# ARIZONA BOARD OF PHARMACY

4 A.A.C. 23, Articles 7, 9, 10

July 2015

## TABLE OF CONTENTS

INTRODUCTION

The Arizona State Board of Pharmacy protects the health, safety and welfare of the citizens of Arizona by regulating the practice of pharmacy and the distribution, sale and storage of prescription medications and devices and non-prescription medications.

The Board accomplishes its mission by:

- Issuing licenses to pharmacists, pharmacy interns and pharmacy technicians,
- Issuing permits to pharmacies, manufacturers, wholesalers and distributors,
- Conducting compliance inspections of permitted facilities,
- Investigating complaints & adjudicating violations of applicable state and federal laws and rules, and
- Promulgating and reviewing state rules and regulations.

The rules in 4 A.A.C. 23, Article 7, establish the requirements for long-term care facility pharmacy services and include sections for the provision of consultant pharmacist services, provider pharmacy services, emergency drugs, prescription orders for emergency drugs, and automated dispensing systems. The rules also include requirements for pharmacy services to hospice inpatient facilities and assisted living facilities, as well as for customized patient medication packages.

The rule in 4 A.A.C. 23, Article 9, references the statute penalties for violations of the rules including the suspension or revocation of a permit or license issued by the Board.

The rules in 4 A.A.C. 23, Article 10, establish the requirements for the maintenance of records and order forms for controlled substances including inventory requirements, loss of controlled substances, manufacturing records, and transaction documentation. The rules also set out the drugs that are excepted from the schedules of controlled substances in Arizona, and the substances that are excepted from the definition of a dangerous drug under the authority of A.R.S. § 32-1904(B)(14).

## ARTICLE 7.

## INFORMATION THAT IS IDENTICAL FOR ALL ARTICLE 7 RULES

**1. Effectiveness in Achieving Objectives**

The rules reviewed are effective in achieving their stated objectives.

**1b. Objective**

The general objective of the rules is to establish the requirements for consultant pharmacist and provider pharmacy services in long-term care facilities, hospice inpatient facilities, and assisted living facilities.

**2. Written Criticisms of the Rules Received in the Past Five Years**

The agency has not received any written criticisms of the rules in the past five years.

**3. Authorization of the Rules by Existing Statutes**

The agency's general rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and 32-1904(B)(3); with specific authority found in A.R.S. §§ 32-1904(A)(1), 32-1904(B)(3), and 32-1968(E).

**4. Consistency with Statutes and Other Rules Made by the Agency**

The rules reviewed are consistent with the statutes for the agency, namely A.R.S. Title 32, Chapter 18. In addition, the rules are consistent both internally and with relation to the agency's other rules.

**4a. Enforcement**

The rules are enforced as written, unless a deviation is specified in the individual rule analysis.

**5. Clarity, Conciseness, and Understandability**

The rules are clear, concise, and understandable as written.

**6. Economic, Small Business, and Consumer Impact Comparison**

The economic impact has not differed from that projected when the rules were amended effective May 4, 2003 (9 A.A.R. 1064) and November 10, 2013 (19 A.A.R. 2894). The main costs were born by the agency for the rulemaking and pharmacies for the administrative costs to update policies and procedures which were minimal. Pharmacies potentially received a moderate benefit from decreased personnel costs in stocking emergency drug supply units less often.

As of May 31, 2015 there are 2158 pharmacies currently permitted by the Board, of which 1319 are resident pharmacies. The total number of resident pharmacies with a limited service pharmacy permit, which includes those pharmacies providing services to long-term care facilities, is 64.

The Board will continue to work with stakeholders to review and amend the rules to ensure the rules protect the citizens of Arizona while also responding to technological advances and changes in pharmacy practice.

**7. Analysis Submitted by Another Person Regarding the Rules' Impact on this State's Business Competitiveness as Compared to the Competitiveness of Businesses in Other States**

No analysis was submitted to the agency.

**8. Completion of the Previous Five-Year-Review Report Process**

The agency's previous five-year-review report was approved by the Council on September 14, 2010. In that report, the agency identified the following issues requiring amendment:

R4-23-701, R4-23-701.01, R4-23-701.02, R4-23-701.03, R4-23-703. In January 2008, the Board convened a task force charged with addressing technological and other changes

in the long-term care industry. The task force included Board members, Board staff, and stakeholder representatives. Based on their recommendations, the Board intended to open a docket to amend the rules, and have the rulemaking completed by March 2009.

All rulemaking stopped on January 22, 2009 at the direction of the Governor. The rulemaking moratorium was then extended and was still in place during the agency's five-year-review report.

The agency proposed to reconvene the task force and move forward with the rulemaking once the rulemaking moratorium ended. The target date for the rulemaking docket opening was December 31, 2012, with rule submission to GRRC by September 30, 2013. R4-23-701.03 was not changed by the rulemaking, because the Task Force determined that is did not need to be changed. R4-23-701.03 was last amended May 4, 2003.

The rulemaking moratorium was in place through September 2011. In June 2012, the Board appointed another task force to review the rules as indicated in the previous five-year rule review. The rulemaking docket was opened on December 14, 2012, and final rules were approved by GRRC on September 10, 2013. See 19 A.A.R. 2894.

**9. Probable Benefits Outweigh Probable Costs / Rules Impose Least Burden on Regulated Persons**

The changes made to the rules in 2013 have benefitted regulated persons by establishing clear standards governing the practice of consultant pharmacists and pharmacies that provide services to long-term care facilities, hospice inpatient facilities, and assisted living facilities, thereby allowing consistent enforcement of the rules by the Board. The changes made to the rules in 2013 imposed minimal mandatory costs to the regulated persons, and those costs have remained minimal. The rules now impose the least burden on regulated persons. The probable costs to regulated persons are outweighed by the probable benefits of the rules.

**10. Stringency Compared with Corresponding Federal Law**

Federal law is applicable for R4-23-701.04, however the rule is not more stringent than federal law. Federal requirements for automated dispensing systems are found in 21 CFR §§ 1301.17 and 1301.27.

**11. For Rules Adopted After July 29, 2010 that Require Issuance of a Regulatory Permit, License, or Agency Authorization, Whether the Rule Complies with the General Permit Requirement in A.R.S. § 41-1037.**

Although the rules were last amended in 2013, the rules comply with the exception in subsection (A)(2) of A.R.S. § 41-1037, because the Board issues a specific permit specified in A.R.S. §§ 32-1929, 32-1930, and 32-1931.

## INDIVIDUAL ANALYSIS ARTICLE 7 RULES

**R4-23-701**

**1b. Objective of the Rule**

The rule establishes the requirements for a long-term care consultant pharmacist in the provision of pharmaceutical patient care services as defined in R4-23-110 within a facility.

**12. Proposed Course of Action**

No further action is required on this rule.

**R4-23-701.01**

**1b. Objective of the Rule**

The rule establishes the procedures for a provider pharmacy to supply prescription medication to residents of a long-term care facility. The rule also establishes the requirements for drug recall and return procedures in order to protect the health and safety of facility residents.

**12. Proposed Course of Action**

No further action is required on this rule.

**R4-23-701.02**

**1b. Objective of the Rule**

The rule establishes the procedures for a provider pharmacy to maintain an emergency drug supply unit using either a manual or automated system within a long-term care facility.

**12. Proposed Course of Action**

No further action is required on this rule.

