	No change
R4-24-304(B)(2): Requiring a physical therapist to document in a patient record the patient’s medical history is duplicative because the medical history probably was obtained at intake.	The comment is correct.	The Board moved this provision from subsection (B), regarding the initial evaluation, to subsection (A), regarding the patient record.
R4-24-304(B)(9): Requiring a physical therapist to include a prognosis in a patient record provides little more than an educated guess and may cause an insurance company to conclude that physical therapy is medically unnecessary.	The Board believes it is important for the physical therapist to assess and document the patient’s chance of responding to therapy.	No change
R4-24-304(C): The requirement that documentation be done for each therapeutic intervention is burdensome in settings where a patient may receive multiple therapeutic interventions in a day.	The comment is correct.	The phrase “each time” was changed to “for each date.”
R4-24-304(E): It is good that the Board is dealing with the issue of documenting conclusion of care when a patient discontinues care rather than being discharged. However, subsection (E)(1) should be applicable to all practice settings if care is provided by a P.T. or P.T.A. and subsection (E)(2) should be applicable only if the patient is actually discharged.	As indicated in the lead to this subsection, the Board believes it is in the interest of public safety and consistent with statute that a physical therapist documents the conclusion of care regardless of the reason that care is concluded. The Board allowed documentation of conclusion of care to be simpler in an acute-care hospital if the last therapeutic intervention was provided by a P.T. because of the nature of an acute-care hospital and the short time that individuals typically stay in an acute-care hospital.	No change
R4-24-304(E)(2)(c) and (d): Requiring that a physical therapist include the inclusive dates of an episode of care and the total number of days on which treatment was provided is burdensome. An interested person can determine this information from the patient record.	The Board believes it is important to have this information readily available in the patient record and that it can be assembled with minimal effort.	No change
R4-24-305(D): It is good that the Board increased the amount of time for a physical therapist to respond to a complaint.	Thank you	No change

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Neither statute nor rule allows physical therapy students to participate in evaluating, re-evaluating, and discharging patients. Students who are in their final clinics certainly could perform these tasks under supervision.	Because statute does not allow students to participate in these activities, the rules cannot allow students to participate in the activities.	No change
R4-24-310: If it is grounds for disciplinary action for a P.T. or P.T.A. to practice while mentally or physically impaired, the parameters for being impaired need to be clarified.	The standard has always been that a P.T. or P.T.A. must be able to practice in a safe and skillful manner. This rule does not change the standard.	No change

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

None

13. Incorporations by reference and their location in the rule:

None

14. Were these rules previously made as emergency rules?

No

15. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 24. BOARD OF PHYSICAL THERAPY

ARTICLE 2. LICENSING PROVISIONS

Section

- R4-24-201. Application for a Physical Therapist License
- R4-24-203. Foreign-educated Applicant Requirements
- R4-24-204. Supervised Clinical Practice
- R4-24-207. Application for a Physical Therapist Assistant Certificate
- R4-24-208. License or Certificate Renewal; Address Change

ARTICLE 3. ~~REGULATION~~ PRACTICE OF PHYSICAL THERAPY

Section

- R4-24-302. Use of Titles
- R4-24-304. Adequate Patient Records
- ~~R4-24-304.~~ R4-24-305. Complaints and Investigations
- ~~R4-24-305.~~ R4-24-306. Informal Interviews Hearings
- ~~R4-24-306.~~ R4-24-307. Issuance of Subpoenas
- ~~R4-24-307.~~ R4-24-308. Rehearing or Review of Board Decisions
- ~~R4-24-308.~~ R4-24-309. Disciplinary Actions; Penalties
- ~~R4-24-310. Expired~~
- ~~R4-24-309.~~ R4-24-310. Substance Abuse Recovery Program
- R4-24-311. Display of License; ~~Posting Notice~~; Disclosure
- R4-24-312. Mandatory Reporting Requirement

ARTICLE 2. LICENSING PROVISIONS

R4-24-201. Application for a Physical Therapist License

- A. No change
 - 1. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change

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- e. No change
- f. No change
- g. No change
- h. No change
- i. No change
- j. No change
- k. No change
- l. No change
- m. No change
- n. No change
- o. No change
- p. No change
- q. No change

2. A passport photograph of the applicant no larger than 1 1/2 x 2 inches that was taken not more than six months before the date of the application; ~~and~~

3. Evidence of the applicant's U.S. citizenship, alien status, legal residency, or lawful presence in the U.S.; and

~~3-4. The fee required in R4-24-107.~~

B. No change

- 1. No change
- 2. No change
- 3. No change

C. No change

- 1. No change
- 2. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - f. No change

D. No change

R4-24-203. Foreign-educated Applicant Requirements

A. No change

- 1. No change
- 2. No change
 - a. No change
 - b. No change
 - i. No change
 - ii. No change
 - iii. No change
- 3. No change
 - a. No change
 - b. No change
 - c. No change
- 4. If English is not the native language of the foreign-educated applicant, to meet the requirements in A.R.S. § 32-2022(B)(6), the applicant shall take and pass either of the following tests no more than 18 months before the date on which the application submitted under R4-24-201 is administratively complete and ensure that the test scores are sent directly to the Board by the testing entity:
 - ~~a. If the applicant passed the following ETS tests before September 30, 2005~~
 - a. The TOEFL. An applicant who takes the TOEFL passes with the following:
 - i. ~~TOEFL with a~~ A score of 560 or more if a paper-based test or ~~with~~ a score of 220 or more if a computer-based test;
 - ii. No change
 - iii. No change
 - b. ~~After September 30, 2005, the~~ The iBT. An applicant who takes the iBT passes with an overall test score of a minimum of 100 and a:
 - i. No change
 - ii. No change
 - iii. No change

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- iv. No change
- 5. No change
- 6. No change
- B.** No change
 - 1. No change
 - a. No change
 - b. No change
 - c. No change
 - 2. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change

