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

[R08-51]

PREAMBLE

1. Sections Affected — **Rulemaking Action**
R4-23-411 — Amend

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)

Implementing statutes: A.R.S. §§ 32-1901(1), (23), (69)

3. A list of all previous notices appearing in the *Register* addressing the proposed rules:

Notice of Rulemaking Docket Opening: 13 A.A.R. 4543, December 21, 2007

4. 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

5. An explanation of the rules, including the agency's reasons for initiating the rules:

During the November 15, 2007 Board meeting, the Board determined that several changes to R4-23-411 (Pharmacist-administered Immunizations) should be made as requested by the Arizona Pharmacy Alliance and interested pharmacists. The changes include the following: replacing the words "hepatitis, influenza, meningococcal, pneumococcal, smallpox, and tetanus booster" with the word "adult" throughout the rule, adding the words "of vaccines in the Center's for Disease Control (CDC) recommended adult immunization schedule and vaccines recommended in the CDC's Health Information for International Travel" after the word "immunizations" in the second sentence of R4-23-411(A), and inserting the word "adult" after the words "pharmacist-administered" wherever found in the rule. The changes will allow certified immunization pharmacists to administer FDA-approved adult vaccines to an adult with a valid prescription order and increase the availability and reduce the cost of necessary adult vaccines for Arizona citizens. 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 this rule will benefit the public health and safety by clearly establishing standards for pharmacist-administered adult immunizations.

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, pharmacists, pharmacies, 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 proposed rule will have minimal economic impact on pharmacists and pharmacies. The rulemaking will increase the number of vaccines that a pharmacist may administer to adult patients. This will increase the number of patients a pharmacist may serve and increase the public's access to needed vaccines. Being able to administer a larger number of vaccines will provide pharmacists or pharmacies with opportunity for increased income. The number of vaccines that could be administered by a pharmacist will increase from six to 16. The Board estimates that the increase in the number of vaccines available for administration by pharmacists will provide a potential increased income for pharmacies of from 20 to 50 percent.

The proposed rules will have minimal to moderate economic impact on the public. The public will benefit from increased access to immunization services from pharmacists, including many more vaccines previously not provided by pharmacists. The Board estimates that the public could save from 40 to 60 percent using a pharmacy setting for vaccinations instead of a scheduled doctor's office visit.

The Board believes that approval of this rule will benefit the public health and safety by clearly establishing standards for pharmacist-administered adult immunizations.

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

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

10. The time, place, and nature of the proceedings for the making, amendment, or repeal of the rules or, if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rules:

Comments may be written or presented orally. Written comments must be received by 5:00 p.m., Monday, April 7, 2008. An oral proceeding is scheduled for:

Date:	April 7, 2008
Time:	10:00 a.m.
Location:	1700 W. Washington St., 3rd Floor Board Room Phoenix, AZ 85007

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

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

Not applicable

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

None

13. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 4. PROFESSIONAL PRACTICES

Section
R4-23-411. Pharmacist-administered Adult Immunizations

ARTICLE 4. PROFESSIONAL PRACTICES

R4-23-411. Pharmacist-administered Adult Immunizations

A. Authority to administer ~~hepatitis, influenza, meningococcal, pneumococcal, smallpox, and tetanus booster~~ adult immunizations and, in an emergency, epinephrine and diphenhydramine. If a pharmacist meets the qualifications and standards specified by this Section and the Board certifies the pharmacist, the pharmacist may administer ~~hepatitis, influenza, meningococcal, pneumococcal, smallpox, and tetanus booster~~ adult immunizations of vaccines in the Center's for Disease Control (CDC) recommended adult immunization schedule and vaccines recommended in the CDC's Health Information for International Travel and, in an emergency, epinephrine and diphenhydramine to an eligible patient 18 years of age and older upon receipt of a valid prescription order. The Board shall certify a pharmacist who meets the qualifications established in subsection (B). A pharmacist who has authority to administer ~~hepatitis, influenza, meningococcal, pneumococcal, smallpox, and tetanus booster~~ adult immunizations and, in an emergency, epinephrine and diphenhydramine shall not delegate the authority to any other pharmacist or employee.