**R4-23-701.03**

**1b. Objective of the Rule**

The rule establishes the requirements for pharmacist evaluation of a prescription order for drugs removed from an emergency drug supply unit within a long-term care facility.

**12. Proposed Course of Action**

No further action is required on this rule.

**R4-23-701.04**

**1b. Objective of the Rule**

The rule establishes the requirements for the use of an automated dispensing system in a long-term care facility including board notification, DEA registration where required, security, drug stocking procedures, labeling, inventory, and record-keeping requirements.

**12. Proposed Course of Action**

In 2014, DEA rescheduled Hydrocodone combination products from Schedule III to Schedule II. Hydrocodone combination products are widely used in a long-term care facility setting, and not providing them in an automated dispensing system could potentially negatively impact patient care. As a result, the Board has found that the restriction on not stocking Schedule II drugs in an automated dispensing system needs to be removed.

Currently, only one pharmacy places automated dispensing systems within long-term care facilities in Arizona. The Board under its statutory authority found in A.R.S. § 32-1904(B)(6) granted a deviation to R4-23-701.04(B)(3) for this pharmacy in August, 2014. The deviation will stand until removed by the Board or the rule is changed.

Once the rulemaking moratorium ends, the agency intends to open a docket and amend the rule to remove the restriction found in subsection (B)(3). The target date for docket opening is March 31, 2016 with rule submission to GRRC by March 31, 2017. If the moratorium does not end, the Board will then decide whether or not to request an exemption.

**R4-23-702**

**1b. Objective of the Rule**

The rule establishes the requirements for the provision of pharmacy services to patients in a hospice inpatient facility.

**12. Proposed Course of Action**

When the rules were amended in 2013, the long-term care task force identified areas where pharmacy services were provided, but where the Board had not yet set out specific requirements in rule. As a result, the requirements for pharmacy services to hospice inpatient facilities were added. The Board has since determined that other inpatient facilities licensed by ADHS with required continuous nursing services such as inpatient behavioral health facilities should be added into rule.

The Board also reconsidered the restriction on the use of an automated dispensing system in a hospice inpatient facility. The Board determined that hospice and other inpatient facilities with required continuous nursing services provided the same storage, security, and record-keeping capabilities as a long-term care facility.

Once the rulemaking moratorium ends, the agency intends to open a docket and amend the rule to include other specified inpatient facilities, and to remove the restriction found in subsection (E). The target date for docket opening is March 31, 2016 with rule submission to GRRC by March 31, 2017. If the moratorium does not end, the Board will then decide whether or not to request an exemption.

**R4-23-703.**

**1b. Objective of the Rule**
The rule establishes the requirements for the provision of pharmacy services in an assisted living facility.

**12. Proposed Course of Action**
No further action is required on this rule.

**R4-23-704.**

**1b. Objective of the Rule**
The rule establishes that a pharmacist who dispenses medications in a customized patient medication package must meet the guidelines of the official compendium for labeling, packaging, and record-keeping as well as any state or federal laws.

**12. Proposed Course of Action**
No further action is required on this rule.

## ARTICLE 9.

## ANALYSIS ARTICLE 9 RULE

**R4-23-901.**

**1. Effectiveness in Achieving Objectives**
The rule reviewed is effective in achieving its stated objective.

**1b. Objective**
The general objective of the rule is informational. The rule references the penalties located in statute for violation of the rules.

**2. Written Criticisms of the Rules Received in the Past Five Years**
The agency has not received any written criticisms of the rule in the past five years.

**3. Authorization of the Rules by Existing Statutes**
The agency's general rulemaking authority is found in A.R.S. §§ 32-1904(A)(1), 32-1904(B)(5), 32-1996, and 36-2531; with specific authority found in A.R.S. §§ 32-1927, 32-1927.01, and 32-1927.02.

**4. Consistency with Statutes and Other Rules Made by the Agency**
The rule reviewed is consistent with the statutes for the agency, namely A.R.S. Title 32, Chapter 18. In addition, the rule is consistent both internally and with relation to the agency's other rules.

**4a. Enforcement**
The rule is intended as an informational rule, and does not lend itself to enforcement.

**5. Clarity, Conciseness, and Understandability**

The rule is clear, concise, and understandable as written.

**6. Economic, Small Business, and Consumer Impact Comparison**

The economic impact has not differed from that projected when the rule was amended effective August 3, 2000 (6 A.A.R. 3177). The main costs were born by the agency in drafting and publishing the rules which were minimal. There is no further economic impact.

**7. Analysis Submitted by Another Person Regarding the Rules' Impact on this State's Business Competitiveness as Compared to the Competitiveness of Businesses in Other States**

No analysis was submitted to the agency.

**8. Completion of the Previous Five-Year-Review Report Process**

The agency's previous five-year-review report was approved by the Council on September 14, 2010. In that report, no further action was required on this rule.

**9. Probable Benefits Outweigh Probable Costs / Rules Impose Least Burden on Regulated Persons**

As an informational rule it is valuable in advising licensees and permittees as to the penalties associated with violation of the rules. The rule imposes the least burden on regulated persons. The probable costs to regulated persons are outweighed by the probable benefits of the rule.

**10. Stringency Compared with Corresponding Federal Law**

There is no federal law that corresponds with the rule reviewed.

**11. For Rules Adopted After July 29, 2010 that Require Issuance of a Regulatory Permit, License, or Agency Authorization, Whether the Rule Complies with the General Permit Requirement in A.R.S. § 41-1037.**

The rule was last amended on August 3, 2000, therefore A.R.S. § 41-1037 does not apply.

**12. Proposed Course of Action**

No further action is required on this rule.

## ARTICLE 10.

## INFORMATION THAT IS IDENTICAL FOR ALL ARTICLE 10 RULES

**1. Effectiveness in Achieving Objectives**

The rules reviewed are effective in achieving their stated objectives.

**1b. Objective**

The general objective of the rules is to establish the record-keeping requirements for controlled substances, and to provide a reference for drugs that are exempted from the schedules of controlled substances by 21 CFR 1308.22, 21 CFR 1308.24, and 21 CFR 1308.32 and those that are excepted from the definition of dangerous drugs under the authority of A.R.S. § 32-1904(B)(14).

**2. Written Criticisms of the Rules Received in the Past Five Years**

The agency has not received any written criticisms of the rules in the past five years.

**3. Authorization of the Rules by Existing Statutes**

The agency's general rulemaking authority is found in A.R.S. §§ 32-1904(A)(1), 32-1904(B)(14), and 36-2521; with specific authority found in A.R.S. §§ 36-2512(B), 36-2513(B), 36-2514(C), 36-2515(B), and 36-2523.

**4. Consistency with Statutes and Other Rules Made by the Agency**

The rules reviewed are consistent with the statutes for the agency, namely A.R.S. Title 32, Chapter 18 and A.R.S. Title 36, Chapter 27. In addition, the rules are consistent both internally and with relation to the agency's other rules.

**4a. Enforcement**

The rules are enforced as written without incident, except the provision of a DEA form 106 to DPS which was eliminated at their request.

**5. Clarity, Conciseness, and Understandability**

The rules are clear, concise, and understandable as written.

