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 1799.)

[R12-125]

PREAMBLE

1. Article, Part, or Section Affected (as applicable) **Rulemaking Action**
R4-23-501 Amend

2. Citations to the agency's statutory rulemaking authority to include the authorizing statute (general) and the implementing statute (specific):
Authorizing statute: A.R.S. §§ 32-1904(A)(1) and 36-2602

Implementing statute: A.R.S. §§ 36-2604 and 36-2606

3. Citations to all related notices published in the *Register* as specified in R1-1-409(A) that pertain to the record of the proposed rule:
Notice of Rulemaking Docket Opening: 18 A.A.R. 1347, June 15, 2012

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 St. Phoenix, AZ 85007
Telephone:	(602) 771-2727
Fax:	(602) 771-2749
E-mail:	dwright@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 An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:
A.R.S. Title 36, Chapter 28 Controlled Substances Prescription Monitoring Program became effect in September 2007. Chapter 28 requires the Board to establish Controlled Substances Prescription Monitoring Program and requires pharmacies and medical practitioners who dispense controlled substances listed in Schedule II, III, and IV to a patient, to report prescription information to the Board of Pharmacy on a weekly basis. Chapter 28 requires the Board to make the monitoring program database available to authorized individuals and make rules to implement this program. The rules were made in a final rulemaking on October 4, 2008. The Board has determined that R4-23-501 Controlled Substances Prescription Monitoring Program Registration needs to be amended to remove subsection (E) that requires a pharmacy to be registered with the monitoring program. Since the Board already issues a permit to all pharmacies we to do not need to issue another registration to pharmacies. The statute only requires the Board to register medial practitioners. In fact the requirements of subsection (E) have never been enforced, as it would have cost the Board to issue a registration that was unnecessary. The Board has not been able to correct this rule because of the rulemaking moratorium imposed by the Governor in 2009. Subsection (F) allows medical practitioners and pharmacies to request access to the monitoring program database, but in reality the program gives access to medical practitioners and pharmacists. Subsection (F) will be amended to remove references to a pharmacy obtaining access and insert pharmacists. The rulemaking will clean up the language to make it more clear and concise, and understandable.

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 rule will impact the Board medical practitioners, pharmacists, and pharmacies. The proposed rule's impact on the Board will be the usual rulemaking-related costs, which are minimal.

The Board estimates the proposed rules will have no economic impact on medical practitioners, pharmacists and pharmacies. The purpose of the existing rule R4-23-501 is to establish the registration requirements of A.R.S. § 36-2606. The registration requirements of A.R.S. § 36-2606 apply only to medical practitioners, not pharmacies. The changes to the rule remove the requirement in subsection (E) for pharmacies to register with the Controlled Substances Prescription Monitoring Program. It is not necessary to register pharmacies with the CSPMP, because every pharmacy is already issued a pharmacy permit by the Board to do business as a pharmacy. A.R.S. § 36-2604 defines to whom the monitoring program may give access to the information in the database. R4-23-501(F) gives access to a medical practitioner and pharmacy, but the program has always given access to medical practitioners and pharmacists. The program has never given access to a pharmacy, but does give access to the pharmacist in the pharmacy that dispenses the drug. The statute [A.R.S. § 36-2604(C)(1)] allows the Board to give access to "a person who is authorized to prescribe or dispense a controlled substance…", which means a medical practitioner or pharmacist. The proposed rule will amend R4-23-501(F) by taking out references to a pharmacy requesting access to the CSPMP database and inserting language for a pharmacist requesting access to the CSPMP database. None of these changes will have an economic impact on medical practitioners, pharmacists, or pharmacies.

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.

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 St. Phoenix, AZ 85007
Telephone:	(602) 771-2727
Fax:	(602) 771-2749
E-mail:	dwright@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 5:00 p.m., Monday August 27, 2012. An oral proceeding is scheduled for:

Date:	August 27, 2012
Time:	10:00 a.m.
Location:	1616 W. Adams St., 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 itself does not require a permit. However, the registration required by statute arguably falls within the definition of general permit in A.R.S. § 41-1001.

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 Program Registration

ARTICLE 5. CONTROLLED SUBSTANCES PRESCRIPTION MONITORING PROGRAM

R4-23-501. 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.~~**E.** CSPMP database access.

1. A medical practitioner ~~or pharmacy that~~ who chooses to use the CSPMP database shall request ~~a user name and password in writing~~ access from the CSPMP Director on forms provided on the Board's web site. Upon receipt of the request, the CSPMP Director or designee shall issue ~~a user name and password~~ access credentials provided the medical practitioner ~~or pharmacy~~ is in compliance with the registration requirements of this Section and has completed the Board's CSPMP Online Training Program.
2. A pharmacist who chooses to use the CSPMP database shall request access from the CSPMP Director on forms provided on the Board's web site. Upon receipt of the request, the CSPMP Director or designee shall issue access credentials provided the pharmacist has a current active pharmacist license and has completed the Board's CSPMP Online Training Program.