R4-24-204. Supervised Clinical Practice

- A.** No change
- B.** No change
 - 1. No change
 - a. No change
 - b. No change
 - 2. No change
- C.** No change
 - 1. No change
 - 2. No change
- D.** An onsite supervisor shall:
 - 1. Observe the interim permit holder during the supervised clinical practice and:
 - a. Rate the interim permit holder's performance, at both the mid-point and completion of the clinical practice, ~~in~~ on each of the clinical performance criteria in the Physical Therapist Clinical Performance Instrument or Physical Therapist Assistant Clinical Performance Instrument, including the dates and hours the onsite supervisor provided onsite supervision; ~~and~~
 - b. Recommend following the mid-point rating whether the interim permit holder be allowed to continue the clinical practice and changes needed, if any, to ensure successful completion of the clinical practice; and
 - ~~b-c.~~ Recommend ~~that~~ following the completion rating whether the interim permit holder be licensed or required to complete further supervised clinical practice; and
 - 2. Submit the ~~completed ratings on the~~ Physical Therapist Clinical Performance Instrument or Physical Therapist Assistant Clinical Performance Instrument to the Board as follows:
 - a. No later than the 55th day of the clinical practice for the mid-point rating, and
 - b. ~~no~~ No later than 30 days after the completion date ~~end~~ of the supervised clinical practice for the completion rating.
- E.** After the Board receives the mid-point rating on the Physical Therapist Clinical Performance Instrument or Physical Therapist Assistant Clinical Performance Instrument, the Board shall review the rating and recommendation of the onsite supervisor and decide whether to allow the interim permit holder to continue the clinical practice or recommend changes in the clinical practice to the onsite supervisor.
- ~~E.F.~~ After the Board receives the ~~completed~~ completion rating on the Physical Therapist Clinical Performance Instrument or Physical Therapist Assistant Clinical Performance Instrument, the Board:
 - 1. No change
 - a. No change
 - b. No change
 - c. No change
 - 2. No change
 - a. No change
 - b. No change
 - 3. No change
 - a. No change
 - b. No change

~~F.G.~~ No change

R4-24-207. Application for a Physical Therapist Assistant Certificate

- A.** No change
 - 1. No change

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- a. No change
- b. No change
- c. No change
- d. No change
- e. No change
- f. No change
- g. No change
- h. No change
- i. No change
- j. No change
- k. No change
- l. No change
- m. No change
- n. No change
- o. No change
- p. No change

2. A passport photograph of the applicant no larger than 1 1/2 x 2 inches that was taken not more than six months before the date of the application; ~~and~~

3. Evidence of the applicant's U.S. citizenship, alien status, legal residency, or lawful presence in the U.S.; and

~~3-4.~~ The fee required in R4-24-107.

B. No change

- 1. No change
- 2. No change
- 3. No change

C. No change

- 1. No change
- 2. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - f. No change

D. No change

R4-24-208. License or Certificate Renewal; Address Change

A. No change

- 1. No change
 - a. No change
 - i. No change
 - ii. No change
 - iii. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - f. No change
 - g. No change
 - h. No change
 - i. No change
 - j. No change
 - k. No change
 - i. No change
 - ii. No change
 - iii. No change
 - l. No change
 - i. No change
 - ii. No change
 - iii. No change
 - m. No change

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- n. No change
- o. No change
- 2. The signature of the applicant attesting to the truthfulness of the information provided by the licensee or certificate-holder; ~~and~~
- 3. Evidence of the applicant's U.S. citizenship, alien status, legal residency, or lawful presence in the U.S.; and
- ~~3-4.~~ The fee required by the Board in R4-24-107.
- B. No change
- C. No change
 - 1. No change
 - 2. No change
- D. No change
- E. No change

ARTICLE 3. ~~REGULATION~~ PRACTICE OF PHYSICAL THERAPY

R4-24-302. Use of Titles

- A. ~~A licensed~~ As required under A.R.S. § 32-2042, a licensed physical therapist shall use the designation "PT" "P.T." immediately following the licensee's name or signature to denote licensure. A licensed physical therapist shall not use the designations "RPT" and "LPT" "R.P.T." or "L.P.T." in connection with the physical therapist's name or place of business.
- B. In addition to and immediately following the "P.T." designation, a physical therapist may list academic degrees earned and professional specialty certifications held.
- ~~B.C.~~ As required under A.R.S. § 32-2042, a physical therapist assistant shall use the designation "PTA" "P.T.A." immediately following the physical therapist assistant's name to denote certification.

R4-24-304. Adequate Patient Records

- A. A physical therapist shall ensure that a patient record meets the following minimum standards:
 - 1. Each entry in the patient record is:
 - a. Legible.
 - b. Accurately dated, and
 - c. Signed with the name and legal designation of the individual making the entry;
 - 2. If an electronic signature is used to sign an entry, the electronic signature is secure;
 - 3. The patient record contains sufficient information to:
 - a. Identify the patient on each page of the patient record.
 - b. Justify the therapeutic intervention.
 - c. Document results of the therapeutic intervention.
 - d. Indicate advice or cautionary warnings provided to the patient.
 - e. Enable another physical therapist to assume the patient's care at any point in the course of therapeutic intervention, and
 - f. Describe the patient's medical history.
 - 4. If an individual other than a physical therapist or physical therapist assistant makes an entry into the patient record, the supervising physical therapist co-signs the entry;
 - 5. If it is determined that erroneous information is entered into the patient record:
 - a. The error is corrected in a manner that allows the erroneous information to remain legible, and
 - b. The individual making the correction dates and initials the correct information; and
 - 6. For each date of service there is an accurate record of the physical therapy services provided and billed.
- B. Initial evaluation. As required by A.R.S. § 32-2043(F)(1), a physical therapist shall perform the initial evaluation of a patient. The physical therapist who performs an initial evaluation shall make an entry that meets the standards in subsection (A) in the patient record and document:
 - 1. The patient's reason for seeking physical therapy services;
 - 2. The patient's relevant medical diagnoses or conditions;
 - 3. The patient's signs and symptoms;
 - 4. Objective data from tests or measurements;
 - 5. The physical therapist's interpretation of the results of the examination;
 - 6. Clinical rationale for therapeutic intervention;
 - 7. A plan of care that includes the proposed therapeutic intervention, measurable goals, and frequency and duration of therapeutic intervention; and
 - 8. The patient's prognosis.
- C. Therapeutic-intervention notes. For each date that a therapeutic intervention is provided to a patient, the individual who provides the therapeutic intervention shall make an entry that meets the standards in subsection (A) in the patient record and document:
 - 1. The patient's subjective report of current status or response to therapeutic intervention;