**6. Economic, Small Business, and Consumer Impact Comparison**

The economic impact has not differed from that projected when the rules were amended effective August 8, 2000 (6 A.A.R. 3177), November 8, 2008 (14 A.A.R. 3670), and December 2, 2012 (18 A.A.R. 2609). The main costs were born by the agency in writing and publishing the rules, and were minimal.

**7. Analysis Submitted by Another Person Regarding the Rules' Impact on this State's Business Competitiveness as Compared to the Competitiveness of Businesses in Other States**

No analysis was submitted to the agency.

**8. Completion of the Previous Five-Year-Review Report Process**

The agency's previous five-year-review report was approved by the Council on September 14, 2010. In that report, the agency identified the following issues requiring amendment:

R4-23-1005. This rule was last amended on August 3, 2000 and the date of the federal regulation incorporated by reference was April 1, 1999. The Board intended to update the incorporation by reference.

All rulemaking stopped on January 22, 2009 at the direction of the Governor. The rulemaking moratorium was then extended and was still in place during the agency's five-year-review report.

The agency proposed to move forward with the rulemaking once the rulemaking moratorium ended. The target date for the rulemaking docket opening was December 31, 2012, with rule submission to GRRC by September 30, 2013.

The rulemaking moratorium was in place through September 2011. Once the rulemaking moratorium was lifted, the incorporation by reference was updated as indicated in the previous five-year rule review. The rulemaking docket was opened on January 6, 2012, and final rules were approved by GRRC on October 2, 2012. See 18 A.A.R. 2609.

**9. Probable Benefits Outweigh Probable Costs / Rules Impose Least Burden on Regulated Persons**

The changes made to the rules in 2012 have benefitted regulated persons by incorporating by reference the federal regulation current at the time of the rulemaking. This creates consistency between federal and state regulations for controlled substances. The changes made to the rules in 2012 imposed minimal costs to the regulated persons, and those costs have remained minimal. The rules now impose the least burden on regulated persons. The probable costs to regulated persons are outweighed by the probable benefits of the rules.

**10. Stringency Compared with Corresponding Federal Law**

Code of Federal Regulations Title 21-Food and Drugs Chapter II-Drug Enforcement Administration and in general parts 1300 to end apply to the rules. A.R.S. § 32-1984(F) sets out the requirements for a purchaser and full-service wholesale permittee to maintain information for three years, which is more stringent than federal law (21 CFR 1304.04).

**11. For Rules Adopted After July 29, 2010 that Require Issuance of a Regulatory Permit, License, or Agency Authorization, Whether the Rule Complies with the General Permit Requirement in A.R.S. § 41-1037.**

Although the rules were last amended in 2013, the rules themselves do not require a permit, license, or agency authorization.

## INDIVIDUAL ANALYSIS ARTICLE 10 RULES

**R4-23-1003**

**1b. Objective of the Rule**

The rule establishes the requirements for record-keeping for controlled substances including inventories, loss reports, and manufacturing records.

**12. Proposed Course of Action**

The Narcotic Division of the Department of Public Safety (DPS) does not require that a copy of the DEA form 106 be provided to them, the requirement is included in Board of Pharmacy rules only. DPS indicated they did not utilize the information and requested the

board office stop requiring pharmacies to forward a copy to them. The Board intends to amend subsection (A)(2)(e) to remove the requirement that a copy of the DEA form 106 be forwarded to DPS in the event of a loss of a controlled substance.

Once the rulemaking moratorium ends, the agency intends to open a docket and amend the rule to remove the requirement that a DEA form 106 be forwarded to DPS. The target date for docket opening is March 31, 2016 with rule submission to GRRC by March 31, 2017. If the moratorium does not end, the Board will then decide whether or not to request an exemption.

**R4-23-1005**

**1b. Objective of the Rule**

The rule incorporates by reference the drugs and chemicals excepted from all schedules of controlled substances in federal regulations.

**12. Proposed Course of Action**

No further action is required on this rule.

**R4-23-1006**

**1b. Objective of the Rule**

The rule establishes that drugs and chemicals excepted from all schedules of controlled substances in R4-23-1005, are also excepted from the definition of dangerous drug as found in A.R.S § 32-1904(B)(14).

**12. Proposed Course of Action**

No further action is required on this rule.

**Analysis of R4-23-601**

1. Authorization of the rules by existing statute(s)

   The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1), 32-1904(B)(3), and 32-1984(A) and (B).

2. Objective

   The rule establishes the requirements to obtain a permit to sell drugs, exempts licensed medical practitioners, delineates length of permit validity and recordkeeping requirements, and prohibits the sale of fire- or water-damaged drugs.

3. Analysis of effectiveness in achieving the objective

   The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes and rules

   During a recent audit by the Office of the Auditor General indicating an inconsistency with statute regarding proration of fees, the OAG auditors felt the Boards statute did not give authority to prorate fees. The Board intends to amend the rule to correct the inconsistency and seek specific statutory authority to prorate fees. Because of a recent consumer complaint review of a pharmacist that showed that resident permit holders have purchased drugs from persons that do not have a current Board permit, then shipped those drugs into other states without obtaining a non-resident permit where required, the Board will amend the rule to require that all permittees verify that their source of supply is properly permitted as specified in A.R.S. § 32-1983.

5. Status of enforcement of the rule

   The rule is fairly and consistently enforced to the extent it is consistent with state statutes.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

   See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

The rule is clear, concise, and understandable with the exception noted in item 4 above.

8. Written criticisms of the rule recieved in the last five years

The agency has not received any written criticism of rule in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

The rule was adopted before July 29, 2010.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

The Board opened a docket to amend the rule to correct inconsistencies with state law on 2/22/08. A Notice of Proposed Rulemaking was published on 5/2/08. The Notice of Final Rulemaking was published on 9/26/08. The amended rules became effective on 11/8/08. All planned action is completed.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

Once the proposed changes are implemented, the Board believes the rule will impose the least burden and costs on persons regulated by the rule.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

The agency has determined that there is no corresponding federal law.

14. Proposed course of action

The agency plans to submit a notice of final rulemaking to the Council by December 31, 2014.

**Analysis of R4-23-602**

1. Authorization of the rules by existing statute(s)

   The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1), 32-1904(B)(3), 32-1929, 32-1930(A), and 32-1931.

2. Objective

   The rule establishes the permit application process and the Board's time-frames for issuing permits.

3. Analysis of effectiveness in achieving the objective

   The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes and rules

   Because of a recent consumer complaint review of a pharmacist that showed that resident permit holders have purchased drugs from persons that do not have a current Board permit, then shipped those drugs into other states without obtaining a non-resident permit where required, the Board will amend the rule to require that all permittees verify that their source of supply is properly permitted as specified in A.R.S. § 32-1983.

5. Status of enforcement of the rule

   The rule is fairly and consistently enforced to the extent it is consistent with state statutes. Because the Board is now processing permit applications online, the rule will be amended to include the electronic application process, since without the amendment, the Board would not be enforcing the rule as written.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

   See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

   The rule is clear, concise, and understandable with the exception noted in item 4 above.

8. Written criticisms of the rule recieved in the last five years

   The agency has not received any written criticism of rule in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

   The rule was adopted before July 29, 2010.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

    No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

    The agency completed its previous five-year review process on September 26, 2008. No action was required for this rule in that approved five-year review report.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

    Once the proposed changes are implemented, the Board believes the rule will impose the least burden and costs on persons regulated by the rule.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

    The agency has determined that there is no corresponding federal law.

