AGENCY RECEIPT

NOTICE OF FINAL RULEMAKING

1. **Agency name:** Board of Pharmacy

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) (in numerical order)	**Rulemaking Action**
R4-23-204	Amend
R4-23-407.2	New Section

AGENCY CERTIFICATE

NOTICE OF FINAL RULEMAKING

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) (in numerical order)	**Rulemaking Action**
R4-23-204	Amend
R4-23-407.2	New Section

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

6. Kam Gandhi — July 5, 2023

Signature of Agency Chief Executive Officer in ink — Date of signing

Kamlesh Gandhi — Executive Director

Printed or typed name of signer — Title of signer

7. **No changes have been made to these rules since the Governor's Regulatory Review Council approved the rules.**

GOVERNOR'S REGULATORY REVIEW COUNCIL

CERTIFICATE OF APPROVAL OF FINAL RULES

1. **Agency Name: Board of Pharmacy**
2. **Chapter Heading: Board of Pharmacy**
3. **Citation for the Chapter: 4 A.A.C. 23**

Subchapters, Articles, Parts and Sections	Action:
R4-23-204	Amend
R4-23-407.2	New Section

4. **The rules described above are approved as final rules.**
   - _x__ **approved as submitted (R1-6-205(A))**
   - ___ **approved in part, returned in part (A.R.S. § 41-1052(C))**
   - ___ **approved with changes accepted by the agency (R1-6-205(B))**
5. **Effective date:**
   - ___ **standard 60-day delayed effective date**
   - _x__ **immediate effective date**
   - ___ **other [specify date:]**

Nicole Sornsin
Council Chair

Jul 6, 2023
Date of Approval

NOTICE OF FINAL 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 both 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. The effective date for the rules:

The Board respectfully requests under A.R.S. § 41-1032(A)(1) and (A)(4) that the rules in this rule package become effective when filed with the Office of the Secretary of State.

a. If the agency selected a date earlier than the 60-day effective date as specified in A.R.S. § 41-1032(A), include the earlier date and state the reason or reasons the agency selected the earlier effective date as provided in A.R.S. § 41-1032(A)(1) through (5):

The Board respectfully requests under A.R.S. § 41-1032(A)(1) and (A)(4) that the rules become effective when filed with the Office of the Secretary of State. The rules will have significant positive effect on public health by making hormonal contraceptives more readily available. Being able to obtain hormonal contraceptives easily is important to consistent use and prevention of unintended pregnancies. This provides an economic and social benefit to the public and there is no penalty associated with violation of the rules. The need for an immediate effective date was not caused by delay or inaction by the Board, which was required by statute to work cooperatively with DHS and consult with a national professional organization specializing in obstetrics and gynecology. Identifying and seeking consultation with The American College of Obstetricians and Gynecologists and coordinating with DHS required time because all entities involved were focused primarily on addressing the consequences of the COVID19 pandemic.

b. If the agency selected a date later than the 60-day effective date as specified in A.R.S. § 41-1032(A), include the later date and state the reason or reasons the agency selected the later effective date as provided in A.R.S. § 41-1032(B):

Not applicable

4. Citation to all related notices published in the *Register* to include the *Register* as specified in R1-1-409(A) that pertain to the record of the final rulemaking package:

Notice of Rulemaking Docket Opening: 29 A.A.R. 833, April 7, 2023

Notice of Proposed Rulemaking: 29 A.A.R. 829, April 7, 2023

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

Name: Kamlesh Gandhi

Address: 1110 W. Washington Street, Suite 260
Phoenix, AZ 85007

Telephone: (602) 771-2740

Fax: (602) 771-2749

E-mail: kgandhi@azpharmacy.gov

Website: www.azpharmacy.gov

6. 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. As required under A.R.S. § 41-1039(B), approval to submit these proposed rules to the Council was provided by Ms. Dedolph, in an e-mail dated May 18, 2023.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on 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:

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, Washington, 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).

8. **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

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

   The rulemaking will have economic impact for pharmacists who will now be able to dispense self-administered hormonal contraceptives under a standing prescription order rather than patient-specific prescription orders. There will be economic benefit for pharmacists who may seek reimbursement for both the consulting they provide to individuals to whom they dispense and the hormonal contraceptive product. There will also be economic impact for pharmacists resulting from requirements regarding recordkeeping and redirecting some hours of continuing education. 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 a patient-specific prescription order.

