

AGENCY RECEIPT

SECRETARY OF STATE

NOTICE OF RULEMAKING DOCKET OPENING

2023 MAR 21 PM 1:34

1. Agency name: Board of Pharmacy

FILED

2. The Subchapters, if applicable; the Articles; the Parts, if applicable, and the Sections involved in the rulemaking, listed in numerical order:

Article, Part, or Section Affected (as applicable) Rulemaking Action

(in numerical order)

R4-23-204

Amend

R4-23-407.2

New Section

NOTICE OF RULEMAKING DOCKET OPENING

SECRETARY OF STATE

2023 MAR 21 PM 1:34

FILED

- 1. Title and its heading:** 4. Professions and Occupations
Chapter and its heading: 23. Board of Pharmacy
Article and its heading: 2. Pharmacist Licensure and 4. Professional Practices
Section numbers: R4-23-204 and R4-23-407.2 (Additional Sections may be made, amended, or repealed as necessary)
- 2. The subject matter of the proposed rule:**
Under Laws 2021, Chapter 429, the legislature enacted A.R.S. § 32-1979.01 authorizing a pharmacist to dispense a self-administered hormonal contraceptive under a standing prescription order to specified individuals. The statute required the Board, in conjunction with the Department of Health Services and in consultation with a national professional organization specializing in obstetrics and gynecology, to make rules establishing standard procedures for pharmacists to follow when dispensing the self-administered hormonal contraceptives. This rulemaking establishes the required standard procedures.

As required under A.R.S. § 41-1039, an exemption for this rulemaking was obtained from Zaida Dedolph, health policy advisor in the governor's office, in an e-mail dated March 3, 2023.

- 3. A citation to all published notices relating to the proceeding:**
None
- 4. Name and address of agency personnel with whom persons may communicate regarding the rule:**
Name: Kamlesh Gandhi
Address: 1616 W Adams Street, Suite 120
Phoenix, AZ 85007
Telephone: (602) 771-2740
Fax: (602) 771-2749
E-mail: kgandhi@azpharmacy.gov
Website: www.azpharmacy.gov
- 5. The time during which the agency will accept written comments and the time and place where oral comments may be made:**

The Board will accept comments during business hours at the address listed in item 4. Information regarding an oral proceeding will be included in the Notice of Proposed Rulemaking.

6. A timetable for agency decisions or other action on the proceeding, if known:

To be determined

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Amend

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**AGENCY CERTIFICATE
NOTICE OF PROPOSED RULEMAKING**

SECRETARY OF STATE

2023 MAR 21 PM 1:35

FILED

1. **Agency name:** Board of Pharmacy
2. **Chapter heading:** Board of Pharmacy
3. **Code citation for the Chapter:** 4 A.A.C. 23
4. **The Subchapters, if applicable; the Articles; the Parts, if applicable, and the Sections involved in the rulemaking, listed in numerical order:**

Article, Part, or Section Affected (as applicable) Rulemaking Action
(in numerical order)

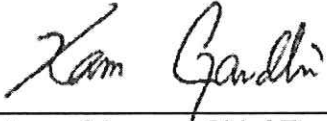
R4-23-204

Amend

R4-23-407.2

New Section

5. **The rules contained in this package are true and correct as proposed.**

6. 

Signature of Agency Chief Executive Officer in ink

3/20/2023

Date of signing

Kamlesh Gandhi
Printed or typed name of signer

Executive Director
Title of signer

NOTICE OF PROPOSED RULEMAKING
TITLE 4. PROFESSIONS AND OCCUPATIONS
CHAPTER 23. BOARD OF PHARMACY

PREAMBLE

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

R4-23-204

Amend

R4-23-407.2

New Section

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)

Implementing statute: A.R.S. §§ 32-1936 and 32-1979.01

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: 29 A.A.R. XX

4. The agency's contact person who can answer questions about the rulemaking:

Name: Kamlesh Gandhi

Address: 1616 W Adams Street, Suite 120
Phoenix, AZ 85007

Telephone: (602) 771-2740

Fax: (602) 771-2749

E-mail: kgandhi@azpharmacy.gov

Website: www.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:

Under Laws 2021, Chapter 429, the legislature enacted A.R.S. § 32-1979.01 authorizing a pharmacist to dispense a self-administered hormonal contraceptive under a standing prescription order to specified individuals. The statute required the Board, in conjunction with the Department of Health Services and in consultation with a national professional organization specializing in obstetrics and gynecology, to make rules establishing standard procedures for pharmacists to follow when dispensing the self-administered hormonal contraceptives. This rulemaking establishes the required standard procedures.