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2. The therapeutic intervention provided or appropriately supervised;
 3. Objective data from tests or measures, if collected;
 4. Instructions provided to the patient, if any; and
 5. Any change in the plan of care required under subsection (B)(7).
- D.** Re-evaluation. As required by A.R.S. § 32-2043(F)(2), a physical therapist shall perform a re-evaluation when a patient fails to progress as expected, progresses sufficiently to warrant a change in the plan of care, or in accordance with R4-24-303(F)(4). A physical therapist who performs a re-evaluation shall make an entry that meets the standards in subsection (A) in the patient record and document:
1. The patient's subjective report of current status or response to therapeutic intervention;
 2. Assessment of the patient's progress;
 3. The patient's current functional status;
 4. Objective data from tests or measures, if collected;
 5. Rationale for continuing therapeutic intervention; and
 6. Any change in the plan of care required under subsection (B)(7).
- E.** Discharge summary. As required by A.R.S. § 32-2043(F)(3), a physical therapist shall document the conclusion of care in a patient's record regardless of the reason that care is concluded.
1. If care is provided in an acute-care hospital, the entry made under subsection (C) on the last date that a therapeutic intervention is provided constitutes documentation of the conclusion of care if the entry is made by a physical therapist.
 2. If care is not provided in an acute-care hospital or if a physical therapist does not make the entry under subsection (C) on the last date that a therapeutic intervention is provided, a physical therapist shall make an entry that meets the standards in subsection (A) in the patient record and document:
 - a. The date on which therapeutic intervention terminated;
 - b. The reason that therapeutic intervention terminated;
 - c. Inclusive dates for the episode of care being terminated;
 - d. The total number of days on which therapeutic intervention was provided during the episode of care;
 - e. The patient's current functional status;
 - f. The patient's progress toward achieving the goals in the plan of care required under subsection (B)(7); and
 - g. The recommended discharge plan.

~~R4-24-304.~~ **R4-24-305. Complaints and Investigations**

- A.** A complainant shall ensure that a complaint filed with the Board is about:
1. An individual licensed or certified under this Chapter; or
 2. An individual believed to be engaged in unlawful practice as described in A.R.S. § 32-2048.
- B.** If the Board determines under A.R.S. § 32-2045(A)(2) that there is reason to believe that an individual may have violated A.R.S. Title 32, Chapter 19, or this Chapter, the Board shall prepare a complaint and serve the complaint as described in subsection (D)(2).
- ~~A-C.~~ Complaint requirements. A complaint complainant shall:
1. Submit the complaint to the Board shall be made in writing; and transmitted to the Board by personal delivery, mail, or facsimile on a form provided by the Board. A complainant shall provide
 2. Provide the following information:
 - 1-a. Name of licensee, or certificate holder certificate holder, or other individual who is the subject of complaint;
 - 2-b. Name and address of person filing complaint complainant;
 - 3-c. Nature of the complaint;
 - 4-d. Details of the complaint with pertinent dates and activities;
 - 5-e. Whether the complainant has contacted any other organization regarding the complaint; and
 - 6-f. Whether complainant has contacted the licensee, or certificate holder certificate holder, or other individual concerning the complaint, and the licensee's or certificate holder's if so, the response, if any; and
 7. Whether the complainant is willing to testify at a hearing.
- B.** The Board shall notify a licensee or certificate holder, in writing, within 90 days after receiving a complaint. The licensee or certificate holder shall submit a written response, including records or documentation as requested by the Board, within 20 days from the date that notice of the complaint is mailed or delivered to the licensee or certificate holder.
- D.** Within 90 days after receiving a complaint, the Board shall ensure that the complaint is reviewed to determine whether the complaint is within the Board's jurisdiction, and:
1. If the complaint is not within the Board's jurisdiction, dismiss the complaint and provide written notice of the dismissal to the complainant; or
 2. If the complaint is within the Board's jurisdiction, serve a copy of the complaint on the individual complained against and provide the individual complained against with 30 days to respond and admit, deny, or further explain each allegation in the complaint.
- E.** If a complaint is within the Board's jurisdiction, the Board shall ensure that an investigation regarding the matters alleged

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in the complaint is conducted.

- F.** After expiration of the 30 days provided under subsection (D)(2), the Board shall review the complaint, response, and investigation results and take action as prescribed under A.R.S. § 32-2045(B) or 32-2046.

~~R4-24-305. R4-24-306. Informal Interviews Hearings~~

- A.** ~~The Board shall, when investigating~~ To facilitate investigation of a complaint, the Board may conduct an informal hearing. The Board shall send written notice of an informal interview hearing to a licensee or certificate holder the individual who is the subject of the complaint, by personal service or certified mail, return receipt requested, at least ~~20~~ 30 days before the informal interview hearing.
- B.** ~~The Board shall ensure that the written notice shall contain~~ of informal hearing contains the following information:
1. The time, date, and place of the interview informal hearing;
 2. An explanation of the informal nature of the proceedings;
 3. The licensee's or certificate holder's individual's right to appear with or without legal counsel;
 4. A statement of the allegations and issues involved with a citation to relevant statutes and rules;
 5. The licensee's or certificate holder's individual's right to a formal hearing under A.R.S. Title 41, Chapter 6, Article 10 instead of the informal interview hearing; and
 6. The licensee's or certificate holder's right to request under A.R.S. § 32-3206(A) a copy of information the Board will use in making its determination; and
 - ~~6-7.~~ Notice that the Board may take disciplinary action as a result of the deliberations of the informal interview hearing if it finds the individual violated A.R.S. Title 32, Chapter 19, or this Chapter;
- C.** ~~And~~ The Board shall ensure that an informal interview shall proceed hearing proceeds as follows:
1. Introduction of the licensee or certificate holder respondent and, if applicable, legal counsel for the licensee or certificate holder respondent;
 2. Introduction of the Board members, staff, and Assistant Attorney General present;
 3. Swearing in of the licensee or certificate holder respondent and witnesses;
 4. Brief summary of the allegations and purpose of the informal interview hearing;
 5. Optional opening comment by licensee or certificate holder the respondent;
 6. Questioning of the licensee or certificate holder respondent by the Board and questioning of witnesses by the Board and the respondent;
 7. Optional additional comments by licensee or certificate holder the respondent; and
 8. Deliberation and deciding the case by the Board.

