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 3. AGRICULTURE

CHAPTER 2. DEPARTMENT OF AGRICULTURE
ANIMAL SERVICES DIVISION

Editor's Note: The following Notice of Proposed Rulemaking was reviewed per the Governor's Regulatory Review Plan memorandum, January 22, 2009 and the continuations issued April 30 and June 30, 2009. (See the memoranda in this issue on pages 1611 through 1613.) The Governor's Office authorized the notice to proceed through the rulemaking process on August 31, 2009.

[R09-90]

PREAMBLE

1. Sections Affected **Rulemaking Action**

R3-2-202 Amend

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. §§ 3-107(A)(1) and 3-1203(A)

Implementing statute: A.R.S. §§ 3-2046 and 3-2161

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

Notice of Rulemaking Docket Opening: 15 A.A.R. 1573, September 25, 2009

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

Name: Stewart Jacobson

Address: Department of Agriculture
1688 W. Adams St.
Phoenix, AZ 85007

Telephone: (602) 542-6398

Fax: (602) 542-4194

E-mail: sjacobson@azda.gov

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

This proposed rulemaking updates the incorporation by reference of federal regulations to the 2009 version of those regulations. New federal regulations became effective on October 1, 2007 entitled "Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle." These new regulations relate to the prevention of the transmission of bovine spongiform encephalopathy (mad cow disease) to humans through the human food supply. The effects of mad cow disease on humans include muscle spasms, lack of muscle control, memory problems and even death. The 2004 version of the federal regulations currently listed in this rule does not include the most recent changes. In addition, the United States Department of Agriculture requires states to have inspection standards at least equal to the federal standards, and this rulemaking will accomplish that.

These provisions attempt to prevent the transmission of bovine spongiform encephalopathy to the human food supply in two primary ways. One, they prevent cattle that cannot walk or rise from being slaughtered for use as human food. Two, they prevent specified risk materials from cattle over 30 months old, including the brain, skull, eyes, trigeminal

ganglia, spinal cord, certain parts of the vertebral column, and dorsal root ganglia, and the tonsils and distal ileum from all cattle from being used in the human food supply.

The 2009 version of the federal regulations contains a few additional minor updates to the 2004 version. These include inserting a definition for a main-dish poultry product and extending existing nutrient content claim requirements to those products; adding requirements for substitute standardized meat and poultry food products named by use of an expressed nutrient content claim (e.g. "low fat" products); and eliminating certain sodium content restrictions on meat and poultry products labeled as healthy.

The proposed rulemaking also simplifies the rule by combining subsections (A) and (B) in order to eliminate the redundant incorporation of the same federal regulations in both subsections.

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:

None

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:

Not applicable

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

The rulemaking will have a minimal impact on the Arizona Department of Agriculture. The Department's employees responsible for meat and poultry inspection are familiar with the new federal requirements, so this rulemaking will not require significant training. Additionally, the requirements adopted in these changes represent a small part of the meat inspection requirements, thus the changes do not add a significant burden to the Department's current responsibilities. The Arizona rulemaking is also anticipated to have a minimal impact on private industry. The latest federal regulations already apply to private industry; this rulemaking gives the State authority to enforce them. Without enforcement by the Department, these regulations would be enforced by federal officials. Notwithstanding, the Department acknowledges that the federal government estimated the (nationwide) economic impact of the federal rule change to be an average of $171.2 million per year for five years and determined that the federal rule change would not have a significant impact on a substantial number of small entities.

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:	Stewart Jacobson
Address:	Department of Agriculture 1688 W. Adams St. Phoenix, AZ 85007
Telephone:	(602) 542-6398
Fax:	(602) 542-4194
E-mail:	sjacobson@azda.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:

A person may request an oral proceeding on the proposed rules by contacting the individual identified in item 4 within 30 days of publication of this notice.

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:

The rule incorporates 9 CFR Chapter III, revised January 1, 2009, except sections 302.2, 307.5, 307.6, 312, 322, 327, 329.7, 329.9, 331, 335, 351, 352, 354, 355, 381.38, 381.39, 381.96 through 381.112, 381.195 through 381.209, 381.218 through 381.225, 390, 391, 590 and 592.