As required under A.R.S. § 41-1039, an exemption for this rulemaking was obtained from Zaida Dedolph, health policy advisor in the governor's office, in an e-mail dated March 3, 2023.

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:

Access to contraception influences public health and well-being. The most widely used form of contraception in the U.S. is the pill. However, in spite of the availability of contraceptive methods, more than 40 percent of U.S. pregnancies are unintended. Unintended pregnancies occur disproportionately among women who are young, less educated, poorer, and of a racial or ethnic minority. Most unintended pregnancies result from not using contraception or from not using it consistently or correctly. (See

<https://www.cdc.gov/reproductivehealth/contraception/unintendedpregnancy/index.htm>)

Clearly, many people could benefit from having access to contraceptives more easily available. A.R.S. § 32-1979.01 was a step in that direction.

In a September 1, 2022, report, the National Alliance of State Pharmacy Associations indicated that Arizona is one of 22 states with statutes or rules that allow pharmacists to prescribe hormonal contraceptives (See <https://naspa.us/resource/contraceptives>). The other states are Arkansas, California, Colorado, Delaware, District of Columbia, Hawaii, Idaho, Illinois, Maryland, Minnesota, Nevada, New Hampshire, New Jersey, New Mexico, North Carolina, Oregon, South Carolina, Utah, Vermont, Virginia, and West Virginia.

A report written by Maria I. Rodriguez and published in the JAMA Network Open (See <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2766072>) found that women receiving hormonal contraceptives from a pharmacist were those most at risk of an unintended pregnancy--younger, less educated, and more likely to be uninsured than women seeing a clinician. Unlike clinicians, pharmacists were more likely to prescribe a 6-month or greater supply of contraceptives, which improved contraceptive continuation by preventing breaks in coverage. Pharmacists have an advantage in making contraceptives more widely available due to the number of pharmacist locations, extended hours compared with clinics, and no appointment requirements. (See <https://www.uspharmacist.com/article/pharmacists-prescribing-hormonal-contraceptives-a->

status-update). Across the U.S., 48 percent of the population lives within one mile of a pharmacy. More than 96 percent of the population lives within 10 miles of a pharmacy. (See [https://www.japha.org/article/S1544-3191\(22\)00233-3/fulltext#:~:text=Across%20the%20overall%20U.S.%20population,distance%20greater%20than%2010%20miles](https://www.japha.org/article/S1544-3191(22)00233-3/fulltext#:~:text=Across%20the%20overall%20U.S.%20population,distance%20greater%20than%2010%20miles)).

7. A showing of good cause why the rulemaking is necessary to promote a statewide interest if the rulemaking 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 rulemaking will have minimal economic impact for pharmacists who will now be able to prescribe self-administered hormonal contraceptives under a standing prescription order rather than individualized prescription orders. The primary economic impact, which results from statute rather than rule, will be on individuals who are able to obtain self-administered hormonal contraceptives under the standing prescription order rather than repeatedly paying to see a primary care physician to obtain an individual prescription order.

9. The agency's contact person who can answer questions about the economic, small business, and consumer impact statement:

Name: Kamlesh Gandhi

Address: 1616 W Adams Street, Suite 120
Phoenix, AZ 85007

Telephone: (602) 771-2740

Fax: (602) 771-2749

E-mail: kgandhi@azpharmacy.gov

Website: www.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:

An oral proceeding regarding the proposed rules will be held as follows:

Date: Tuesday, May 16, 2023

Time: 9:00 a.m.

Location: 1616 W Adams St, Suite 120, Phoenix, AZ 85007

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.R.S. § 32-1979.01(C) requires the Board to make rules in conjunction with the Department of Health Services and in consultation with a national professional organization specializing in obstetrics and gynecology. This was done. The national profession organization was The American College of Obstetricians and Gynecologists.

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:

Pharmacists are licensed by the Board however no rule in this rulemaking addresses licensure.

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:

There are numerous federal laws regarding drugs but none in applicable to the specific subject matter of this rulemaking.

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 analysis was submitted.