~~R4-24-306. R4-24-307. Issuance of Subpoenas~~

- A.** ~~All subpoenas issued in connection with Board disciplinary proceedings pursuant to Title 32, Chapter 19, Arizona Revised Statutes, shall be approved and issued by the Board or the executive director of the Board.~~
- A.** A party desiring issuance of a subpoena to compel the appearance of a witness or the production of documents or other evidence at a hearing shall file a written request with the Board that includes the following information:
1. The caption and docket number of the matter;
 2. A list or description of any documents or other evidence sought;
 3. The name and business address of the custodian of the documents or other evidence sought;
 4. The name and business or residential address of all persons to be subpoenaed;
 5. A brief statement of the reason the evidence is relevant to the matter;
 6. The date, time, and place to appear or produce documents or other evidence; and
 7. The name, address, and telephone number of the party, or the party's attorney, requesting the subpoena.
- B.** ~~A~~ The party requesting a subpoena to be issued shall serve the subpoena as provided ensure that the subpoena is served in the manner prescribed by the Arizona Rules of Civil Procedure and pay all costs involved in serving the subpoena.
- C.** A party or the person served with a subpoena who objects to the subpoena, in whole or in part, may file a written objection with the Board within five days after service of the subpoena or at the beginning of the hearing if the subpoena is served fewer than five days before the hearing.
- D.** The Board shall quash or modify a subpoena if:
1. It is unreasonable or oppressive;
 2. It requests information that is confidential or privileged; or
 3. The desired testimony or evidence can be obtained by an alternative method.

~~R4-24-307. R4-24-308. Rehearing or Review of Board Decisions~~

- A.** The Board shall provide for a rehearing and review of its decisions under A.R.S. Title 41, Chapter 6, Article 10.
- A.B.** ~~Except as provided in subsection (G) (J), a party to a contested case who is aggrieved by the Board's decision in the case may file with the Board a written motion for rehearing or review. The motion shall be filed within 15 days after service of the decision and shall particularly state the grounds for the motion. For purposes of this subsection, a decision is served when personally delivered or sent by certified mail to the party's last known residential or business address is required to file a motion for rehearing or review of a decision of the Board to exhaust the party's administrative remedies.~~

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- ~~B-C.~~ A party may amend a motion for rehearing or review ~~may be amended~~ at any time before it is ruled upon by the Board ~~rules on the motion~~. A response may be filed to a motion or amended motion by any other party, within 10 days of service of the motion or amended motion. The Board may require the filing of written briefs upon the issues raised in the motion and may provide for oral argument.
- ~~C-D.~~ ~~A~~ The Board may grant a rehearing or review of a decision ~~may be granted~~ for any of the following ~~causes~~ reasons materially affecting ~~the moving~~ a party's rights:
1. Irregularity in the ~~administrative~~ proceedings of the Board ~~or the prevailing party~~, or any order or abuse of discretion that deprived the moving party of a fair hearing;
 2. Misconduct of the Board, ~~its staff~~, or ~~the prevailing party~~ an administrative law judge;
 3. Accident or surprise ~~which 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 ~~original~~ hearing;
 5. Excessive or insufficient ~~penalties or disciplinary action~~ penalty;
 6. Error in the admission or rejection of evidence or other errors of law ~~is occurring at the original hearing or during the progress of the proceedings; or and~~
 7. ~~A~~ The findings of fact or decision that is not justified by the evidence or is contrary to law.
- ~~D-E.~~ The Board may affirm or modify a decision or grant a rehearing or review to any or all of the parties. ~~The rehearing or review may cover on~~ all or part of the issues for any of the reasons ~~stated listed~~ in subsection (C) (D). An order modifying a decision or granting a rehearing or review shall ~~particularly state~~ specify with particularity the grounds for the order granting the If a rehearing or review is granted, and the rehearing or review shall cover only the ~~grounds stated~~ matters specified in the order.
- ~~E-F.~~ No later than ~~15-30~~ days after making a decision and after giving the parties notice and an opportunity to be heard, the Board may order a rehearing or review on its own initiative for any of the reasons ~~stated listed~~ in subsection (C) (D). ~~After giving notice to the parties or the parties' counsel, the~~ The Board may grant a motion for rehearing or review, timely served, on grounds for a reason not stated in the motion. ~~In either case, the~~ An order granting a rehearing or review shall ~~specifically state~~ specify with particularity the grounds for on which the rehearing or review is granted.
- ~~F-G.~~ 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 within 10 days of service of the original affidavits. This ~~10-day~~ period may be extended for not more than 20 days by the Board for good cause ~~shown~~ as described in subsection (I) or by written stipulation of the parties. The Board may permit reply affidavits.
- ~~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 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 a ruling on the motion will:
1. Further administrative convenience, expedition, or economy; or
 2. Avoid undue prejudice to any party.
- ~~G-J.~~ If the Board makes a specific finding that immediate effectiveness of a particular decision is necessary for the preservation of the public health, safety, or welfare and that rehearing or review is impracticable, unnecessary, or contrary to public interest, the decision shall may be issued as a final decision without an opportunity for rehearing or review. If an application for judicial review of the a decision is issued as final, the time limits for judicial review of the Board's final decisions, at made, it shall be made under A.R.S. § 12-901 et seq., apply.

~~R4-24-308. R4-24-309. Disciplinary Actions, Penalties~~

- A. ~~All~~ As required by A.R.S. § 39-121.01, a record of Board disciplinary actions, including a decree of censure, shall remain a part of a licensee's or certificate holder's is a public record open to public inspection.
- B. ~~The~~ If the Board decides to restrict a license or certificate, the Board shall include ensure that the restriction and any required corrective action specific to address the grounds upon which conduct that led to the disciplinary action is based when restricting a license or certificate restriction and protect the public. Supervision If the Board decides to require that an individual with of a restricted licensee license or certificate holder shall certificate be supervised during the period of restriction, the Board shall appoint by an unrestricted licensee approved by the Board to provide the supervision.
- C. A physical therapist or physical therapist assistant ~~who's whose~~ whose license or certificate is suspended, revoked, or voluntarily surrendered shall return the license or certificate to the Board within 10 days ~~of after~~ after receipt of ~~a final Board~~ the Board's final order.
- D. ~~Following~~ At the end of a period of restricted license or certificate restriction, the Board shall terminate the restriction only if a the licensee or certificate holder shall appear before the Board and submit certificate holder submits to the Board evidence of having completed all Board requirements and stipulations before termination of the restriction required corrective actions and complied with all terms of the restriction. If the Board believes it will help the Board determine whether to terminate a restriction, the licensee or certificate holder shall appear before the Board.
- ~~E.~~ Following revocation of a license or certificate in any jurisdiction, an individual may not reapply for a license or certifi-

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cate for two years.

~~F.E.~~ An applicant whose who had a previous license or certificate was previously revoked by the Board shall appear before the Board before a license is granted before the Board acts on the application.

