

The legislature passed and Governor Jan Brewer signed Senate Bill 1298, which significantly modified the authority granted by the legislature for pharmacist administered immunizations and collaborative practice agreements that were authorized by previous legislatures. These changes will take effect on July 20, 2011. Unfortunately the governor's office has placed a moratorium on rules changes by state agencies including the Arizona State Board of Pharmacy, which has been in effect for at least the last two years and will continue indefinitely. In the absence of a rules moratorium, the Board's normal practice would have been to write rules that "flesh out" the statutes and the Board would modify and/or eliminate those rules that have been made obsolete by the new statutes. Since the Board is bound to abide by the existing rules moratorium, the existing rules will continue to be published and will contradict the new statutes resulting in a state of confusion which may persist for some period of time. As a general "rule of thumb" statutes passed by the legislature and signed by the governor "trump" or take precedence over rules promulgated by the Board. Therefore, until the Board's proposed rules have been finalized (hopefully by early 2012), the Board will be enforcing the legislative statute changes in Senate Bill 1298 and not enforcing the Board administrative rules in all cases of conflict between them.

ARTICLE 4. PROFESSIONAL PRACTICES

R4-23-411. Pharmacist-administered Adult or Pharmacy or Graduate Intern-administered Immunizations

A. Authority Certification to administer immunizations, vaccines, and, in an emergency, epinephrine and diphenhydramine to an eligible adult patient or eligible minor patient. As used in this Section, "eligible adult patient" means an eligible patient 18 years of age or older and "eligible minor patient" means an eligible patient at least six years of age but under eighteen years of age. A pharmacist or a pharmacy or graduate intern, in the presence of and under the immediate personal supervision of a certified pharmacist, may administer, without a prescription, immunizations or vaccines and, in an emergency, epinephrine and diphenhydramine to an eligible adult patient or eligible minor patient, if:

1. The pharmacist or pharmacy or graduate intern meets the qualifications and standards specified by A.R.S. § 32-1974 and this Section;
2. The Board certifies the pharmacist or pharmacy or graduate intern as specified in subsection ~~(C)~~(D);
3. ~~The~~ For an eligible adult patient, 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~~ For an eligible adult patient, the immunization or vaccine is not on the Arizona Department of Health Services list specified in A.A.C. R9-6-1301 as required under A.R.S. § 32-1974 and subsection ~~(H)~~(I);
5. For an eligible minor patient, the immunization or vaccine is for influenza; and

6. For an eligible minor patient, any immunizations or vaccines other than influenza are administered in response to a public health emergency declared by the Governor under A.R.S. § 36-787.

B. A pharmacist or a pharmacy or graduate intern, in the presence of and under the immediate personal supervision of a certified pharmacist, may administer, with a prescription, any immunizations or vaccines and, in an emergency, epinephrine and diphenhydramine to an eligible adult patient or eligible minor patient, if:

1. The pharmacist or pharmacy or graduate intern meets the qualifications and standards specified by A.R.S. § 32-1974 and this Section;

2. The Board certifies the pharmacist or pharmacy or graduate intern as specified in subsection (D).

B.C. A pharmacist or pharmacy or graduate intern who ~~has authority~~ is certified to administer immunizations or vaccines and, in an emergency, epinephrine and diphenhydramine to an eligible adult patient or eligible minor patient shall not:

1. Not delegate the authority to any other pharmacist, pharmacy or graduate intern, or employee; and

2. Maintain their current certificate for inspection by the Board or its designee or review by the public.

C.D. Qualifications for ~~authorization~~ certification to administer immunizations or vaccines and, in an emergency, epinephrine and diphenhydramine to an eligible adult patient or eligible minor 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 or eligible minor patient to a pharmacist or pharmacy or graduate intern 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 ~~(D)~~(E); and

3. Has a current certificate in basic cardiopulmonary resuscitation.

D.E. ~~Pharmacist administered adult immunizations~~ Immunizations training program requirements. A training program for pharmacists or pharmacy or graduate interns to administer immunizations or vaccines and, in an emergency, epinephrine and diphenhydramine to an eligible adult patient or eligible minor 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 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 ~~(E)~~(F).

E.F. Recordkeeping and reporting requirements.

1. A pharmacist or pharmacy or graduate intern granted ~~authorization~~ certification under this Section to administer immunizations or vaccines and, in an emergency, epinephrine and diphenhydramine to an eligible 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 diphenhydramine;
 - d. The name and address of the patient's primary health care provider or physician, as identified by the patient;
 - e. The name of the pharmacist or pharmacy or graduate intern administering the immunization;
 - f. A record of the pharmacist's or pharmacy or graduate intern's consultation with the patient determining that the patient is an eligible patient as defined in R4-23-110;
 - g. The date and time that the written report specified in subsection ~~(E)~~(F)(2) was sent to the patient's primary health care provider or physician;
 - h. Consultation or other professional information provided to the patient by the pharmacist or pharmacy or graduate intern; ~~and~~
 - i. The name and date of the vaccine information sheet provided to the patient; and
 - j. For immunizations or vaccines given to an eligible minor patient, a consent form signed by the minor's parent or guardian.
2. The pharmacist or pharmacy or graduate intern shall provide a written report to the patient's primary health care provider or physician containing the documentation required in subsection ~~(E)~~(F)(1) within 48 hours after the immunization. The pharmacy shall make the required records specified in subsection ~~(E)~~(F)(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 ~~(E)~~(F)(1) in the pharmacy for a minimum of seven years from the immunization's administration date.

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

G.H. Renewal of a certificate for pharmacist-administered or pharmacy or graduate intern-administered ~~adult~~ immunizations. A certificate authorizing a pharmacist or pharmacy or graduate intern 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 or pharmacy or graduate intern 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.

H.I. Pharmacist-administered or pharmacy or graduate intern-administered adult immunizations that require a prescription order. A pharmacist or pharmacy or graduate intern 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 or pharmacy or graduate intern who administers an immunization or vaccine listed in A.A.C. R9-6-1301 shall comply with the recordkeeping requirements of subsection ~~(E)~~(F)(1).