NOTICES OF SUPPLEMENTAL PROPOSED RULEMAKING

After an agency has filed a Notice of Proposed Rulemaking with the Secretary of State's Office for Register publication and filing, and the agency decides that, due to public comment or internal review, the rules needs to be substantially changed, the agency shall prepare a Notice of Supplemental Proposed Rulemaking for submission to the Office. The Secretary of State shall publish the Notice, including the Preamble and the full text, in the next available issue of the Arizona Administrative Register.

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 Supplemental Proposed Rulemaking in the Register before holding any oral proceedings (A.R.S. § 41-1022).

NOTICE OF SUPPLEMENTAL PROPOSED RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS CHAPTER 23. BOARD OF PHARMACY

PREAMBLE

1. Register citation and date for the original Notice of Proposed Rulemaking:

1 A.A.R. 1908, October 20, 1995

	Vol.# Page # Issue date	
2.	Sections Affected	Rulemaking Action
	R4-23-110	Amend
	R4-23-612	Amend
	R4-23-651	Amend
	R4-23-671	New Section
	R4-23-672	New Section
	R4-23-673	New Section

3. The specific 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) and (2), and (B)(3), (4), and (6). Implementing statutes: A.R.S. §§ 32-1929, 32-1930(A)(2), (B), and (C), and 32-1931.

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

Name: Dean Wright, Compliance Officer

Address: Board of Pharmacy

5060 North 19th Avenue, Suite 101

Phoenix, Arizona 85015

Telephone: (602) 255-5125, ext. 131

Fax: (602) 255-5740

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

The practice of pharmacy is changing rapidly and a big part of this change is specialization. Pharmacies can no longer be viewed as just community or hospital. To protect the citizens of Arizona, the Board proposes to change the rules to better define and control today's pharmacy practice. R4-23-110 is amended to define Correctional facility, Limited-service Correctional and Mail-order Pharmacy, Limited-service Pharmacy Permittee, and Remote drug storage area. R4-23-612 is amended to update the requirement of a professional reference library. Instead of 2 current references from a limited list, each pharmacy would need a minimum of one current reference addressing four pharmacy topics. R4-23-651 is amended to more concisely define hospital pharmacy and the definition of Hospital is deleted because it is defined in statute, A.R.S. § 32-1901. R4-23-671 is a new Section providing general requirements for limited-service pharmacies. R4-23-672 is a new Section governing pharmacies in correctional facilities. Presently, correctional pharmacies are classified as community pharmacies. The practice of pharmacy in a correctional facility more closely resembles a hospital than a community pharmacy. These rules use the limited-service pharmacy permit to address the scope of pharmacy practice inside the closed and very tightly controlled system of a correctional facility. The new class of pharmacy will give the Board satisfactory guidelines to monitor the practice of correctional pharmacy and protect the health and welfare of the correctional facility population. The rule is specific for the type of practice and utilizes a Board-approved policy and procedure manual which personalizes the rules to better regulate a particular pharmacy. R4-23-673 is a new Section providing rules governing mail-order pharmacies. Mail-order pharmacies have always been classified as community pharmacy. Mail-order pharmacies are alread of most pharmacy permit to address the scope of practice in this rapidly growing area of pharmacy. Mail-order ph

The Board believes that adoption of these rules will benefit the public health and safety by establishing clear standards governing pharmacy practice in specialized settings. The Board further believes that specific regulation and enforcement are necessary to regulate and control the rapidly evolving role of pharmacists in a dynamic healthcare system.