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 2. PHARMACIST LICENSURE

Section

R4-23-204. Continuing Education Requirements

ARTICLE 4. PROFESSIONAL PRACTICES

R4-23-407.1. Prescribing a Self-administered Hormonal Contraceptive

ARTICLE 2. PHARMACIST LICENSURE

R4-23-204. Continuing Education Requirements

A. Under A.R.S. § 32-1936, continuing professional pharmacy education is mandatory for all licensees.

1. General continuing education requirement. In accordance with A.R.S. § 32-1925(F), the Board shall not renew a license unless the licensee has, during the two years preceding the application for renewal, participated in 30 contact hours (3.0 CEUs) of continuing education activity sponsored by an Approved Provider as defined in R4-23-110.
2. Special continuing education requirement. The Board shall not renew a license unless:
 - a. A licensee certified under R4-23-411 to administer immunizations, vaccines, and emergency medications has participated in at least two contact hours of continuing education activity related to administering immunizations, vaccines, and emergency medications; ~~and~~
 - b. A licensee authorized to dispense controlled substances has participated in at least three contact hours of opioid-related, substance use disorder-related, or addiction-related continuing education activity; and
 - c. A licensee who prescribes self-administered hormonal contraceptives under a standing prescription order has participated in at least three contact hours of continuing education activity related to self-administered hormonal contraceptives.
3. A pharmacist is exempt from the continuing education requirement in subsections (A)(1) and (2) between the time of initial licensure and first renewal.

B. Acceptance of continuing education units CEUs. The Board shall:

1. Accept CEUs for continuing education activities sponsored only by an Approved Provider;
2. Accept CEUs accrued only during the two-year period immediately before licensure renewal;
3. Not allow CEUs accrued in a biennial renewal period to be carried forward to the succeeding biennial renewal period;
4. Allow a pharmacist who leads, instructs, or lectures to a group of health professionals on pharmacy-related topics in a continuing education activity sponsored by an Approved Provider to receive CEUs for a presentation by following the same attendance procedures as any other attendee of the continuing education activity; and

5. Not accept as CEUs the performance of normal teaching duties within a learning institution by a pharmacist whose primary responsibility is the education of health professionals.
- C. Continuing education records and reporting CEUs. A pharmacist shall:
1. Maintain continuing education records that:
 - a. Verify the continuing education activities the pharmacist participated in during the preceding five years; and
 - b. Consist of a statement of credit or a certificate issued by an Approved Provider at the conclusion of a continuing education activity;
 2. At the time of licensure renewal, attest to the number of CEUs the pharmacist participated in during the renewal period on the biennial renewal form; and
 3. When requested by the Board office, submit proof of continuing education participation within 20 days of the request.
- D. The Board may revoke, suspend, or place on probation the license of a pharmacist who fails to comply with continuing education participation, recording, or reporting requirements of this Section.
- E. A pharmacist who is aggrieved by any decision of the Board or its administrative staff concerning continuing education units may request a hearing before the Board.

ARTICLE 4. PROFESSIONAL PRACTICES

R4-23-407.2. Prescribing a Self-administered Hormonal Contraceptive

- A. Standard procedures. The first time a pharmacist prescribes a self-administered hormonal contraceptive under a standing prescription order, as authorized under A.R.S. § 32-1979.01, to a patient, the pharmacist shall:**
- 1. Determine the patient is at least 18 years old;**
 - 2. Obtain from the patient a completed nationally recognized self-screening risk assessment;**
 - 3. Provide the patient with written information prepared by the manufacturer of the hormonal contraceptive; and**
 - 4. Provide the following information orally to the patient:**
 - a. How hormonal contraception works;**
 - b. When and how to take the self-administered hormonal contraceptive;**

- c. Risks associated with taking a self-administered hormonal contraceptive; and
 - d. When to seek medical assistance while taking a self-administered hormonal contraceptive.
- B. A pharmacist who prescribes a self-administered hormonal contraceptive under a standing prescription order shall have a patient complete the nationally recognized self-screening risk assessment required under subsection (A)(2) annually.
- C. A pharmacist who prescribes a self-administered hormonal contraceptive under a standing prescription order shall maintain evidence of the patient's age at the time of initial dispensing and the completed nationally recognized self-screening risk assessment for at least seven years. The pharmacist shall ensure this information is readily retrievable and available to the Board on request.
- D. When prescribing a self-administered hormonal contraceptive under a standing prescription order, a pharmacist shall comply with R4-23-407 except subsection (A)(1)(b), R4-23-408, and R4-23-409.
- E. During each biennial renewal period, a pharmacist who prescribes self-administered hormonal contraceptives under a standing prescription order shall complete the three contact hours of continuing education specified under R4-23-204(A)(2)(c).