R4-24-310. Expired

~~R4-24-309, R4-24-310, Substance Abuse Recovery Program~~

~~In addition to the requirements of A.R.S. § 32-2050, to participate in a Board approved substance abuse recovery program, a licensee or certificate holder shall submit to the Board:~~

- ~~1. Evidence that the program is licensed by the Arizona Department of Health Services to provide substance abuse recovery services;~~
- ~~2. If ordered by the Board or its designee, results of body fluid examinations at any time;~~
- ~~3. An agreement, signed by an authorized representative of the program and the licensee or certificate holder, that the program shall provide to the Board:
 - ~~a. Periodic reports regarding treatment program activity;~~
 - ~~b. All treatment records when requested by the Board;~~
 - ~~c. Periodic reports regarding the licensee's or certificate holder's diagnosis, prognosis, and the recommendations for continuing care, treatment, and supervision; and~~
 - ~~d. An immediate report if the licensee or certificate holder refuses to submit to treatment, is in noncompliance with the established program, or if the licensee's or certificate holder's impairment is not substantially alleviated through treatment.~~~~

~~A. Under A.R.S. § 32-2044(8), practicing as a physical therapist or working as a physical therapist assistant while mentally or physically impaired is grounds for disciplinary action.~~

~~B. The Board shall allow an impaired licensee or certificate holder to enter into a substance abuse recovery program rather than conduct a disciplinary proceeding if:~~

- ~~1. The impaired licensee or certificate holder is qualified under A.R.S. § 32-2050(2).~~
- ~~2. The Board believes the proposed program will assist the impaired licensee or certificate holder to recover, and~~
- ~~3. The impaired licensee or certificate holder enters into the written agreement required under A.R.S. § 32-2050(3) and (4).~~

R4-24-311. Display of License; ~~Posting Notice~~; Disclosure

~~A. A licensee or certificate holder shall display a copy or provide documentation of the licensee's license or certificate and current renewal certificate verification in a location accessible to public view at the licensee's place of practice as specified in A.R.S. § 32-2051(G).~~

~~B. A Upon request, a licensee or certificate holder shall post notice at the licensee's place of practice in a location accessible to inform a member of the public view the name, how to file a complaint by providing the address, and telephone number of the Board office; and a statement informing the public that a complaint against a licensee or certificate holder should can be directed to the Board.~~

~~C. Before conducting an evaluation or initiating physical therapy, a licensee shall ~~Written disclosure~~ disclose to a patient shall be provided prior to evaluation and initiation of physical therapy when a referring practitioner is deriving direct or indirect compensation from the referral. The licensee shall ensure that the ~~written~~ disclosure is in writing and shall state that states "Under A.R.S. § 32-2051(C), I am required by law to inform you in writing that your referring physician [or specify if different than from a physician] derives either direct or indirect compensation related to your physical therapy."~~

R4-24-312. Mandatory Reporting Requirement

~~A. As required by A.R.S. § 32-3208, an applicant, licensee, or certificate holder who is charged with a misdemeanor involving conduct that may affect patient safety or a felony shall provide written notice of the charge to the Board within 10 days after the charge is filed.~~

~~B. An applicant, licensee, or certificate holder may request a list of reportable misdemeanors from the Board.~~

NOTICE OF FINAL RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 45. BOARD OF RESPIRATORY CARE EXAMINERS

[R08-260]

PREAMBLE

- 1. Sections Affected**
R4-45-214
R4-45-218

Rulemaking Action
Amend
New Section
- 2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):**
Authorizing statute: A.R.S. § 32-3504(A)(2)
Implementing statute: A.R.S. § 32-3554
- 3. The effective date for the rules:**
October 4, 2008
- 4. List of all previous notices appearing in the Register addressing the final rules:**
Notice of Rulemaking Docket Opening: 14 A.A.R. 895, March 28, 2008
Notice of Rulemaking Docket Opening: 14 A.A.R. 1144, April 11, 2008
Notice of Proposed Rulemaking: 14 A.A.R. 1492, May 2, 2008
- 5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:**

Name:	Mary Hauf Martin
Address:	Board of Respiratory Care Examiners 1400 W. Washington St., Suite 200 Phoenix, AZ 85007
Telephone:	(602) 542-5995
Fax:	(602) 542-5900
E-mail:	Mary@rb.az.gov
- 6. An explanation of the rules, including the agency's reasons for initiating the rulemaking:**
Under A.R.S. § 32-3554, the Board has authority to reinstate a revoked license or amend conditions of probation. In this rulemaking, the Board establishes procedures to exercise this authority. Additionally, the Board is clarifying that failure to obey an order issued by any regulatory board or court amounts to unprofessional conduct.
- 7. A reference to any study relevant to the rule that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:**
None
- 8. A showing of good cause why the rules are necessary to promote a statewide interest if the rules will diminish a previous grant of authority of a political subdivision of this state:**
Not applicable
- 9. The summary of the economic, small business, and consumer impact:**
The economic impact of the reinstatement rule will be minimal and will be assumed voluntarily by an individual who wishes to resume practice as a respiratory therapist or to practice without conditions of probation. The clarification regarding unprofessional conduct will have an economic impact only on individuals who disobey an order issued by a regulatory board or court.
- 10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):**
The Board added a subsection to R4-45-218 that clarifies the standard the Board uses to decide whether to grant or deny a request for modification of conditions of probation. The Board also clarified that an applicant for reinstatement must be qualified for licensure under A.R.S. § 32-3523.
- 11. A summary of the comments made regarding the rules and the agency response to them:**
The Board received no comments regarding the proposed rules.

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

None

13. Incorporations by reference and their location in the rule:

None

14. Were these rules previously made as emergency rules?

No

15. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 45. BOARD OF RESPIRATORY CARE EXAMINERS

ARTICLE 2. LICENSURE

Section

R4-45-214. Standards of Professional Conduct

R4-45-218. Reinstatement Following Revocation; Modification of Probation

ARTICLE 2. LICENSURE

R4-45-214. Standards of Professional Conduct

Conduct or practice that is contrary to recognized standards of ethics of the respiratory therapy profession, as used in A.R.S. § 32-3501(10)(i), includes the following:

1. No change
2. No change
3. Violating a formal order, condition of probation, or stipulation issued by the Board, another regulatory entity of any state, or a court of law;
4. No change
5. No change
6. No change
7. No change
8. No change
9. No change
10. No change
11. No change
12. No change
13. No change
14. No change
15. No change
16. No change
17. No change
18. No change
19. No change
20. No change
21. No change

R4-45-218. Reinstatement Following Revocation; Modification of Probation

- A.** Under A.R.S. § 32-3554, a former licensee whose license is revoked may apply to the Board after one year to have the license reinstated. A licensee who is placed on probation may apply to the Board after one year to have the conditions of probation modified.
- B.** If a former licensee wishes to have a revoked license reinstated after the time stated in subsection (A), the former licensee shall meet the qualifications in A.R.S. § 32-3523(A) and comply with R4-45-201. The Board shall not issue a temporary license to a former licensee who applies for reinstatement.
- C.** A licensee who is placed on probation shall comply with R4-45-207 while on probation. If the licensee wishes to have the conditions of probation modified after the time stated in subsection (A), the licensee shall submit to the Board:
 - 1.** A letter that contains the following information:
 - a.** Name and address of licensee.

