

# NOTICES OF PROPOSED RULEMAKING

Unless exempted by A.R.S. § 41-1005, each agency shall begin the rulemaking process by first submitting to the Secretary of State's Office a Notice of Rulemaking Docket Opening followed by a Notice of Proposed Rulemaking that contains the preamble and the full text of the rules. The Secretary of State's Office publishes each Notice in the next available issue of the *Register* according to the schedule of deadlines for *Register* publication. Under the Administrative Procedure Act (A.R.S. § 41-1001 et seq.), an agency must allow at least 30 days to elapse after the publication of the Notice of Proposed Rulemaking in the *Register* before beginning any proceedings for making, amending, or repealing any rule. (A.R.S. §§ 41-1013 and 41-1022)

## NOTICE OF PROPOSED RULEMAKING

### TITLE 4. PROFESSIONS AND OCCUPATIONS

#### CHAPTER 23. BOARD OF PHARMACY

*Editor's Note: The following Notice of Proposed Rulemaking was exempt from Executive Order 2012-03 as issued by Governor Brewer. (See the text of the executive order on page 475.)*

[R14-24]

#### PREAMBLE

- 1. Articles, Parts, and Sections Affected (as applicable)**

	<b><u>Rulemaking Action</u></b>
Article 5	New Article
R4-23-501	New Section
R4-23-502	New Section
R4-23-503	New Section
R4-23-504	New Section
R4-23-505	New Section
- 2. Citations to the agency's statutory rulemaking authority to include the authorizing statute (general) and the implementing statute (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. Citations to all related notices published in the Register as specified in R1-1-409(A) that pertain to the record of the proposed rule:**

Notice of Expiration of Rules: 20 A.A.R. 133, January 17, 2014

Notice of Rulemaking Docket Opening: 20 A.A.R. 461, February 21, 2014 (*in this issue*)
- 4. The agency's contact person who can answer questions about the rulemaking:**

Name:	Dean Wright, Compliance Officer
Address:	Board of Pharmacy 1616 W. Adams Phoenix, AZ 85007
Telephone:	(602) 771-2727
Fax:	(602) 771-2749
E-mail:	dwright@azpharmacy.gov
Website:	www.azpharmacy.gov
- 5. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:**

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. The rules were made by final rulemaking at 14 A.A.R. 3410, effective October 4, 2008. Because of a mix up with the five-year review scheduled by the Governor's Regulatory Review Council for submission on August 31, 2013, the Board staff failed to meet the deadline and the rules were terminated as required by A.R.S. § 41-

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1056(J). The Notice of Expiration of Rules was published at 20 A.A.R. 133, January 17, 2014. The Board intends to make new rules to replace the expired rules to comply with H.B. 2136. The new rules will be placed in a new Article 5 (Controlled Substances Prescription Monitoring Program) with new Sections for: program registration and database access, requirements for data format and transmission, access to program data, computerized central database tracking system task force, and reports.

The rule will include format, style, and grammar necessary to comply with the current rules of the Secretary of State and the 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 licit controlled substances.

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

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

**7. 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

**8. The preliminary 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 program. 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 30,000 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.

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

Name: Dean Wright, Compliance Officer  
Address: Board of Pharmacy  
1616 W. Adams, Suite 120  
Phoenix, AZ 85007  
Telephone: (602) 771-2727  
Fax: (602) 771-2749  
E-mail: dwright@azpharmacy.gov  
Website: www.azpharmacy.gov

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

Comments may be written or presented orally. Written comments must be received by 5 p.m., Monday, April 7, 2014. An oral proceeding is scheduled for:

Date: April 7, 2014  
Time: 10:00 a.m.  
Location: 1616 W. Adams, 1st Floor Board Room  
Phoenix, AZ 85007

A person may request information about the oral proceeding by contacting the person listed above.

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

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

The rule complies with the exception in subsection (A)(2) of A.R.S. § 41-1037, because the rule issues an alternative registration specified in A.R.S. § 36-2606.

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

No

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

No

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

None

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

**TITLE 4. PROFESSIONS AND OCCUPATIONS**

**CHAPTER 23. BOARD OF PHARMACY**

**ARTICLE 5. CONTROLLED SUBSTANCES PRESCRIPTION MONITORING PROGRAM**

Section

- R4-23-501. Controlled Substances Prescription Monitoring (CSPMP) Program Registration and Database Access
- R4-23-502. Requirements for Data Format and Transmission
- R4-23-503. Access to Controlled Substances Prescription Monitoring Program Data
- R4-23-504. Computerized Central Database Tracking System Task Force
- R4-23-505. Reports

**ARTICLE 5. CONTROLLED SUBSTANCES PRESCRIPTION MONITORING PROGRAM**

**R4-23-501. Controlled Substances Prescription Monitoring (CSPMP) Program Registration and Database Access**

**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.**

1. An applicant for CSPMP registration shall:

- a. Submit a completed application for CSPMP registration electronically or manually on a form furnished by the Board, and
- b. Submit with the application form the documents specified in the application form.

2. The Board office shall deem an application form received on the date the Board office electronically or manually date-stamps the form.

**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 reg-

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istration number and provide a current registration certificate to the applicant by mail or electronic transmission. If the application is incomplete, the Board office shall issue a written notice of incompleteness. An applicant with an incomplete application shall comply with the requirements of R4-23-202(F).

**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 with CSPMP database access credentials is prohibited from accessing information in the prescription monitoring program database.

**E.** CSPMP database access.

1. A medical practitioner that chooses to use the CSPMP database shall request access from the CSPMP Director by completing an access user registration form electronically. Upon receipt of the access user registration form, the CSPMP Director or designee shall issue access credentials provided the medical practitioner is in compliance with the registration requirements of this Section.

2. A pharmacist that chooses to use the CSPMP database shall request access from the CSPMP Director by completing an access user registration form electronically. Upon receipt of the access user registration form, the CSPMP Director or designee shall issue access credentials provided the pharmacist has a current active pharmacist license.

3. A medical practitioner or pharmacist who is not licensed in Arizona may request access from the CSPMP Director by:

a. Completing an access user registration form electronically;

b. Printing the access user registration form;

c. Having the access user registration form signed and notarized; and

d. Mailing the notarized access user form along with a current copy of the applicant's nonresident state license and driver's license. Upon receipt of the notarized access user registration form and other required documents, the CSPMP Director or designee shall issue access credentials provided the nonresident licensed medical practitioner or pharmacist credential's show an current active license in another state.

**R4-23-502. 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 or its designee 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 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 or its designee. The Board or its designee 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 or its designee 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

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dize the public health.

**R4-23-503. 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;
  - 7. A person who is authorized to prescribe or dispense a controlled substance and who performs an evaluation on an individual under A.R.S. § 23-1026; and
  - 8. 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. 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. Reports**

- A.** Before releasing prescription monitoring program data, the Board or its designee shall receive a written or electronic request for controlled substance prescription information.
- B.** A person authorized to access CSPMP data under R4-23-503(C)(1) through (7) shall submit a written or electronic 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 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 photo 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.