14. Proposed course of action

    The agency plans to submit a notice of final rulemaking to the Council by December 31, 2014.

**Analysis of R4-23-603**

1. Authorization of the rules by existing statute(s)

The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1), 32-1904(B)(3), 32-1930(A), and 32-1931.

2. Objective

The rule establishes the requirement to obtain a permit before selling nonprescription drugs and delineates the responsibility of a permittee to file an application and sell only original, unopened, clean, and presentable product. The rule establishes the specific requirements for selling nonprescription drugs in a vending machine.

3. Analysis of effectiveness in achieving the objective

The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes and rules

The rule is consistent with state statutes and rules.

5. Status of enforcement of the rule

The rule is fairly and consistently enforced to the extent it is consistent with state statutes. Because the Board is now processing permit applications online, the rule will be amended to include the electronic application process, since without the amendment, the Board would not be enforcing the rule as written.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

The rule is clear, concise, and understandable.

8. Written criticisms of the rule recieved in the last five years

The agency has not received any written criticism of rule in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

The rule was adopted before July 29, 2010.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

    No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

    The agency completed its previous five-year review process on September 26, 2008. No action was required for this rule in that approved five-year review report.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

    Once the proposed changes are implemented, the Board believes the rule will impose the least burden and costs on persons regulated by the rule.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

    The agency has determined that there is no corresponding federal law.

14. Proposed course of action

    The agency plans to submit a notice of final rulemaking to the Council by December 31, 2014.

**Analysis of R4-23-604**

1. Authorization of the rules by existing statute(s)

   The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1), (3), and (4), 32-1904(B)(3), 32-1930(A), and 32-1931.

2. Objective

   The rule establishes standards for drug manufacturing by firms that reside in Arizona.

3. Analysis of effectiveness in achieving the objective

   The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes and rules

The rule is consistent with state and federal statutes and rules.

5. Status of enforcement of the rule

The rule is fairly and consistently enforced to the extent it is consistent with state statutes. Because the Board is now processing permit applications online, the rule will be amended to include the electronic application process, since without the amendment, the Board would not be enforcing the rule as written.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

The rule is clear, concise, and understandable.

8. Written criticisms of the rule recieved in the last five years

The agency has not received any written criticism of rule in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

The rule complies with the exception in subsection (A)(2) of A.R.S. § 41-1037, because the rule issues an alternative permit specified in A.R.S. § 32-1930.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

The Board opened a docket to amend the rule to comply with the previous five-year rule review on 9/14/12. A Notice of Proposed Rulemaking was published on 11/23/12. The Notice of Final Rulemaking was published on

4/12/13. The amended rules became effective on 6/1/13. All planned action is completed.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

Once the proposed changes are implemented, the Board believes the rule will impose the least burden and costs on persons regulated by the rule.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

The rule is not more stringent than federal law as it relates to current good manufacturing practice and record keeping. To ensure that the rule is not more stringent, the Board has chosen to incorporate the federal law by reference, specifically 21 CFR 210 through 211.

14. Proposed course of action

The rule was last amended June 1, 2013. The agency plans to submit a notice of final rulemaking to the Council by December 31, 2014.

**Analysis of R4-23-605**

1. Authorization of the rules by existing statute(s)

The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and (4), 32-1904(B)(3), 32-1930(A), 32-1931, 32-1981, 32-1982, 32-1983, and 32-1984.

2. Objective

The rule establishes standards for the wholesale distribution of drugs by firms that reside in Arizona.

3. Analysis of effectiveness in achieving the objective

The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes and rules

During a recent audit by the Office of the Auditor General indicating an inconsistency with statute regarding fingerprinting, the Board intends to amend the rule to correct the inconsistency. The Board statute states that

the Board may require fingerprinting, but the existing rule states that the Board shall fingerprint drug wholesaler employees. The rule will be amended to change the language to the Board may fingerprint drug wholesaler employees.

5. Status of enforcement of the rule

   The rule is fairly and consistently enforced to the extent it is consistent with state statutes. Because the Board is now processing permit applications online, the rule will be amended to include the electronic application process, since without the amendment, the Board would not be enforcing the rule as written.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

   See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

   The rule is clear, concise, and understandable.

8. Written criticisms of the rule recieved in the last five years

   The agency has not received any written criticism of rule in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

   The rule complies with the exception in subsection (A)(2) of A.R.S. § 41-1037, because the rule issues an alternative permit specified in A.R.S. § 32-1930.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

    No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

The agency completed its previous five-year review process on September 26, 2008. No action was required for this rule in that approved five-year review report.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

    Once the proposed changes are implemented, the Board believes the rule will impose the least burden and costs on persons regulated by the rule.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

    The agency has determined that there is no corresponding federal law.

14. Proposed course of action

    The rule was last amended June 1, 2013. The agency plans to submit a notice of final rulemaking to the Council by December 31, 2014.

**Analysis of R4-23-606**

1. Authorization of the rules by existing statute(s)

   The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1), (2), (3), and (4), 32-1904(B)(3), 32-1930(A), and 32-1931.

2. Objective

   The rule delineates the process of obtaining a pharmacy permit and establishes procedures for opening and operating a pharmacy, including procedures for change of ownership and remodel or relocation of a pharmacy.

3. Analysis of effectiveness in achieving the objective

   The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes and rules

   The rule is consistent with state statutes and rules.

5. Status of enforcement of the rule

The rule is fairly and consistently enforced to the extent it is consistent with state statutes. Because the Board is now processing permit applications online, the rule will be amended to include the electronic application process, since without the amendment, the Board would not be enforcing the rule as written.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

   See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

   The rule is clear, concise, and understandable.

8. Written criticisms of the rule recieved in the last five years

   The agency has not received any written criticism of rule in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

   The rule complies with the exception in subsection (A)(2) of A.R.S. § 41-1037, because the rule issues an alternative permit specified in A.R.S. § 32-1930.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

    No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

    The agency completed its previous five-year review process on September 26, 2008. No action was required for this rule in that approved five-year review report.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

Once the proposed changes are implemented, the Board believes the rule will impose the least burden and costs on persons regulated by the rule.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

The agency has determined that there is no corresponding federal law.

14. Proposed course of action

The agency plans to submit a notice of final rulemaking to the Council by December 31, 2014.

**Analysis of R4-23-607**

1. Authorization of the rules by existing statute(s)

The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1), (2), and (4), 32-1904(B)(3), 32-1930(A), 32-1931, 32-1981, 32-1982, 32-1983, and 32-1984.

2. Objective

The rule establishes the requirements for obtaining a nonresident permit for any firm that ships drugs to Arizona residents. The rule requires permits for the following nonresident firms when the firm ships a drug to an Arizona resident: nonresident pharmacy, nonresident drug manufacturer, nonresident full-service drug wholesaler, nonresident nonprescription drug wholesaler, and nonresident nonprescription drug retailer.

3. Analysis of effectiveness in achieving the objective

The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes and rules

During a recent audit by the Office of the Auditor General indicating an inconsistency with statute regarding fingerprinting, the Board intends to amend the rule to correct the inconsistency. The Board statute states that

the Board may require fingerprinting, but the existing rule states that the Board shall fingerprint drug wholesaler employees. The rule will be amended to change the language to the Board may fingerprint drug wholesaler employees.

