

NOTICE OF EXEMPT RULEMAKING
 TITLE 9. HEALTH SERVICES
 CHAPTER 6. DEPARTMENT OF HEALTH SERVICES
 COMMUNICABLE DISEASES AND INFESTATIONS
 ARTICLE 13. IMMUNIZATIONS OR VACCINES REQUIRING PRESCRIPTIONS FOR
 PHARMACIST ADMINISTRATION

PREAMBLE

1. Sections Affected Rulemaking Action
 R9-6-1301 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. § 36-136(A)(7) and (G)
 Implementing statute: A.R.S. § 32-1974

3. The effective date of the rules:
 Date filed with the Office of the Secretary of State: November 14, 2017

4. A list of all previous notices appearing in the Register addressing the exempt rule:
 Notice of Public Information: 23 A.A.R. 2763, October 6, 2017

5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:
 Name: Karen Lewis, M.D.
 Address: Arizona Department of Health Services
 Office of Immunizations
 150 N. 18th Avenue, Suite 120
 Phoenix, AZ 85007
 Telephone: (602) 364-3856
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 or
 Name: Robert Lane, Chief
 Address: Office of Administrative Counsel and Rules
 Arizona Department of Health Services
 150 N. 18th Avenue, Suite 200
 Phoenix, AZ 85007

Telephone: (602) 542-1020
Fax: (602) 364-1150
E-mail: Robert.Lane@azdhs.gov

6. An explanation of the rule, including the agency's reasons for the rule, including the statutory citation to the exemption from regular rulemaking procedures:

A.R.S. § 32-1974 authorizes pharmacists to administer certain immunizations in compliance with rules adopted by the Arizona Board of Pharmacy. A.R.S. § 32-1974(I) requires the Arizona Department of Health Services (Department) to establish and maintain “a list of immunizations or vaccines that may be administered to adults by a pharmacist only pursuant to a prescription order.” A.R.S. § 32-1974(I) also makes the Department exempt from rulemaking requirements of Title 41, Chapter 6, in establishing and maintaining the list. The Department had adopted a rule in 9 A.A.C. 6, Article 13 specifying those immunizations or vaccines that require a prescription order before being administered by a pharmacist.

A new vaccine for cholera just became available and needs to be added to the list. The new cholera vaccine is a live-attenuated vaccine, and the safety of the vaccine has not been widely studied, including in immunocompromised people. People with weakened immune systems are at higher risk of complications from live-attenuated vaccines. A physician or registered nurse practitioner should evaluate an individual before the vaccine is administered to discuss the risks to the individual and those in close contact with the individual before the individual receives this vaccine. Therefore, it is critical that this vaccine be added to the list in 9 A.A.C. 6, Article 13 to protect an individual who may ask to be immunized by a pharmacist without knowing the potential consequences. The Department is also clarifying the rule to conform to changes made to A.R.S. § 32-1974 by Laws 2011, Ch. 103, § 2 and Laws 2016, Ch. 267, § 3.

After receiving an exception from the rulemaking moratorium established by Executive Order 2017-02, the Department is revising the rule in 9 A.A.C. 6, Article 13 to clarify requirements and add the new cholera vaccine to the list of immunizations or vaccines that may be administered to an adult by a pharmacist only pursuant to a prescription order.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on in its evaluation of or justification for the rule or did not 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 Department did not review or rely on any study related to this rulemaking package.

8. 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

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

Not applicable

10. A description of the changes between the proposed rules, including supplemental notices, and final rules:

Not applicable

11. A summary of the comments made regarding the rule and the agency response to them:

Not applicable

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

Not applicable

13. Incorporations by reference and their location in the rule:

None

14. Was this rule previously made as an emergency rule? If so, please indicate the Register citation:

No

15. The full text of the rules follows:

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Section

R9-6-1301. Immunizations or Vaccines Requiring a Prescription Order for Pharmacist
Administration

**ARTICLE 13. IMMUNIZATIONS OR VACCINES REQUIRING PRESCRIPTIONS FOR
PHARMACIST ADMINISTRATION**

R9-6-1301. Immunizations or Vaccines Requiring a Prescription Order for Pharmacist Administration

- A. In this Section, unless otherwise specified, the following definitions apply:
1. "Certified pharmacist" means an individual licensed under A.R.S. Title 32, Chapter 18, who is authorized under A.A.C. R4-23-411 to administer immunizations or vaccines to adults.
 2. "Immunization" has the same meaning as in A.R.S. § 36-671.
 3. "Prescription order" has the same meaning as in A.R.S. § 32-1901.
 4. ~~"Vaccine" has the same meaning as "biological product" defined in 21 CFR 600.3 (April 1, 2008).~~
- B. The following immunizations or vaccines require a prescription order before the immunization or vaccine may be administered under R4-23-411 by a certified pharmacist:
1. Japanese Encephalitis vaccine,
 2. Rabies vaccine,
 3. Typhoid vaccines, and
 4. Yellow fever vaccine, and
 5. Cholera vaccine.