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liabilities and, hence, protection of policy holders and claimants prior to the Department's acceptance of an insurer's termination of its certificate of authority. With the extensive due diligence procedures, the hearing is unnecessary.

Over the past two years, approximately 30 hearings have been held as required under the current R20-6-303. No insurer, policyholder, claimant or creditor has made an objection to termination of any of these 30 certificates of authority or release of deposit, all of which underwent the extensive due diligence procedures. Based on this data, the Department determined that the hearing requirement unnecessarily adds costs for the Department, Office of Administrative Hearings (OAH), and insurers, but adds no meaningful layer of protection for policyholders or claimants.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

None

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

Not applicable

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

The portions of this rulemaking that repeal or amend existing rules will have intangible benefits for the regulated community by repealing obsolete provisions and provisions that were not clear, concise and understandable. The businesses that will be directly impacted by this rulemaking are insurers seeking to terminate a certificate and the release of a statutory deposit in Arizona. There are approximately 450 insurers currently licensed in Arizona with deposits posted that are subject to regulation under this Section. Over the past two years, the Department has received 30 requests for termination of a certificate of authority and release of statutory deposit. The elimination of the hearing requirement will result in cost savings to the Department, OAH, and to insurers who seek termination of their certificate of authority.

The Department will have savings from not incurring costs for preparing notices of hearing, reviewing waivers of notice of hearing and other hearing-related documents, coordinating hearing dates, mailing notices of hearing, reviewing hearing orders, tracking information related to hearings, or conducting tasks as follow-up to hearings.

OAH will have savings from not incurring costs for coordinating and scheduling hearings, using an administrative law judge time to conduct the hearings, reviewing hearing notices and hearing-related documents, conducting hearings, preparing and reviewing orders, or conducting tasks as follow-up to hearings.

Insurers will have savings from not incurring hearing-related costs which could include paying attorney fees, costs associated with publication of the Notice of Hearing, staff time used to provide information and conduct activities in preparation for a hearing, copying, mailing, courier fees, hearing-related travel time, time spent at the hearing and conducting tasks as follow-up to hearings.

The local newspaper industry will be impacted by a loss of revenue from not publishing Notices of Hearing as is currently required. This loss of revenue will be insignificant for any individual newspaper as there is an average of only 15 notices published per year spread out among many newspapers that publish in this local industry.

The Department does not expect this rulemaking to have a direct economic impact on consumers or any other public agencies.

10. A description of changes between the proposed rules, including supplemental notices, and final rules (if applicable):

The Department held an oral proceeding on this rulemaking but no comments were received at that oral proceeding. The Department did not receive any written public comments on this rulemaking, so, no changes were made as a result of public comments on this rulemaking. The Department did make non-substantive changes to make the rule more clear, concise and understandable based on comments from the staff of the Governor's Regulatory Review Council.

11. A summary of comments made regarding the rule and agency response to them:

None

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

Not applicable

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

Not applicable

14. Was this rule previously adopted as an emergency rule?

No

15. The full text of the rules follows:

TITLE 20. COMMERCE, FINANCIAL INSTITUTIONS, AND INSURANCE

CHAPTER 6. DEPARTMENT OF INSURANCE

ARTICLE 3. FINANCIAL PROVISIONS AND PROCEDURES

Section

R20-6-303. ~~Withdrawal of Insurers from the Insurance Business and Release of Statutory Deposit~~ Termination of Certificate of Authority and Release of Deposit

ARTICLE 3. FINANCIAL PROVISIONS AND PROCEDURES

R20-6-303. ~~Withdrawal of Insurers from the Insurance Business and Release of Statutory Deposit~~ Termination of Certificate of Authority and Release of Deposit

- ~~A.~~ WHEREAS, A.R.S. § 20-143 confers upon the Director of Insurance the power and discretion to make reasonable rules and regulations necessary for effectuating any provisions of Title 20, such rules and regulations being subject to the provisions of A.R.S. §§ 41-1001 through 41-1008, and
- ~~B.~~ WHEREAS, it appears that the regulations hereafter proposed in this General Rule are required to assure preservation of the public peace, health and safety, and
- ~~C.~~ WHEREAS, the regulations embodied in this rule shall be construed as severable, so that should one or more Sections of the rule be held invalid, the remaining Sections shall not be adversely affected, and
- ~~D.~~ WHEREAS, A.R.S. § 20-588(B), relating to the release of deposits under Title 20, requires application to, and the written order of, the Director, and
- ~~E.~~ WHEREAS, in order to establish an orderly procedure whereby insurers desiring to withdraw from the insurance business, and thereafter to secure the release of their deposits made under A.R.S. § 20-581, may do so without placing their policyholders or former policyholders and creditors in jeopardy, the Director of Insurance (hereafter called "the Director") adopts the following rule:
1. ~~Reinsurance—An insurer in seeking to withdraw from the insurance business (hereafter called "the insurer") shall first reinsure all of its business in force with another insurer by entering into an agreement of bulk reinsurance which shall become effective only when filed with and approved in writing by the Director pursuant to A.R.S. §§ 20-732 or 20-734, as may be applicable. The agreement of bulk reinsurance shall provide for the assumption by the reinsurer of all the insurer's liability as to policyholder claims incurred but unreported as of the effective date of the agreement and it may also include recapture provisions exercisable by the insurer in the event its withdrawal from the insurance business as contemplated by this rule is not completed.~~
 2. ~~Withdrawal from the insurance business~~
 - a. ~~With the approval of the Director, an insurer may withdraw from the insurance business either:~~
 - i. ~~By amending its articles of incorporation pursuant to A.R.S. § 20-707, so as to eliminate its insuring powers and to adopt a new corporate name which shall not include the word "insurance," or~~
 - ii. ~~By dissolution pursuant to A.R.S. §§ 10-361 to 10-363 inclusive. The insurer shall not seek from the Arizona Corporation Commission the issuance of a certificate of dissolution or of withdrawal until authorized by the Director, as hereinafter provided. The insurer shall not file with the Arizona Corporation Commission a certificate of amendment of its articles of incorporation without first obtaining the written approval of the Director to such amendment and filing. The Director may authorize or approve any such filing if it is a part of a program for withdrawal from the insurance business and release of statutory deposit calculated to protect policyholders and creditors in accordance with the further provisions of this rule.~~
 - b. ~~Prior to the filing with the Arizona Corporation Commission of either a certificate of amendment to its articles of incorporation or a resolution of dissolution, the insurer shall file with the Director a certified copy of a resolution passed at a meeting of stockholders or members, as may be applicable, adopting the amendment to the articles of incorporation or the resolution of dissolution.~~
 - c. ~~At the time of filing the certified copy of resolution specified in subparagraph (b) of this paragraph, the insurer shall surrender to the Director its certificate of authority issued pursuant to A.R.S. § 20-216. If no such surrender is made within 10 days of completion of the filing specified in subparagraph (b) of this paragraph, the Director may revoke or suspend the certificate of authority as provided by A.R.S. § 20-219, or take any other appropriate action to compel surrender of said certificate.~~
 3. ~~Release of statutory deposit~~
 - a. ~~The Director may approve the amendment of the articles of incorporation of the insurer to eliminate its insuring powers and its change of name or the resolution of dissolution, and may, pursuant to A.R.S. § 20-588, approve the release to the insurer of deposited funds in accordance with the following procedure:~~
 - i. ~~The insurer shall file with the Director an application for release of deposited funds together with a statement of its financial condition verified by its president and secretary. The statement shall include a schedule~~