5. Status of enforcement of the rule

   The rule is fairly and consistently enforced to the extent it is consistent with state statutes. Because the Board is now processing permit applications online, the rule will be amended to include the electronic application process, since without the amendment, the Board would not be enforcing the rule as written.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

   See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

   The rule is clear, concise, and understandable.

8. Written criticisms of the rule recieved in the last five years

   The agency has not received any written criticism of rule in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

   The rule complies with the exception in subsection (A)(2) of A.R.S. § 41-1037, because the rule issues an alternative permit specified in A.R.S. § 32-1930.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

    No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

The agency completed its previous five-year review process on September 26, 2008. No action was required for this rule in that approved five-year review report.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

Once the proposed changes are implemented, the Board believes the rule will impose the least burden and costs on persons regulated by the rule.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

The agency has determined that there is federal law for drug manufacturers, but the rule is not more stringent than federal law as it relates to current good manufacturing practice and record keeping, specifically 21 CFR 210 through 211. The rule simply requires that nonresident drug manufactures possess an Arizona non resident drug manufacturer permit and comply with federal law, specifically 21 CFR 210 through 211. The agency has determined there are no corresponding federal law for pharmacies, drug wholesalers, and nonprescription drug retailers.

14. Proposed course of action

The agency plans to submit a notice of final rulemaking to the Council by December 31, 2014.

**Analysis of R4-23-608**

1. Authorization of the rules by existing statute(s)

The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1), 32-1926(B), 32-1934(B)(5), and 32-1963(A).

2. Objective

The rule establishes the parameters of responsibility for the owner or manager of a pharmacy.

3. Analysis of effectiveness in achieving the objective

The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes

The rule is consistent with state statutes and rules.

5. Status of enforcement of the rule

The rule is fairly and consistently enforced to the extent it is consistent with state statutes.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

The rule is clear, concise, and understandable.

8. Written criticisms of the rule recieved in the last five years

The agency has not received any written criticism of rule in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

The rule was adopted before July 29, 2010 and does not issue a permit.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

The agency completed its previous five-year review process on September 26, 2008. No action was required for this rule in that approved five-year review report.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

The agency has determined that the rule imposes the least burden and costs on the regulated community necessary to achieve its regulatory objective.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

The agency has determined that there is no corresponding federal law.

14. Proposed course of action

The rule was last amended on September 11, 2001. No action is required on this rule.

**Analysis of R4-23-609**

1. Authorization of the rules by existing statute(s)

The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and (2), 32-1904(B)(3), 32-1929, and 32-1930.

2. Objective

The rule establishes minimum standards for community pharmacies relevant to: over all area, size and configuration of counter work space, storage area, security concerns, and other structural requirements.

3. Analysis of effectiveness in achieving the objective

The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes and rules

The rule is consistent with state statutes and rules.

5. Status of enforcement of the rule

The rule is fairly and consistently enforced to the extent it is consistent with state statutes.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

The rule is clear, concise, and understandable.

8. Written criticisms of the rule recieved in the last five years

   The agency has not received any written criticism of rule in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

   The rule does not issue a permit.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

    No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

    The Board opened a docket to amend the rule to comply with the previous five-year rule review on 6/15/12. A Notice of Proposed Rulemaking was published on 7/20/12. The Notice of Final Rulemaking was published on 1/25/13. The amended rule became effective on 3/10/13. All planned action is completed.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

    The agency has determined that the rule imposes the least burden and costs on the regulated community necessary to achieve its regulatory objective.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

    The agency has determined that there is no corresponding federal law.

14. Proposed course of action

The rule was last amended by final rulemaking at 19 A.A.R. 97, effective March 10, 2013. No action is required on this rule.

**Analysis of R4-23-610**

1. Authorization of the rules by existing statute(s)

   The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and 32-1901(62).

2. Objective

   The rule ties the physical structure requirements to the actual operation of a community pharmacy including personnel, security, and handling of drugs.

3. Analysis of effectiveness in achieving the objective

   The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes and rules

   The rule is consistent with state statutes and rules.

5. Status of enforcement of the rule

   The rule is fairly and consistently enforced to the extent it is consistent with state statutes.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

   See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

   The rule is clear, concise, and understandable.

8. Written criticisms of the rule recieved in the last five years

   The agency has not received any written criticism of rule in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

   The rule was adopted before July 29, 2010 and does not issue a permit.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

    No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

    The agency completed its previous five-year review process on September 26, 2008. No action was required for this rule in that approved five-year review report.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

    The agency has determined that the rule imposes the least burden and costs on the regulated community necessary to achieve its regulatory objective.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

    The agency has determined that there is no corresponding federal law.

14. Proposed course of action

    The rule was last amended on September 8, 2007. No action is required on this rule.

**Analysis of R4-23-611**

1. Authorization of the rules by existing statute(s)

   The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and 32-1904(B)(3).

2. Objective

   The rule establishes baseline requirements for the cleanliness of any pharmacy in Arizona including general house keeping, animals in pharmacies, and the physical conditions of drug inventory.

3. Analysis of effectiveness in achieving the objective

The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes and rules

The rule is consistent with state statutes and rules.

5. Status of enforcement of the rule

The rule is fairly and consistently enforced to the extent it is consistent with state statutes.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

The rule is clear, concise, and understandable.

8. Written criticisms of the rule recieved in the last five years

The agency has not received any written criticism of rule in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

The rule does not issue a permit.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

The Board opened a docket to amend the rule to comply with the previous five-year rule review on 7/27/12. A Notice of Proposed Rulemaking was published on 6/14/13. The Notice of Final Rulemaking was published on 12/20/13. The amended rule becomes effective on 2/1/14. All planned action is completed.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

    The agency has determined that the rule imposes the least burden and costs on the regulated community necessary to achieve its regulatory objective.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

    The agency has determined that there is no corresponding federal law.

14. Proposed course of action

    A Notice of Final Rulemaking was approved by the Governer's Regulatory Review Council on December 3, 2013. The Notice of Final Rulemaking was published in 19 A.A.R. 4165, December 20, 2013. The final rule becomes effective on February 1, 2014. No further action is need on this rule.

**Analysis of R4-23-612**

1. Authorization of the rules by existing statute(s)

   The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and 32-1904(B)(3).

2. Objective

   The rule lists the minimum equipment required to operate a pharmacy.

3. Analysis of effectiveness in achieving the objective

   The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes and rules

   The rule is consistent with state statutes and rules.

5. Status of enforcement of the rule

   The rule is fairly and consistently enforced to the extent it is consistent with state statutes.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

The rule is clear, concise, and understandable.

8. Written criticisms of the rule recieved in the last five years

The agency has not received any written criticism of rule in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

The rule does not issue a permit.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

The Board opened a docket to amend the rule to comply with the previous five-year rule review on 7/27/12. A Notice of Proposed Rulemaking was published on 6/14/13. The Notice of Final Rulemaking was published on 12/20/13. The amended rule becomes effective on 2/1/14. All planned action is completed.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

The agency has determined that the rule imposes the least burden and costs on the regulated community necessary to achieve its regulatory objective.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

The agency has determined that there is no corresponding federal law.

14. Proposed course of action

A Notice of Final Rulemaking was approved by the Governer's Regulatory Review Council on December 3, 2013. The Notice of Final Rulemaking was published in 19 A.A.R. 4165, December 20, 2013. The final rule becomes effective on February 1, 2014. No further action is need on this rule.