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

    Jessica Rainbow of the American College of Obstetricians and Gynecologists contacted the governor's office to call attention to a drafting error in the Notice of Proposed Rulemaking. In the NPR, the term "prescribe" was used rather than "dispense" to describe actions by a licensed pharmacist. This is inconsistent with statute (see A.R.S. § 32-1979.01(A)) and with the statutorily defined practice of pharmacy (See A.R.S. § 32-1901(79)).

    The change from using "prescribe" in the NPR to using "dispense" in this NFR is not a substantial change under the terms of A.R.S. § 41-1025(B). Both the subject matter and persons affected by the rule remain the same. The effect also remains the same because a licensed pharmacist or pharmacy permittee would have known prescribing is outside the practice of pharmacy.

    Rob Geddes, on behalf of Albertsons Companies, Inc., suggested additional flexibility by changing "nationally recognized self-screening risk assessment" to "self-screening risk assessment based on nationally recognized guidelines." The Board made the suggested change in two places in R4-23-407.2. This change is not substantial under the terms of A.R.S. § 41-1025(B).

11. An agency's summary of the public or stakeholder comments made about the rulemaking and the agency response to comments:

Jessica Rainbow of the American College of Obstetricians and Gynecologists contacted the governor's office to call attention to a drafting error in the Notice of Proposed Rulemaking. In the NPR, the term "prescribe" was used rather than "dispense" to describe actions by a licensed pharmacist. In a follow-up letter, Dr. Laura Mercer of the American College of Obstetricians and Gynecologist called the Board's attention to the same drafting error. This is inconsistent with statute (see A.R.S. § 32-1979.01(A)) and with the statutorily defined practice of pharmacy (See A.R.S. § 32-1901(79)). The Board thanks Ms. Rainbow and Dr. Mercer for their careful review of the NPR and changed "prescribe" to "dispense" throughout the rulemaking when used to refer to actions by a licensed pharmacist.

Rob Geddes, on behalf of Albertsons Companies, Inc., commented in support of the rulemaking but suggested additional flexibility by changing "nationally recognized self-screening risk assessment" to "self-screening risk assessment based on nationally recognized guidelines." The Board made the suggested change in two places in R4-23-407.2.

The Board received comments supporting the rulemaking from the Arizona Pharmacy Association, Planned Parenthood Arizona, and the March of Dimes.

12. All agencies shall list any 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 is 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.

13. **A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rule:**

None

14. **Whether the rule was previously made, amended, or repealed as an emergency rule. If so, cite the notice published in the *Register* as specified in R1-1-409(A). Also, the agency shall state where the text was changed between the emergency and the final rulemaking packages:**

Neither rule in the rulemaking was previously made, amended, or repealed as an emergency rule.

15. **The full text of the rules follows:**

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 2. PHARMACIST LICENSURE

Section

ARTICLE 4. PROFESSIONAL PRACTICES

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 dispenses 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 attender 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. Dispensing a Self-administered Hormonal Contraceptive

A. Standard procedures. The first time a pharmacist dispenses 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 self-screening risk assessment based on nationally recognized guidelines;
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 dispenses a self-administered hormonal contraceptive under a standing prescription order shall have a patient complete the self-screening risk assessment based on nationally recognized guidelines, required under subsection (A)(2), annually.

C. A pharmacist who dispenses 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 dispensing 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 dispenses 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).

ECONOMIC, SMALL BUSINESS, AND CONSUMER IMPACT STATEMENT[1]

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

1. Identification of 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. As required under A.R.S. § 41-1039(B), approval to submit these proposed rules to the Council was provided by Ms. Dedolph, in an e-mail dated May 18, 2023.

   a. The conduct and its frequency of occurrence that the rule is designed to change:
      Until the rulemaking is completed, the Board will not be in compliance with statute (See A.R.S. § 32-1979.01) requiring the Board to make rules establishing standard procedures for pharmacists to follow when dispensing a self-administered hormonal contraceptive under a standing prescription order.
   b. The harm resulting from the conduct the rule is designed to change and the likelihood it will continue to occur if the rule is not changed:
      It is not good government for the Board to delay establishing the required standard procedures. The delay may negatively impact the health and well-being of individuals who need ready access to hormonal contraceptives.
   c. The estimated change in frequency of the targeted conduct expected from the rule change:

[1] If adequate data are not reasonably available, the agency shall explain the limitations of the data, the methods used in an attempt to obtain the data, and characterize the probable impacts in qualitative terms. (A.R.S. § 41-1055(C)).

When the rulemaking is completed, the Board will be in compliance with statute and licensed pharmacists will be able to dispense hormonal contraceptives under a standing prescription order by following the established standard procedures.