6. An explanation of the substantial change which resulted in this supplemental notice:

This supplemental proposal results from comments received from the Governor's Regulatory Review Council staff. The changes address clarity, style, grammar, punctuation, and format issues in the proposed rules. In R4-23-110, the labels of all the definitions

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Notices of Supplemental Proposed Rulemaking

have been deleted. This allows future changes to be made without requiring the relabeling of the entire Section. A statement of applicability is inserted at the beginning of the Section. Changes to specific definitions have been made as follows:

- a. Abbreviations and symbols have been added and deleted and the definition, Correctional facility, now reads: has the same meaning as set forth in A.R.S. §§ 13-2501 and 31-341.
- b. In the definitions of limited-service correctional pharmacy and limited-service mail-order pharmacy, the word "holding" is changed to "that holds" and the words "state" and "of Pharmacy" are deleted.
- c. In the definition, limited-service correctional pharmacy, a comma is inserted after 32-1931, facility, and dispensing. The word "which" after 32-1931 is deleted.
- d. In the definition, limited-service mail-order pharmacy, a comma is inserted after the word "carrier" and the word "which" is deleted and replaced with the word "and".
- e. In the definition, limited-service pharmacy permittee, the words "or persons" are deleted.
- f. A new definition is added for the term "Remote drug storage area".

In Subsections R4-23-612(12)(a) through (c), the semi-colons are changed to commas.

Section R4-23-651 is a definition Section which applies to hospital pharmacy. To make updating easier, the labels are deleted. The opening statement is changed to read: The following definitions apply to R4-23-651 through R4-23-659:.

The definition, Hospital, is deleted from R4-23-651. The same definition already exists in statute, A.R.S. § 32-1901(35).

In the definition, Hospital pharmacy, several words are changed, deleted, or added and a comma is added. The definition now reads: "Hospital pharmacy" means a pharmacy, as defined in A.R.S. § 32-1901, that holds a current permit issued by the Board pursuant to A.R.S. § 32-1931 and is located in a hospital, as defined in A.R.S. § 32-1901.

Subsections R4-23-672(A) and R4-32-673(A) are deleted. These subsections are combined with some wording changes and inserted into R4-23-671 at subsection (A). Subsection R4-23-671(A) now reads: Before opening a limited-service pharmacy, a person shall obtain a permit in compliance with A.R.S. §§ 32-1929, 32-1930, 32-1931, and R4-23-606.

Subsections R4-23-671(A) through (D) are relabeled R4-23-671(B) through (E).

With two word deletions and some additions, Section R4-23-671(B)(1) now reads: Permit no one to be in the limited-service pharmacy unless a pharmacist authorized by the pharmacist-in-charge pursuant to R4-23-672(B) or R4-23-673(E) is present;.

In the first sentence of R4-23-671(C) and after the word "requirement", add the following: set forth in R4-23-609 or R4-23-673.

In subsections R4-23-671(D)(1) through (3), the semi-colons are changed to commas.

As stated earlier, subsection R4-23-672(A) is deleted. Subsections R4-23-672(B) through R4-23-672(H) are relabeled R4-23-672(A) through R4-23-672(G).

The words "standards for, and, of drugs, drugs, set forth in A.A.C." are added and "standards of" is deleted from R4-23-672(A), which now reads: The limited-service pharmacy permittee shall ensure that the limited-service correctional pharmacy complies with the standards for area, personnel, security, sanitation, equipment, drug distribution and control, administration of drugs, drug source, quality assurance, investigational drugs, and inspections set forth in R4-23-608, R4-23-609(A) through (D) and (F) through (H), R4-23-610(A), R4-23-611, R4-23-612, R4-23-653(D), except subsection (D)(2)(e), R4-23-658(B) through (H) and R4-23-660 through R4-23-664.

Subsection R4-23-672(D)(1) is deleted because it is not necessary with the addition of the definition "Remote drug storage area" in Section R4-23-110.

Subsections R4-23-672(D)(2) through (5) are relabeled R4-23-672(D)(1) through (4) and all semi-colons are changed to commas. A typographical error occurred at R4-23-672(D)(4)(a)(i). The apostrophe is changed to a comma.

In R4-23-672(D)(3), the phrase "during the absence of the pharmacist" is changed to "when no pharmacist is on duty".