**Analysis of R4-23-613**

` 1. Authorization of the rules by existing statute(s)

The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1), 32-1904(B)(3), and 36-2523.

2. Objective

The rule establishes the procedures for discontinuing a pharmacy.

3. Analysis of effectiveness in achieving the objective

The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes and rules

The rule is consistent with state statutes and rules.

5. Status of enforcement of the rule

The rule is fairly and consistently enforced to the extent it is consistent with state statutes.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

The rule is clear, concise, and understandable.

8. Written criticisms of the rule recieved in the last five years

The agency has not received any written criticism of rule in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

The rule was adopted before July 29, 2010 and does not issue a permit.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

    No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

    The Board opened a docket to amend the rule to comply with the previous five-year rule review on 2/22/08. A Notice of Proposed Rulemaking was published on 5/2/08. The Notice of Final Rulemaking was published on 9/26/08. The amended rule becomes effective on 11/8/08. All planned action is completed.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

    The agency has determined that the rule imposes the least burden and costs on the regulated community necessary to achieve its regulatory objective.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

    The agency has determined that there is no corresponding federal law.

14. Proposed course of action

    The rule was last amended on November 8, 2008. No action is required on this rule.

**Analysis of R4-23-614**

1. Authorization of the rules by existing statute(s)

   The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and 32-1904(B)(3).

2. Objective

The rule establishes the minimum requirements for use of an automated storage and distribution system by an Arizona pharmacy.

3. Analysis of effectiveness in achieving the objective

The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes and rules

The rule is consistent with state statutes and rules.

5. Status of enforcement of the rule

The rule is fairly and consistently enforced to the extent it is consistent with state statutes.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

The rule is clear, concise, and understandable.

8. Written criticisms of the rule recieved in the last five years

The agency has not received any written criticism of rule in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

The rule was adopted before July 29, 2010 and does not issue a permit.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

The agency completed its previous five-year review process on September 26, 2008. No action was required for this rule in that approved five-year review report.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

The agency has determined that the rule imposes the least burden and costs on the regulated community necessary to achieve its regulatory objective.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

The agency has determined that there is no corresponding federal law.

14. Proposed course of action

This rule was made by final rulemaking on April 7, 2007. No action is required on this rule.

**Analysis of R4-23-615**

1. Authorization of the rules by existing statute(s)

The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and 32-1904(B)(3).

2. Objective

The rule establishes the minimum requirements for use of a mechanical storage and counting device by an Arizona pharmacy.

3. Analysis of effectiveness in achieving the objective

The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes and rules

The rule is consistent with state statutes and rules.

5. Status of enforcement of the rule

The rule is fairly and consistently enforced to the extent it is consistent with state statutes.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

   The rule is clear, concise, and understandable.

8. Written criticisms of the rule recieved in the last five years

   The agency has not received any written criticism of rule in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

   The rule was adopted before July 29, 2010 and does not issue a permit.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

    No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

    The agency completed its previous five-year review process on September 26, 2008. No action was required for this rule in that approved five-year review report.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

    The agency has determined that the rule imposes the least burden and costs on the regulated community necessary to achieve its regulatory objective.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

    The agency has determined that there is no corresponding federal law.

14. Proposed course of action

The rule was last amended on November 8, 2008. No action is required on this rule.

**Analysis of R4-23-616**

1. Authorization of the rules by existing statute(s)

   The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and 32-1904(B)(3).

2. Objective

   The rule establishes the minimum requirements for use of a mechanical counting device by an Arizona pharmacy.

3. Analysis of effectiveness in achieving the objective

   The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes and rules

   The rule is consistent with state statutes and rules.

5. Status of enforcement of the rule

   The rule is fairly and consistently enforced to the extent it is consistent with state statutes.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

   See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

   The rule is clear, concise, and understandable.

8. Written criticisms of the rule recieved in the last five years

   The agency has not received any written criticism of rule in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

   The rule was adopted before July 29, 2010 and does not issue a permit.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

    No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

    The agency completed its previous five-year review process on September 26, 2008. No action was required for this rule in that approved five-year review report.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

    The agency has determined that the rule imposes the least burden and costs on the regulated community necessary to achieve its regulatory objective.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

    The agency has determined that there is no corresponding federal law.

14. Proposed course of action

    This rule was made by final rulemaking on April 7, 2007. No action is required on this rule.

**Analysis of R4-23-617**

1. Authorization of the rules by existing statute(s)

   The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and (2), 32-1904(B)(3), and 32-1910.

2. Objective

   The rule establishes the requirements for temporary pharmacy facilties or mobile pharmacies during a declared state of emergency.

3. Analysis of effectiveness in achieving the objective

   The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes and rules

   The rule is consistent with state statutes and rules.

5. Status of enforcement of the rule

   The rule is fairly and consistently enforced to the extent it is consistent with state statutes.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

   See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

   The rule is clear, concise, and understandable.

8. Written criticisms of the rule recieved in the last five years

   The agency has not received any written criticism of rule in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

   The rule was adopted before July 29, 2010 and does require a permit as specified in A.R.S. § 32-1931. The permit is not a general permit, but is a specific permit authorized by statute.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

    No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

    No previous five-year rule review. This rule was made by final rulemaking on January 3, 2009.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

The agency has determined that the rule imposes the least burden and costs on the regulated community necessary to achieve its regulatory objective.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

The agency has determined that there is no corresponding federal law.

14. Proposed course of action

This rule was made by final rulemaking on January 3, 2009. No action is required on this rule.

**Analysis of R4-23-620**

1. Authorization of the rules by existing statute(s)

The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and 32-1973.

2. Objective

The rule establishes the program, policy and procedure, and recordkeeping requirements for each pharmacy to implement or participate in a continuous quality assurance program to review pharmacy procedures in order to identify methods for addressing pharmacy medication errors.

3. Analysis of effectiveness in achieving the objective

The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes and rules

The rule is consistent with state statutes and rules.

5. Status of enforcement of the rule

The rule is fairly and consistently enforced to the extent it is consistent with state statutes.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

The rule is clear, concise, and understandable.

8. Written criticisms of the rule recieved in the last five years

The rule was made by final rulemaking at 18 A.A.R. 2603, effective December 2, 2012. No written criticism has been receive to date.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

The rule does not issue a permit.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

The new program was mandated by A.R.S. § 32-1973, which passed in 2007. The rule was made by final rulemaking at 18 A.A.R. 2603, October 19, 2012. A five-year review has not been required.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

The agency has determined that the rule imposes the least burden and costs on the regulated community necessary to achieve its regulatory objective.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

The agency has determined that there is no corresponding federal law.

14. Proposed course of action

The rule was made by final rulemaking at 18 A.A.R. 2603, effetive December 2, 2012. No action is required on this rule.

**Analysis of R4-23-621**

1. Authorization of the rules by existing statute(s)

   The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and (2), 32-1904(B)(3), 32-1929, 32-1930, and 32-1931.

2. Objective

   The rule establishes the standards for a pharmacy to share pharmacy services with another pharmacy, for example, Pharmacy A could process orders or fill and dispense orders or both for Pharmacy B.

3. Analysis of effectiveness in achieving the objective

   The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes and rules

   The rule is consistent with state statutes and rules.

5. Status of enforcement of the rule

   The rule is fairly and consistently enforced to the extent it is consistent with state statutes.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

   See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

   The rule is clear, concise, and understandable.