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- of all assets and liabilities, with itemization and adequate detail with respect to all outstanding liabilities, if any. The statement shall reflect the condition of the insurer as of a date not more than 60 days prior to the day the insurer files with the Director its application for release of its statutory deposit.
- ii. If there are any outstanding liabilities, actual or contingent, set forth in the schedule required to be filed under subdivision (i) of this subparagraph, there shall also be filed with the Director a plan of extinguishment of substantially all liability for the security of which the deposit is held, together with such documents or assurances as may be reasonably necessary to insure such extinguishment. For the purpose of this rule, the term "substantially all liability" is defined as all known or reasonably ascertainable direct obligations, whether or not liquidated in amount and shall include any former policyholder who may have a claim, or a right to a refund under a policy of insurance. The Director may require an agreement from a person whose financial responsibility is demonstrated to the Director guaranteeing all obligations of the insurer of any kind, other than policyholder claims covered by the agreement of bulk reinsurance.
 - iii. The Director shall thereupon appoint a time and place for hearing the application for release of deposit, which shall be not less than 10 days after notice is given to creditors as provided in subdivision (iv) of this subparagraph, and notice thereof shall be given in accordance with A.R.S. § 20-163.
 - iv. The insurer shall thereupon give notice to all known creditors of the date, place, nature and purpose of the hearing. The notice shall be published in a newspaper of general circulation published in the county in which the insurer has its principal place of business and as may be approved by the Director, and by mailing a copy of said notice by first class mail, postage prepaid, to the last known address of all known or reasonably ascertainable creditors, and such other persons designated by the Director. The notice shall inform such creditors that a verified statement of financial condition, together with a copy of the plan for extinguishment of remaining liabilities, if applicable, has been filed with the Director and is available for their inspection and shall advise such creditors to present to the Director prior to the hearing any objections or additional claims. A copy of such notice, in a form approved by the Director, together with an affidavit of publication and mailing, shall be filed with the Director prior to the hearing.
 - v. Unless there is an assumption by reinsurance substantially all the insurer's policy liability, including liability on claims incurred but unreported as of the effective date of the agreement of bulk reinsurance referred to in paragraph (1), subsection (E) hereof, the notice required by subdivision (iv) of this subparagraph shall also be given to all former policyholders who may or could have outstanding claims not barred by statute or by policy limitations.
 - vi. Prior to the hearing, the Director may cause to be conducted an examination of the affairs, transactions, accounts, records and assets of the insurer pursuant to Chapter 1, Article 2, Title 20, A.R.S. The cost of any such examination shall be taxed to the insurer.
 - vii. At the hearing, the Director shall review evidence presented by the insurer as to its compliance with A.R.S. § 20-588, and any other evidence available to the Director, together with any objections or additional claims presented by creditors whose claims have not been reinsured or otherwise secured. On his own motion, or on request of the insurer, or of any such creditors, policyholders, or former policyholders, but only for good cause shown, the Director may adjourn the hearing from time to time.
 - viii. A plan for extinguishment of substantially all liability for the security of which the deposit is held may provide for the use of the deposit for the payment of claims of creditors, policyholders and former policyholders whose claims have not been reinsured or otherwise secured. If the proposed plan contains such a provision, the Director shall exercise his discretion in approving the plan so as to provide the maximum reasonable security to creditors, policyholders and former policyholders whose claims are unsatisfied by such payment, or he may condition his approval upon an amendment of the plan by providing for partial withdrawals of deposits as claims are extinguished and by providing for the establishment of an escrow to insure extinguishment of substantially all liability for the security of which the deposit is held, or such other method of protecting such creditors and former policyholders as shall appear to be reasonable.
 - ix. At such time as the Director has determined that all creditors, former policyholders and policyholders of the insurer are adequately secured and the insurer has demonstrated that it has complied with A.R.S. § 20-588 and this rule, the Director shall issue a written order directing release of the deposit and authorizing the filing with the Arizona Corporation Commission of the amendment of the articles of incorporation eliminating insuring powers and changing name or the filing of the resolution of dissolution of the insurer; said release to be conditioned upon filing with the Director proof of filing with the Arizona Corporation Commission the amendment of the articles of incorporation or the resolution of dissolution as approved by the Director.
 - x. Should the Director find that the insurer is unable to extinguish substantially all of its liability for the security of which the deposit is held, or otherwise has not complied with this rule, he shall decline the application by written notice to the insurer setting forth his reasons therefor. The insurer thereafter may reapply for release of its deposit when it extinguishes, or is able to submit an acceptable plan for the extinguishment of, substantially all of its liability for the security of which the deposit is held, which application shall be acted

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upon as in the case of an original application.