2. A brief summary of the information included in the economic, small business, and consumer impact statement:

   The rulemaking will have economic impact for pharmacists who will now be able to dispense self-administered hormonal contraceptives under a standing prescription order rather than patient-specific prescription orders. There will be economic benefit for pharmacists who may seek reimbursement for both the consulting they provide to individuals to whom they dispense and the hormonal contraceptive product. There will also be economic impact for pharmacists resulting from requirements regarding recordkeeping and redirecting some hours of continuing education. 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 a patient-specific prescription order.

3. The person to contact to submit or request additional data on the information included in the economic, small business, and consumer impact statement:

   Name: Kamlesh Gandhi
   Address: 1110 W. Washington Street, Suite 260
   Phoenix, AZ 85007
   Telephone: (602) 771-2740
   Fax: (602) 771-2749
   E-mail: kgandhi@azpharmacy.gov
   Website: www.azpharmacy.gov

4. Persons who will be directly affected by, bear the costs of, or directly benefit from the rulemaking:

   Licensed pharmacists and the Board will be directly affected by, bear the costs of, and directly benefit from this rulemaking.

   There are currently 6700 licensed pharmacists in Arizona. The Board expects the Department of Health Services will issue a standing order for the entire state. There may be other standing orders issued by a retail pharmacy chain for use by pharmacists employed by the chain or by county health departments. The standing

order will specify conditions, such as those in statute, under which a pharmacist may dispense a hormonal contraceptive under the order. When a pharmacist dispenses under a standing prescription order, the name of the health professional who issued the standing prescription order is recorded in the patient's record and written on the medication dispensed.

Because there is no doctor-patient relationship when a hormonal contraceptive is dispensed under a standing prescription order, the standard procedures established in R4-23-407.2 require a licensed pharmacist to obtain certain information from and provide certain information to the patient seeking the hormonal contraceptive. This consultation will require the pharmacist's time. However, the pharmacist may be able to obtain payment for the consultation from the patient. As with any prescription order dispensed by the pharmacist, the pharmacist is required to maintain certain records. The standard procedures also require the pharmacist to complete three contact hours of continuing education related to self-administered hormonal contraceptives biennially. These are not additional hours of continuing education but rather, a redirection of hours currently required. As a result, the continuing education requirement should have minimal economic impact for the licensed pharmacist.

The Board incurred the cost of completing the rulemaking and will incur the cost of implementing it. The Board has the benefit of being in compliance with statute.

5. Cost-benefit analysis:
   a. Costs and benefits to state agencies directly affected by the rulemaking including the number of new full-time employees at the implementing agency required to implement and enforce the proposed rule:
      The Board is the only state agency directly affected by the rulemaking. The Board's costs and benefits are described in item 4.
   b. Costs and benefits to political subdivisions directly affected by the rulemaking:
      No political subdivision is directly affected by the rulemaking. Some political subdivisions may issue standing prescription orders.
   c. Costs and benefits to businesses directly affected by the rulemaking:
      Licensed pharmacists are businesses directly affected by the rulemaking. Their costs and benefits are described in item 4.
6. Impact on private and public employment:

The rulemaking has no impact on private or public employment.

7. Impact on small businesses[2]:
   a. Identification of the small business subject to the rulemaking:
      Licensed pharmacists who choose to dispense hormonal contraceptives under a standing prescription order are small businesses subject to this rulemaking.
   b. Administrative and other costs required for compliance with the rulemaking:
      Under R4-23-407.2, a pharmacist who chooses to dispense hormonal contraceptives under a standing prescription order is required to obtain certain information from and provide certain information to the patient. As with all drugs dispensed, the pharmacist is also required to maintain records of the dispensing. The pharmacist is also required to obtain three contact hours of continuing education related to self-administered hormonal contraceptives biennially.
   c. Description of methods that may be used to reduce the impact on small businesses:
      Because all licensed pharmacists are small businesses, there is no way to reduce the impact and still achieve the statutory goal of making hormonal contraceptives readily available under a standing prescription order.
8. Cost and benefit to private persons and consumers who are directly affected by the rulemaking:
   Private persons and consumers are not directly affected by the rulemaking.
9. Probable effects on state revenues:
   None
10. Less intrusive or less costly alternative methods considered:
    The Board believes the standard procedures established in the rulemaking are the least intrusive and least costly procedures possible. No alternatives were considered.

[2] Small business has the meaning specified in A.R.S. § 41-1001(23).