8. Written criticisms of the rule recieved in the last five years

   The agency has not received any written criticism of rule in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

   The rule complies with the exception in subsection (A)(2) of A.R.S. § 41-1037, because the rule issues an alternative permit specified in A.R.S. § 32-1930.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

    No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

    The Board opened a docket to amend the rule to comply with the previous five-year rule review on 6/15/12. A Notice of Proposed Rulemaking was published on 7/20/12. The Notice of Final Rulemaking was published on 1/25/13. The amended rules became effective on 3/10/13. All planned action is completed.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

    The agency has determined that the rule imposes the least burden and costs on the regulated community necessary to achieve its regulatory objective.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

    The agency has determined that there is no corresponding federal law.

14. Proposed course of action

    The rule was last amended by final rulemaking at 19 A.A.R. 97, effective March 10, 2013. No action is required on this rule.

**Analysis of R4-23-651**

1. Authorization of the rules by existing statute(s)

   The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and (2), 32-1904(B)(3) and (5), 32-1929, 32-1930, 32-1931, and 32-1934.

2. Objective

The rule defines the terms and phrases used in R4-23-651 through R4-23-660 of the Board's rules whose meanings in this context are not self-evident or obvious.

3. Analysis of effectiveness in achieving the objective

The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes and rules

The rule is consistent with existing state statutes and rules. However, on January 24, 2013, the Board appointed a Task Force to review and recommend changes to the specific rules related to compounding, specifically sterile pharmaceutical compounding. The Task Force continues to meet, but has not presented recommendations to the Board. Those rule changes will require the Board staff to look at the hospital rules, which have not been amended as a whole since January 5, 2003. The Board intends to amend the hospital rules where necessary to conform with the changes to the compounding rules, specifically looking at the designation in hospital rules about "director of pharmacy," any references to sterile compounding, and issues related to urgent care centers. The Board will also look at the hospital rules as they relate to changes to the Long-term Care Pharmacy rules that will go into effect on 11/10/13.

5. Status of enforcement of the rule

The rule is fairly and consistently enforced to the extent it is consistent with state statutes.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

The rule is clear, concise, and understandable.

8. Written criticisms of the rule recieved in the last five years

The agency has not received any written criticism of rule in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

   The rule was adopted before July 29, 2010 and does not issue a permit.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

    No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

    The agency completed its previous five-year review process on September 26, 2008. No action was required for this rule in that approved five-year review report.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

    Once the proposed changes are implemented, the Board believes the rule will impose the least burden and costs on persons regulated by the rule.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

    The agency has determined that there is no corresponding federal law.

14. Proposed course of action

    The agency plans to submit a notice of final rulemaking to the Council by December 31, 2015.

**Analysis of R4-23-652**

1. Authorization of the rules by existing statute(s)

   The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and (2), 32-1904(B)(3) and (5), 32-1929, 32-1930, 32-1931, and 32-1934.

2. Objective

The rule delineates the applicability of these rules to hospital pharmacies, establishes the need to obtain a permit, and addresses procedures in the event of closing a hospital pharmacy.

3. Analysis of effectiveness in achieving the objective

The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes and rules

The rule is consistent with existing state statutes and rules. However, on January 24, 2013, the Board appointed a Task Force to review and recommend changes to the specific rules related to compounding, specifically sterile pharmaceutical compounding. The Task Force continues to meet, but has not presented recommendations to the Board. Those rule changes will require the Board staff to look at the hospital rules, which have not been amended as a whole since January 5, 2003. The Board intends to amend the hospital rules where necessary to conform with the changes to the compounding rules, specifically looking at the designation in hospital rules about "director of pharmacy," any references to sterile compounding, and issues related to urgent care centers. The Board will also look at the hospital rules as they relate to changes to the Long-term Care Pharmacy rules that will go into effect on 11/10/13.

5. Status of enforcement of the rule

The rule is fairly and consistently enforced to the extent it is consistent with state statutes.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

The rule is clear, concise, and understandable.

8. Written criticisms of the rule recieved in the last five years

The agency has not received any written criticism of rule in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

The rule was adopted before July 29, 2010.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

The agency completed its previous five-year review process on September 26, 2008. No action was required for this rule in that approved five-year review report.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

Once the proposed changes are implemented, the Board believes the rule will impose the least burden and costs on persons regulated by the rule.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

The agency has determined that there is no corresponding federal law.

14. Proposed course of action

The agency plans to submit a notice of final rulemaking to the Council by December 31, 2015.

**Analysis of R4-23-653**

1. Authorization of the rules by existing statute(s)

The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and (2), 32-1904(B)(3) and (5), 32-1929, 32-1930, 32-1931, and 32-1934.

2. Objective

The rule establishes personnel staffing requirements and outlines tasks that various personnel may or may not perform.

3. Analysis of effectiveness in achieving the objective

The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes and rules

The rule is consistent with existing state statutes and rules. However, on January 24, 2013, the Board appointed a Task Force to review and recommend changes to the specific rules related to compounding, specifically sterile pharmaceutical compounding. The Task Force continues to meet, but has not presented recommendations to the Board. Those rule changes will require the Board staff to look at the hospital rules, which have not been amended as a whole since January 5, 2003. The Board intends to amend the hospital rules where necessary to conform with the changes to the compounding rules, specifically looking at the designation in hospital rules about "director of pharmacy," any references to sterile compounding, and issues related to urgent care centers. The Board will also look at the hospital rules as they relate to changes to the Long-term Care Pharmacy rules that will go into effect on 11/10/13.

5. Status of enforcement of the rule

The rule is fairly and consistently enforced to the extent it is consistent with state statutes.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

The rule is clear, concise, and understandable.

8. Written criticisms of the rule recieved in the last five years

   The agency has not received any written criticism of rule in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

   The rule was adopted before July 29, 2010 and does not issue a permit.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

    No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

    The agency completed its previous five-year review process on September 26, 2008. No action was required for this rule in that approved five-year review report.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

    Once the proposed changes are implemented, the Board believes the rule will impose the least burden and costs on persons regulated by the rule.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

    The agency has determined that there is no corresponding federal law.

14. Proposed course of action

    The agency plans to submit a notice of final rulemaking to the Council by December 31, 2015.

**Analysis of R4-23-654**

1. Authorization of the rules by existing statute(s)

The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and (2), 32-1904(B)(3) and (5), 32-1929, 32-1930, 32-1931, and 32-1934.

2. Objective

The rule establishes protocol for hospital personnel to obtain necessary drug product at times when a pharmacist is not on duty.

3. Analysis of effectiveness in achieving the objective

The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes and rules

The rule is consistent with existing state statutes and rules. However, on January 24, 2013, the Board appointed a Task Force to review and recommend changes to the specific rules related to compounding, specifically sterile pharmaceutical compounding. The Task Force continues to meet, but has not presented recommendations to the Board. Those rule changes will require the Board staff to look at the hospital rules, which have not been amended as a whole since January 5, 2003. The Board intends to amend the hospital rules where necessary to conform with the changes to the compounding rules, specifically looking at the designation in hospital rules about "director of pharmacy," any references to sterile compounding, and issues related to urgent care centers. The Board will also look at the hospital rules as they relate to changes to the Long-term Care Pharmacy rules that will go into effect on 11/10/13.