In R4-23-672(D)(3)(c), the phrase "nurses who have" is changed to "a nurse who has".

In R4-23-672(D)(4)(d), the phrase "and the attached order for the drug" is inserted after the word "removal".

In R4-23-672(E), the words "on duty" are inserted after the word "pharmacist".

In R4-23-672(F)(1), the phrase "the pharmacist is present" is changed to "a pharmacist is on duty".

In R4-23-672(F)(1)(b), the phrase "duties as outlined in R4-23-653(D)(2)" is changed to "duties outlined in R4-23-653(D)(2)" and "the pharmacist" at the end of the subsection is changed to "a pharmacist".

In R4-23-672(F)(2), the word "service" is inserted between limited and correctional and the semi-colon is changed to a period.

In R4-23-672(G)(4)(g), the phrase "In-service training" is changed to "Education" to conform with similar usage in R4-23-672(G)(15)(f).

In R4-23-672(G)(10), a comma is inserted between "dispensing" and "and".

In R4-23-672(G)(15)(c), a hyphen is inserted between "beyond" and "use".

In R4-23-672(G)(19), the phrase "After hours access:" is changed to "Access to remote drug storage areas by non-pharmacists; and" and subsections (a) through (c) are deleted.

Subsection R4-23-672(G)(20) is added and reads: Access to limited-service correctional pharmacy by non-pharmacists.

As stated earlier, subsection R4-23-673(A) is deleted. Subsections R4-23-673(B) through R4-23-673(I) are relabeled R4-23-673(A) through R4-23-673(H).

In R4-23-673(A)(1), the words "the" and "of" are deleted.

In R4-23-673(A)(2) and (3) and R4-23-673(B)(2) and (3), the word "will" is deleted.

The words "standards of" are deleted and "standards for" and "set forth in" are added to R4-23-672(D), which now reads: The limited-service pharmacy permittee shall ensure that the limited-service mail-order pharmacy complies with the standards for area, personnel, security, sanitation, and equipment set forth in R4-23-608, R4-23-609(B) through (H), R4-23-610 (A) and (C) through (F), R4-23-611(A) through (I), and R4-23-612.

In R4-23-673(G), the word "or" is changed to "and". The phrase "at the limited-service mail-order pharmacy" is inserted after the word "records" and the phrase "from the limited-service mail-order pharmacy" is inserted after the word "dispensed".

In R4-23-673(H)(2)(e), the phrase "In-service training" is changed to "Education" to conform with similar usage in R4-23-672(H)(8)(e).

In R4-23-673(H)(6), a comma is inserted after the word "dispensing".

In R4-23-673(H)(8)(c), a hyphen is inserted between the words "beyond" and "use".

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 preliminary summary of the economic, small business, and consumer impact:

The principal impact of the rule will be on pharmacies and pharmacists. For pharmacists, the rule will place additional responsibility on them for writing and reviewing a policy and procedure manual. The upside for the pharmacist will be better control of all aspects of the pharmacy practice through established written policy and procedure.

For pharmacies, the rule will establish concise and specific regulation and control over individual areas of limited pharmacy service. These specialized pharmacies will be able to practice within a set of rules which provide protection of public health and safety and allow service by a unique method or to a particular population. Since the fees for a pharmacy are the same for community, hospital, and limited-service, the rule will have minimal economic impact for most pharmacies. The rule requires mail-order pharmacies to provide toll-free telephone service for a minimum of 40 hours per week. However, this will have little real impact, since all mail-order pharmacies in Arizona to date already provide toll-free telephone service. Since all pharmacies are presently required to have two current references, the proposed rule will have little or no economic effect.

There is no expected economic impact on consumers or small business by these rules.

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

5060 North 19th Avenue, Suite 101

Phoenix, Arizona 85015

Telephone:

(602) 255-5125, ext. 131

Fax:

(602) 255-5740

10. The time, place, and nature of the proceedings for the adoption, amendment, or repeal of the rule or, if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:

No proceedings scheduled.