- xi. ~~The Director may, in his discretion, decline to approve any application for release of a deposit, or any part thereof, until such time as the statute of limitations has run as to any disclosed or undisclosed liability of the insurer.~~

- 4. ~~Qualification of reinsurance carrier. The contract of reinsurance, as above provided, may be entered into only with a reinsurer approved by the Director. If the withdrawing insurer has policies of insurance in force within the State of Arizona, or has creditors within the State of Arizona, the Director may, as a prerequisite to the approval of any plan for the extinguishment of liability of the withdrawing company, require that the reinsurer be licensed to do business within the State of Arizona.~~
- 5. ~~Applicability of rule to foreign and alien insurers. The provisions of this rule shall apply with equal force and effect, to the extent permissible, to any deposits required by the Director and made by any foreign or alien insurer, including any deposit made pursuant to the retaliatory provisions of A.R.S. § 20-230.~~
- 6. ~~Exemptions—The provisions of this rule shall not be applicable to:~~
 - a. ~~Exchange and substitution of cash or eligible securities by an insurer as authorized by A.R.S. § 20-586.~~
 - b. ~~Withdrawal of excess deposits by an insurer, either cash or eligible securities, as authorized by A.R.S. §§ 20-587 and 20-588(A)(2).~~
 - e. ~~Release of the deposit of any insurer as directed by the order of a court of competent jurisdiction, as provided by A.R.S. § 20-588(A)(3).~~

A. Domestic Insurers. To request termination of a certificate of authority and, if applicable, release of statutory deposit, a domestic insurer shall file all of the following with the director:

- 1. A written request for termination of certificate of authority and release of deposit;
- 2. The insurer's original certificate of authority or an affidavit of lost certificate of authority;
- 3. A statement of the insurer's financial condition as of a date within 60 days of the filing date of the request for termination that includes a written statement, signed by two officers of the insurer as authorized on the jurat page of the insurer's most recent annual statement, verifying that the statement of financial condition reflects the insurer's financial position as of the date signed.
- 4. A plan of extinguishment for its outstanding liabilities that satisfies the requirements of subsection (C) or a sworn affidavit stating that the insurer has no outstanding liabilities to policyholders or claimants under subsection (C);
- 5. A certified copy of the insurer's Board of Directors resolution or other documentation of the insurer's official action taken according to the insurer's statutorily required organizational documents approving the insurer's:
 - a. Withdrawal from the insurance business,
 - b. Dissolution of the insurer,
 - c. Merger with an insurer authorized in Arizona to transact the insurer's previously written and active lines of business of the insurer requesting termination, or
 - d. Transfer of domicile to another state or country.
- 6. A copy of the insurer's Articles of Dissolution, Articles of Merger, Articles of Amendment, Articles of Redomestication, or other documentation that the insurer intends to file with the Arizona Corporation Commission after issuance of the Director's order as provided in subsection (D)(2);
- 7. If requested by the director, a written agreement that guarantees payment of substantially all liabilities of the domestic insurer, other than obligations extinguished under subsection (C).

B. Foreign and Alien Insurers. To request termination of its certificate of authority and, if applicable, release of its deposit, a foreign or alien insurer shall file all of the following with the director:

- 1. A written request for termination of certificate of authority and release of deposit;
- 2. The insurer's original certificate of authority or an affidavit of lost certificate of authority;
- 3. A statement of the insurer's financial condition as of a date within 60 days of the filing date of the request for termination that includes a written statement, signed by two officers of the insurer as authorized on the jurat page of the insurer's most recent annual statement, verifying that the statement of financial condition reflects the insurer's financial position as of the date signed.
- 4. A plan of extinguishment for its Arizona liabilities that satisfies the requirements of subsection (C) or a sworn affidavit stating that the insurer has no Arizona liabilities under subsection (C);
- 5. A copy of an order issued by the insurance director or other appropriate regulatory authority in the insurer's state or country of domicile that approves or authorizes either the insurer's:
 - a. Withdrawal from the insurance business,
 - b. Dissolution of the insurer,
 - c. Merger (approval of the merger from the states of domicile of the insurers), or
 - d. Transfer of domicile, if applicable.
- 6. A copy of the insurer's Articles of Dissolution, Articles of Merger, Articles of Amendment, Articles of Redomestication or other required documentation that the insurer filed in its state of domicile; and
- 7. If requested by the director, a written agreement that guarantees payment of substantially all Arizona liabilities of the

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insurer, other than obligations extinguished under subsection (C).

C. Insurer's Plan for Extinguishment of Liabilities.

1. To extinguish substantially all liabilities under subsection (A)(4) or subsection (B)(4) as applicable, an insurer may:
 - a. Reinsure the insurer's business in force with another insurer by entering into an agreement of bulk reinsurance that shall be effective when filed with and approved in writing by the director.
 - i. The agreement shall provide for assumption of all policyholder claims by the reinsurer including claims incurred but unreported as of the effective date of the agreement.
 - ii. The agreement may include recapture provisions exercisable by the insurer in the event the termination of its certificate of authority is not completed.
 - iii. Unless the director otherwise approves, the agreement shall provide that the reinsurer be licensed in Arizona for the particular lines of business reinsured.
 - b. Merge with another insurer that:
 - i. Assumes the liabilities of the non-surviving insurer; and
 - ii. Is authorized in Arizona for the previously written and active lines of business assumed, unless otherwise approved by the director.
 - c. Use its deposit, any additional security deposit or both to secure payment of former policyholder, policyholder, or claimant liabilities that are not reinsured or otherwise secured.
2. For purposes of this Section, "substantially all liabilities" under Title 20 means all policyholder and claimant obligations reported by the insurer in the statement of financial condition, whether or not liquidated in amount, and shall include former policyholder claims and rights to refunds.

D. Consideration of the Request for Termination of Certificate of Authority and Release of Deposit under subsections (A) and (B).

1. If the director determines that the insurer has extinguished substantially all liabilities as required under this Section and has otherwise demonstrated compliance with this Section and A.R.S. Title 20, the director shall grant the request to terminate the certificate of authority and, if appropriate, release the insurer's deposit, provided:
 - a. The insurer has no fees, taxes, assessments or filings outstanding to the Department; and
 - b. The insurer is not subject of any pending investigation or examination under Title 20 by the Department.
2. The director's order shall condition the release of a domestic insurer's deposit upon receipt by the director of evidence of the official filing with the Arizona Corporation Commission of the documentation described in subsection (A)(6).
3. If the director determines that the insurer is unable to extinguish substantially all liabilities as required under this Section, or otherwise has not complied with this Section or with A.R.S. Title 20, the director shall notify the insured in writing that the request has been denied and the reasons for the denial.

E. Exclusions. This Section does not apply to:

1. An insurer's exchange and substitution of cash or eligible securities under A.R.S. § 20-586;
2. An insurer's withdrawal of excess deposits, either cash or eligible securities, under A.R.S. §§ 20-587 and 20-588(A)(2); or
3. Releases of deposits made under A.R.S. § 20-588(A)(3).