13. The full text of the rule follows:

TITLE 3. AGRICULTURE

CHAPTER 2. DEPARTMENT OF AGRICULTURE
ANIMAL SERVICES DIVISION

ARTICLE 2. MEAT AND POULTRY INSPECTION

Section
R3-2-202. Meat and Poultry Inspection; Slaughtering Standards

ARTICLE 2. MEAT AND POULTRY INSPECTION

R3-2-202. Meat and Poultry Inspection; Slaughtering Standards

~~A.~~ All meat and poultry inspection and slaughtering procedures shall be conducted as prescribed in 9 CFR Chapter III, ~~Subchapters A and E, revised as of January 1, 2003, amended at 69 FR 250-255, January 5, 2004~~ revised January 1, 2009, except sections 302.2, 307.5, 307.6, 312, 322, 327, 329.7, 329.9, 331, 335, 351, 352, 354, 355, 381.38, 381.39, 381.96 through 381.112, 381.195 through 381.209, 381.218 through 381.225, 390, 391, 590 and 592. This material is incorporated by reference~~, on file with the Department,~~ and does not include any later amendments or editions. ~~The following parts and sections of 9 CFR are excepted from incorporation: 302.2, 307.5, 307.6, 312, 322, 327, 329.7, 329.9, 331, and 335.~~ A copy of the incorporated material ~~may be~~ is available from the Department and may also be viewed at www.gpoaccess.gov/cfr/index.html or purchased from the U.S. Government Online Bookstore at ~~www.bookstore.gpo.gov~~ bookstore.gpo.gov.

~~B. All poultry inspection and slaughtering procedures shall be conducted as prescribed in 9 CFR Chapter III, Subchapters A and E, revised as of January 1, 2003, amended at 69 FR 250-255, January 5, 2004. This material is incorporated by reference, on file with the Department, and does not include any later amendments or editions. The following sections of 9 CFR are excepted from incorporation: 381.38, 381.39, 381.96 through 381.112, 381.195 through 381.209, 381.218, and 381.220 through 381.225. A copy of the incorporated material may be purchased from the U.S. Government Online Bookstore at www.bookstore.gpo.gov.~~

NOTICE OF PROPOSED RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

Editor's Note: The following Notice of Proposed Rulemaking was reviewed per the Governor's Regulatory Review Plan memorandum, January 22, 2009 and the continuations issued April 30 and June 30, 2009. (See the memoranda in this issue on pages 1611 through 1613.) The Governor's Office authorized the notice to proceed through the rulemaking process on August 28, 2009.

[R09-91]

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 rules are implementing (specific):
Authorizing statutes: A.R.S. § 32-1904(A)(1)

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

3. A list of all previous notices appearing in the Register addressing the proposed rules:
Notice of Rulemaking Docket Opening: 15 A.A.R. 1513, September 11, 2009

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:
H.B. 2164 passed by the 49th Legislature allows pharmacists to administer certain vaccines to adult patients without a prescription based on approved protocols. The rulemaking will amend the language of R4-23-411 (Pharmacist-

administered Adult Immunizations) to comply with the requirements of H.B. 2164. 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 moderate economic impact on pharmacists and pharmacies. The rulemaking will allow properly certified pharmacists to administer the majority of adult vaccines recommended by the Centers for Disease Control without a prescription from a medical practitioner. This will increase the number of patients a pharmacist may serve and increase the public's access to needed vaccines. Being able to administer vaccines without a prescription will provide pharmacists or pharmacies with opportunity for increased income. The Board estimates that the ability to administer vaccines without a prescription 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 reduced time to receive vaccination without the need to obtain a prescription from a medical practitioner. 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, November 2, 2009. An oral proceeding is scheduled for:

Date:	November 2, 2009
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 immunizations, vaccines, and, in an emergency, epinephrine and diphenhydramine to an eligible adult patient. As used in this Section, "eligible adult patient" means an eligible patient 18 years of age or older. ~~If a pharmacist meets the qualifications and standards specified by this Section and the Board certifies the pharmacist, the pharmacist may, upon receipt of a valid prescription order, administer vaccines listed in the Center for Disease Control's (CDC) Recommended Adult Immunization Schedule, published October 1, 2008, and no future amendments or editions, which is incorporated by reference, vaccines recommended in the CDC Health Information for International Travel 2008, published May 15, 2007, and no future amendments or editions, which is incorporated by reference, and, in an emergency, epinephrine and diphenhydramine to an eligible adult patient. The documents incorporated by reference are on file with the Board and available from the CDC at http://www.cdc.gov/vaccines/recs/schedules/adult-schedule.htm and http://wwwn.cdc.gov/travel/contentYellowBook.aspx. The Board shall certify a pharmacist who meets the qualifications established in subsection (B).~~ A pharmacist may administer, without a prescription, immunizations or vaccines and, in an emergency, epinephrine and diphenhydramine to an eligible adult patient, if:

1. The pharmacist meets the qualifications and standards specified by A.R.S. § 32-1974 and this Section;
2. The Board certifies the pharmacist as specified in subsection (B);
3. The immunization or vaccine is listed in the United States Centers for Disease Control and Prevention's Recommended Adult Immunization Schedule, or the immunization or vaccine is recommended in the United States Centers for Disease Control and Prevention's Health Information for International Travel; and
4. The immunization or vaccine is not on the Arizona Department of Health Services list established in A.A.C. R9-6-1301 as required under A.R.S. § 32-1974 and specified in subsection (G).
5. A pharmacist who has authority to administer immunizations or vaccines and, in an emergency, epinephrine and diphenhydramine to an eligible adult patient shall not delegate the authority to any other pharmacist or employee.

B. Qualifications for authorization to administer immunizations or vaccines and, in an emergency, epinephrine and diphenhydramine to an eligible adult patient. After receipt of a completed application form, the Board shall issue a certificate authorizing the administration of immunizations or vaccines and, in an emergency, epinephrine and diphenhydramine to an eligible adult patient 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 immunizations or vaccines and, in an emergency, epinephrine and diphenhydramine to an eligible adult patient 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 approved protocol or 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~~ A pharmacist granted authorization under this Section to administer immunizations or vaccines and, in an emergency, epinephrine and diphenhydramine to an eligible adult patient shall provide to the pharmacy the following documentation regarding each immunization or vaccine 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, epinephrine, or diphenhy-

dramine;

d. The name and address of the patient's primary health care provider or physician, 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.~~e. The name of the pharmacist administering the immunization;

~~g.~~f. 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.~~g. The date and time that the written report specified in subsection (D)(2) was sent to the patient's primary health care provider or physician;

~~i.~~h. Consultation or other professional information provided to the patient by the pharmacist; and

~~j.~~i. 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 or physician containing the documentation required in subsection (D)(1) within ~~14 days of~~ 48 hours after the immunization. The pharmacy shall make the required records specified in subsection (D)(1) and a record of compliance with this subsection available in the pharmacy for inspection by the Board or its designee.
3. A pharmacy's pharmacist-in-charge shall maintain the records required in subsection (D)(1) in the pharmacy for a minimum of seven years from the immunization's administration date.

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 immunizations or vaccines and, in an emergency, epinephrine and diphenhydramine to an eligible adult patient shall be renewed biennially by submitting a renewal request within the 30 days before the certificate's expiration date. A 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.

G. Pharmacist-administered adult immunizations that require a prescription order. A pharmacist certified by the Board to administer adult immunizations or vaccines shall not administer any immunization or vaccine listed in A.A.C. R9-6-1301 without a prescription order. In addition to filing a prescription order as required in A.R.S. § 32-1964, a pharmacist who administers an immunization or vaccine listed in A.A.C. R9-6-1301 shall comply with the recordkeeping requirements of subsection (D)(1).