Requests for an oral proceeding should be submitted in writing to:

Name:

L.A. Lloyd, Executive Director

Address:

Board of Pharmacy

5060 N. 19th Ave., Suite 101

Phoenix, AZ 85015

Time:

8 a.m. to 5 p.m., Monday through Friday

- 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. <u>Incorporations by reference and their location in the rules:</u>
 None.
- 13. The full text of the changes follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 1. ADMINISTRATION

Section

R4-23-110. Definitions

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

Section

R4-23-612. Equipment

R4-23-651. Definitions

R4-23-671. General Requirements for limited-service

Pharmacy

R4-23-672. limited-service Correctional Pharmacy

R4-23-673. limited-service Mail-order Pharmacy

ARTICLE 1. ADMINISTRATION

R4-23-110. Definitions

In addition to the definitions set forth in A.R.S. § 32-1901, the following definitions apply to this Chapter:

- A. No change.
- B. No change.
- C. No change.
- D. No change.E. No change.
- E No change.
- G. No change.
- H. No change.
- "Correctional facility" has the same meaning as set forth in A.R.S. §§ 13-2501 and A.R.S. § 31-341.
- LJ. No change.

J.K. No change.

K.L.No change.

L.M. No change.

M.N. No change.

NO. No change.

P. "Limited-service correctional pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, holding that holds a current permit issued by the state Board of

Pharmacy pursuant to A.R.S. § 32-1931, is located in a correctional facility, and engages in the compounding.

- production, dispensing, and distribution of drugs.
 "Limited-service mail-order pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, holding that holds a current permit issued by the state Board of Pharmacy pursuant to A.R.S. § 32-1931 which and dispenses a majority of its prescription medications or prescription-only devices by mailing or delivering the prescription medication or prescription-only device to an individual by the United States mail, a common or contract carrier, or a delivery service.
- R. "Limited-service pharmacy permittee" means a person or persons who has applied for and obtained a limited-service pharmacy permit in compliance with A.R.S. §§ 32-1929, 32-1930, 32-1931, and A.A.C. R4-23-606.
- O.S. No change.
- P.T. No change.
- Q.U. No change.
- ŘV. No change.
- S.W. No change.
- TX. No change.
- U.Y. No change.
- VZ. No change.
- W.AA. No change.
- X.BB. No change.
- Y.CC. No change.
- Z.DD. No change.
- AA.EE. No change.

"Remote drug storage area" means an area that is outside the premises of the pharmacy, used for the storage of drugs, locked to deny access by unauthorized persons, and secured against the use of force.

- BB.FF. No change.
- CC.GG. No change.
- DD.HH.- No change.
- **EE.II.** No change.
- FF.JJ. No change.
- GG.KK.-No change.
- HH.LL. No change.
- H.MM. No change.

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

R4-23-612. Equipment

No change.

- 1. No change.
- 2. No change.
- No change.
- 4. No change. 5.
- No change. б. No change.
- No change.
- No change. No change.
- 10. No change.
- 11. No change.
- 12. No change.
 - Pharmacology or toxicology;
 - Therapeutics:.
 - Drug compatibility; and
 - Drug product equivalency.
- 13. No change.
- 14. No change.
- 15. No change.
- 16. No change.

R4-23-651. Definitions

For the purposes of these rules, the The following definitions apply to R4-23-651 through R4-23-659:

- 4. No change.
- 2. No change.
- 3-No change.
- 4. No change.
- 5. No change.
- No change.
- "Hospital" means any institution for the care and treatment of the sick and injured which is approved and licensed as a hospital by the state Department of Health
- "Hospital pharmacy" means a pharmacy, as defined in A.R.S. § 32-1901, holding that holds a current permit issued by the state Board of Pharmacy pursuant to A.R.S. § 32-1931 which and is located in a hospital, as defined in A.R.S. § 32-1901.
- No change.
- 10. No change.
- 11. No change.
- 12. No change.
- 13. No change.
- 14. No change.
- 15. No change.
- 16. No change.
- 17. No change.
- 18. No change.