B. Qualifications for authorization to administer ~~hepatitis, influenza, meningococcal, pneumococcal, smallpox, and tetanus booster~~ adult immunizations and, in an emergency, epinephrine and diphenhydramine. After receipt of a completed application form, the Board shall issue a certificate authorizing the administration of ~~hepatitis, influenza, meningococcal, pneumococcal, smallpox, and tetanus booster~~ adult immunizations and, in an emergency, epinephrine and diphenhydramine to a pharmacist who meets the following qualifications:

1. Has a current, unrestricted license to practice pharmacy in this state;
2. Successfully completes a training program specified in subsection (C); and
3. Has a current certificate in basic cardiopulmonary resuscitation.

C. Pharmacist-administered adult immunizations training program requirements. A training program for pharmacists to administer ~~hepatitis, influenza, meningococcal, pneumococcal, smallpox, and tetanus booster~~ adult immunizations and, in an emergency, epinephrine and diphenhydramine shall include the following courses of study:

1. Basic immunology and the human immune response;
2. Mechanics of immunity, adverse effects, dose, and administration schedule of available vaccines;
3. Response to an emergency situation as a result of the administration of an immunization, including administering epinephrine and diphenhydramine to counteract the adverse effects of an immunization given based on a patient-specific prescription order received before administering the immunization;
4. Administration of intramuscular injections;
5. Other immunization administration methods; and
6. Recordkeeping and reporting requirements specified in subsection (D).

D. Recordkeeping and reporting requirements.

1. In addition to filing the prescription order as required in A.R.S. § 32-1964, a pharmacist granted authorization under this Section to administer ~~hepatitis, influenza, meningococcal, pneumococcal, smallpox, and tetanus booster~~ adult immunizations and, in an emergency, epinephrine and diphenhydramine shall provide to the pharmacy and the pharmacist-in-charge shall maintain in the pharmacy for a minimum of seven years the following documentation regarding each immunization administered:
   a. The name, address, and date of birth of the patient;
   b. The date of administration and site of injection;
   c. The name, dose, manufacturer's lot number, and expiration date of the vaccine or, in an emergency, epinephrine or diphenhydramine;
   d. The name and address of the patient's primary health care provider, as identified by the patient;
   e. The name and address of the prescribing medical practitioner, if different from the patient's primary health care provider;
   f. The name of the pharmacist administering the immunization;
   g. A record of the pharmacist's consultation with the patient determining that the patient is an eligible patient as defined in R4-23-110;
   h. The date that the written report specified in subsection (D)(2) was sent to the patient's primary health care provider;
   i. Consultation or other professional information provided to the patient by the pharmacist; and
   j. The name of the vaccine information sheet provided to the patient.
2. The pharmacist shall provide a written report to the patient's primary health care provider containing the documentation required in subsection (D)(1) within 14 days of the immunization. The pharmacy shall make the required records specified in subsection (D)(1) available in the pharmacy for inspection by the Board or its designee.

E. Confidentiality of records. A pharmacist, pharmacy permittee, or pharmacist-in-charge shall comply with applicable state and federal privacy statutes and rules when releasing patient health information.

F. Renewal of a certificate for pharmacist-administered adult immunizations. A certificate authorizing a pharmacist to administer ~~hepatitis, influenza, meningococcal, pneumococcal, smallpox, and tetanus booster~~ adult immunizations and, in

an emergency, epinephrine and diphenhydramine shall be renewed biennially by submitting a renewal request within the 30 days before the certificate's expiration date. Any pharmacist desiring to renew the certificate shall provide to the Board proof of the following:

1. Current certification in basic cardiopulmonary resuscitation, and
2. Completion of a minimum of two contact hours (0.2 CEU) of continuing education related to immunizations. A pharmacist may use the continuing education hours required in this subsection as part of the total continuing education hours required for pharmacist license renewal.

NOTICE OF PROPOSED RULEMAKING

TITLE 18. ENVIRONMENTAL QUALITY

CHAPTER 4. DEPARTMENT OF ENVIRONMENTAL QUALITY SAFE DRINKING WATER

[R08-54]

PREAMBLE

1. Articles and Sections Affected **Rulemaking Action**

R18-4-121 New Section

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. Title 49, Chapter 2, Article 9

Implementing statutes: A.R.S. §§ 49-351, 49-352, 49-353, 49-353.01

3. A list of all previous notices appearing in the *Register* addressing the final rulemaking:

Notice of Rulemaking Docket Opening: 13 A.A.R. 2688, August 3, 2007

Notices of Rulemaking Docket Opening: 14 A.A.R. 752, March 7, 2008 *(in this issue)*

Notice of Proposed Rulemaking: 14 A.A.R. 567, February 29, 2008

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

Name:	Sean P. McCabe
Address:	Department of Environmental Quality 1110 W. Washington St. (MC 5415B-2) Phoenix, AZ 85007
Telephone:	(602) 771-4600 (Toll-free number in Arizona: (800) 234-5677)
Fax:	(602) 771-4634
E-mail:	mccabe.sean@azdeq.gov

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

A. Background and Summary for Proposed Rules

This is a companion rulemaking to the other current notice of proposed rulemaking affecting 18 A.A.C. 4, Department of Environmental Quality, Safe Drinking Water. The text of R18-4-121, incorporating 40 CFR 141, Subpart S, was inadvertently left out of the companion rulemaking, although the preamble of the rulemaking discusses the rule. The Arizona Department of Environmental Quality (ADEQ) plans to combine the two proposed rulemakings into one notice of final rulemaking. The substance of this rulemaking is discussed in the preamble to the companion rulemaking from which it was inadvertently excluded.

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:

EPA's Ground Water Rule (71 FR 65574; Nov. 8, 2006) and associated guidance documents have been reviewed by ADEQ staff; EPA's rules and guidance documents can be downloaded from EPA's drinking water regulations and guidance web page at http://www.epa.gov/safewater/regs.html):

7. 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:

The proposed amendments do not diminish a previous grant of authority of a political subdivision of this state.

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

The Department has a statutory obligation both to ensure that all potable water distributed or sold to the public in Arizona is safe to drink (A.R.S. § 49-351(A)), and to adopt rules as required in order to retain primacy of the Safe Drinking Water Act (A.R.S. § 4-353(A)(2)(a)). The preliminary summary of the economic, small business, and consumer impact of the rule are contained in the companion rulemaking published in the February 29, 2008, edition of the *Arizona Administrative Register*.

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

A person may submit written comments to the person listed in item 4.

10. The time, place, and nature of the proceedings for the making, amendment, or repeal of the rule or, if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:

ADEQ is not scheduling separate oral proceedings for this rulemaking docket, since oral proceedings were already scheduled for the companion rulemaking. Anyone wishing to provide written comments regarding the rulemaking may submit their comments to ADEQ between 8:00 a.m. and 5:00 p.m., Monday through Friday, up until 5:00 p.m., April 4, 2008, to the person and address in item 4.

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

None

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

40 CFR 141, Subpart S, Groundwater Rule (40 CFR 141.400 through 141.405)

13. The full text of the rules follows:

TITLE 18. ENVIRONMENTAL QUALITY

CHAPTER 4. DEPARTMENT OF ENVIRONMENTAL QUALITY
SAFE DRINKING WATER

ARTICLE 1. GENERAL REQUIREMENTS

Section
R18-4-121. ~~Renumbered~~ Ground Water Rule – 40 CFR 141, Subpart S

ARTICLE 1. GENERAL REQUIREMENTS

R18-4-121. ~~Renumbered~~ Ground Water Rule – 40 CFR 141, Subpart S

40 CFR 141, Subpart S (40 CFR 141.400 through 141.405), is hereby incorporated by reference as of the date specified in R18-4-102; this incorporation does not include any later amendments or editions.