R4-23-671. General Requirements for Limited-service **Pharmacy**

A. Before opening a limited-service pharmacy, a person shall obtain a permit in compliance with A.R.S. §§ 32-1929, 32-1930, 32-1931, and R4-23-606.

A.B. No change.

- Permit no one to be in the limited-service pharmacy unless an authorized a pharmacist authorized by the pharmacist-in-charge pursuant to R4-23-672(B) or R4-23-673(E) is present;
- 2. No change.
- 3. No change.
- 4. No change.
- <u>₿.С.</u> To obtain permission to deviate from the minimum area requirement set forth in R4-23-609 or R4-23-673, a limitedservice pharmacy permittee shall submit a written request to the Board and include documentation that the deviation will facilitate experimentation or technological advances in the practice of pharmacy as defined in A.R.S. § 32-1901. If the Board determines the requested deviation from the minimum area requirement will enhance the practice of pharmacy and benefit the public, the Board shall grant the requested deviation,

C.D. No change.

D.E. No change.

- Prepare written policies and procedures for pharmacy operations and drug distribution;
- Submit a copy of the written policies and procedures to the Board office with the original permit application;
- Conduct a biennial review and revision of the policies and procedures and submit a copy of any revision to the Board office; and
- No change.

R4-23-672. Limited-service Correctional Pharmacy

- A. Before opening a limited service correctional pharmacy a person or persons shall obtain a permit in compliance with A.R.S. § 32-1929, 32-1930, 32-1931 and R4-23-606.
- B.A. The limited-service pharmacy permittee shall ensure that the limited-service correctional pharmacy complies with the standards for area, personnel, security, sanitation, equipment, drug distribution, and control, administration of drugs, drug source, quality assurance, investigational drugs, and inspections standards of set forth in R4-23-608, R4-23-609(A) through (D) and (F) through (H), R4-23-610(A), R4-23-611, R4-23-612, R4-23-653(D), except subsection (D)(2)(e), R4-23-658(B) through (H) and R4-23-660 through R4-23-664.

C.B. No change.

D.C. No change.

- The limited service pharmacy permittee shall ensure that remote drug storage areas, if used, conform to the following requirements:
 - a. Located outside the pharmacy area;
 - b. Locked in a manner that denies access to unauthorized persons; and
 - c. Secured against the use of force.

2.1. No change.

- Contain only properly labeled drugs that might reasonably be needed and can be administered safely during the absence of a pharmacist;
- b. Contain drugs packaged only in amounts sufficient for immediate therapeutic requirements;
- Are accessible only with a physician's written order;
- d. Provide a written record of each drug withdrawn;
- e. Are inventoried at least once each week; and
- f. No change.
- 3-2. The pharmacist-in-charge shall, in consultation with the appropriate committee of the correctional facility, develop and implement procedures to ensure that access to the limited-service correctional pharmacy during the absence of the pharmacist when no pharmacist is on duty conforms to the following requirements:
 - a. No change.
 - b. No change.
 - c. Is delegated only to a nurses nurse who have has received training from the pharmacist-in-charge in proper methods of access, removal of drugs, and records and procedures required; and
 - d. No change.

4.3. No change.

- No change.
 - i. Patient's name',
 - Name of the drug and it's strength and dosage form;
 - iii. Dose prescribed;
 - iv. Amount of drug removed; and
 - v. Date and time of removal;
- b. Sign the form recording the drug removal;
- Attach the original or a direct copy of a physician's written order for the drug to the form recording the drug removal; and
- d. No change.

5.4. No change.

E.D. No change.

E.E. The limited-service pharmacy permittee shall ensure that the limited-service correctional pharmacy is without a pharmacist on duty for no more than 96 consecutive hours.

G.E. No change.

- Permit no one to be in the limited-service correctional pharmacy unless the a pharmacist is present on duty except:
 - a. No change,
 - b. Pharmacy technicians may remain to perform duties as outlined in R4-23-653(D)(2), except subsection (D)(2)(e), when a pharmacist is on duty and available in the correctional facility but temporarily absent from the pharmacy, provided all controlled substances are secured in a manner that prohibits access by persons other than the a pharmacist;
- Provide keyed or programmable locks to all areas of the limited-service correctional pharmacy;

H.G. No change.

- 1. No change.
- 2. No change.
- No change.
- 4. No change.
 - No change.
 - b. No change,
 - c. No change.
 - d. No change.
 - e. No change.
 - f. No change.
 - g. In service training Education of pharmacy and other health professionals;
- No change.
- No change.
- 7. No change.
- 8. No change.
- 9. No change.
- 10. Drug compounding, dispensing, and storage;
- 11. No change.
- 12. No change.
- 13. No change.
- 14. No change.
- 15. No change.
 - a. No change.
 - b. No change.
 - Expired and beyond_use date drugs;
 - d. No change.
 - e. No change.
 - f. No change.
 - 16. No change.
- 17. No change.
- 18. Security; and
- After hours access: Access to remote drug storage areas by non-pharmacists; and
 - To remote drug storage areas;
 - By authorized nursing staff; and
 - To record drug removal.
- Access to limited service correctional pharmacy by non-pharmacists.

R4-23-673. Limited-service Mail-order Pharmacy

A. Before opening a limited service mail order pharmacy a person or persons shall obtain a permit pursuant to A.R.S. § 32-1929, 32-1930, 32-1931, and R4-23-606.

B.A. No change.

A dispensing area devoted to the stocking, compounding, and dispensing of prescription medications, which
is physically separate from a non-dispensing area
devoted to non-dispensing pharmacy services;

- A dispensing area of at least 300 square feet if three or fewer persons will work in the dispensing area simultaneously;
- A dispensing area that provides 300 square feet plus 60 square feet for each person in excess of three persons if more than three persons will work in the dispensing area simultaneously;
- 4. No change.
- No change.
- No change.

C.B. No change.

- No change.
- A contiguous area of at least 300 square feet if three or fewer persons will work in the area simultaneously;
- A contiguous area that provides 300 square feet plus 60 square feet for each person in excess of three persons if more than three persons will work in the area simultaneously; and
- 4. No change.

D.C.No change.

E.D. The limited-service pharmacy permittee shall ensure that the limited-service mail-order pharmacy complies with the standards for area, personnel, security, sanitation, and equipment standards of set forth in R4-23-608, R4-23-609(B) through (H), R4-23-610(A) and (C) through (F), R4-23-611(A) through (I), and R4-23-612.

F.E. No change.

G.E. No change.

H.G. In addition to the delivery requirements of R4-23-402, the limited-service pharmacy permittee shall, during regular hours of operation but not less than six days or and a minimum 40 hours per week, provide toll-free telephone service to facilitate communication between patients and a pharmacist who has access to patient records at the limited-

service mail-order pharmacy. The limited-service pharmacy permittee shall disclose this toll-free number on a label affixed to each container of drugs dispensed from the limited-service mail-order pharmacy.

I.H. No change.

- 1. No change.
- No change.
 - a. No change.
 - b. No change.
 - c. No change.
 - d. No change.
 - e. In service training Education of pharmacy and other health professionals;
- 3. No change.
- 4. No change.
- No change.
- 6. Drug compounding, dispensing, and storage;
- 7. No change.
- 8. No change.
 - a. No change.
 - b. No change.
 - Expired and beyond-use date drugs;
 - d. No change,
- e. No change.
- 9. No change.
- 10. No change.
- 11. No change.
- 12. No change.
 - a. No change.
 - b. No change.
 - c. No change.
- d. No change.