5. Status of enforcement of the rule

The rule is fairly and consistently enforced to the extent it is consistent with state statutes.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

The rule is clear, concise, and understandable.

8. Written criticisms of the rule recieved in the last five years

   The agency has not received any written criticism of rule in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

   The rule was adopted before July 29, 2010 and does not issue a permit.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

    No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

    The agency completed its previous five-year review process on September 26, 2008. No action was required for this rule in that approved five-year review report.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

    Once the proposed changes are implemented, the Board believes the rule will impose the least burden and costs on persons regulated by the rule.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

    The agency has determined that there is no corresponding federal law.

14. Proposed course of action

    The agency plans to submit a notice of final rulemaking to the Council by December 31, 2015.

**Analysis of R4-23-655**

1. Authorization of the rules by existing statute(s)

The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and (2), 32-1904(B)(3) and (5), 32-1929, 32-1930, 32-1931, and 32-1934.

2. Objective

The rule outlines minimum equipment and physical facilities needed to operate a hospital pharmacy, including compounding, dispensing and storage areas.

3. Analysis of effectiveness in achieving the objective

The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes and rules

The rule is consistent with existing state statutes and rules. However, on January 24, 2013, the Board appointed a Task Force to review and recommend changes to the specific rules related to compounding, specifically sterile pharmaceutical compounding. The Task Force continues to meet, but has not presented recommendations to the Board. Those rule changes will require the Board staff to look at the hospital rules, which have not been amended as a whole since January 5, 2003. The Board intends to amend the hospital rules where necessary to conform with the changes to the compounding rules, specifically looking at the designation in hospital rules about "director of pharmacy," any references to sterile compounding, and issues related to urgent care centers. The Board will also look at the hospital rules as they relate to changes to the Long-term Care Pharmacy rules that will go into effect on 11/10/13.

5. Status of enforcement of the rule

The rule is fairly and consistently enforced to the extent it is consistent with state statutes.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

The rule is clear, concise, and understandable.

8. Written criticisms of the rule recieved in the last five years

   The agency has not received any written criticism of rule in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

   The rule was adopted before July 29, 2010 and does not issue a permit.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

    No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

    The agency completed its previous five-year review process on September 26, 2008. No action was required for this rule in that approved five-year review report.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

    Once the proposed changes are implemented, the Board believes the rule will impose the least burden and costs on persons regulated by the rule.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

    The agency has determined that there is no corresponding federal law.

14. Proposed course of action

    The agency plans to submit a notice of final rulemaking to the Council by December 31, 2015.

**Analysis of R4-23-656**

1. Authorization of the rules by existing statute(s)

   The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and (2), 32-1904(B)(3) and (5), 32-1929, 32-1930, 32-1931, and 32-1934.

2. Objective

   The rule delineates minimum standards for space and technical equipment required to operate a hospital pharmacy including: library, lighting, sinks, refrigeration, sterile products preparation, and secure drug storage.

3. Analysis of effectiveness in achieving the objective

   The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes and rules

   The rule is consistent with existing state statutes and rules. However, on January 24, 2013, the Board appointed a Task Force to review and recommend changes to the specific rules related to compounding, specifically sterile pharmaceutical compounding. The Task Force continues to meet, but has not presented recommendations to the Board. Those rule changes will require the Board staff to look at the hospital rules, which have not been amended as a whole since January 5, 2003. The Board intends to amend the hospital rules where necessary to conform with the changes to the compounding rules, specifically looking at the designation in hospital rules about "director of pharmacy," any references to sterile compounding, and issues related to urgent care centers. The Board will also look at the hospital rules as they relate to changes to the Long-term Care Pharmacy rules that will go into effect on 11/10/13.

5. Status of enforcement of the rule

   The rule is fairly and consistently enforced to the extent it is consistent with state statutes.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

   See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

   The rule is clear, concise, and understandable.

8. Written criticisms of the rule recieved in the last five years

   The agency has not received any written criticism of rule in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

   The rule was adopted before July 29, 2010 and does not issue a permit.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

    No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

    The agency completed its previous five-year review process on September 26, 2008. No action was required for this rule in that approved five-year review report.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

    Once the proposed changes are implemented, the Board believes the rule will impose the least burden and costs on persons regulated by the rule.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

    The agency has determined that there is no corresponding federal law.

14. Proposed course of action

    The agency plans to submit a notice of final rulemaking to the Council by December 31, 2015.

**Analysis of R4-23-657**

1. Authorization of the rules by existing statute(s)

   The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and (2), 32-1904(B)(3) and (5), 32-1929, 32-1930, 32-1931, and 32-1934.

2. Objective

   The rule specifies various security provisions that are necessary to insure the integrity and availability of drug products for hospital use.

3. Analysis of effectiveness in achieving the objective

   The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes and rules

   The rule is consistent with existing state statutes and rules. However, on January 24, 2013, the Board appointed a Task Force to review and recommend changes to the specific rules related to compounding, specifically sterile pharmaceutical compounding. The Task Force continues to meet, but has not presented recommendations to the Board. Those rule changes will require the Board staff to look at the hospital rules, which have not been amended as a whole since January 5, 2003. The Board intends to amend the hospital rules where necessary to conform with the changes to the compounding rules, specifically looking at the designation in hospital rules about "director of pharmacy," any references to sterile compounding, and issues related to urgent care centers. The Board will also look at the hospital rules as they relate to changes to the Long-term Care Pharmacy rules that will go into effect on 11/10/13.

5. Status of enforcement of the rule

   The rule is fairly and consistently enforced to the extent it is consistent with state statutes.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

   See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

   The rule is clear, concise, and understandable.

8. Written criticisms of the rule recieved in the last five years

   The agency has not received any written criticism of rule in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

   The rule was adopted before July 29, 2010 and does not issue a permit.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

    No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

    The agency completed its previous five-year review process on September 26, 2008. No action was required for this rule in that approved five-year review report.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

    Once the proposed changes are implemented, the Board believes the rule will impose the least burden and costs on persons regulated by the rule.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

    The agency has determined that there is no corresponding federal law.

14. Proposed course of action

    The agency plans to submit a notice of final rulemaking to the Council by December 31, 2015.

**Analysis of R4-23-658**

1. Authorization of the rules by existing statute(s)

   The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and (2), 32-1904(B)(3) and (5), 32-1929, 32-1930, 32-1931, and 32-1934.

2. Objective

   The rule establishes the standards of drug distribution within a hospital, including labeling, receipt and maintenance of orders, formulary listing, drug recalls, and handling out of date drugs.

3. Analysis of effectiveness in achieving the objective

   The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes and rules

   The rule is consistent with existing state statutes and rules. However, on January 24, 2013, the Board appointed a Task Force to review and recommend changes to the specific rules related to compounding, specifically sterile pharmaceutical compounding. The Task Force continues to meet, but has not presented recommendations to the Board. Those rule changes will require the Board staff to look at the hospital rules, which have not been amended as a whole since January 5, 2003. The Board intends to amend the hospital rules where necessary to conform with the changes to the compounding rules, specifically looking at the designation in hospital rules about "director of pharmacy," any references to sterile compounding, and issues related to urgent care centers. The Board will also look at the hospital rules as they relate to changes to the Long-term Care Pharmacy rules that will go into effect on 11/10/13.

5. Status of enforcement of the rule

   The rule is fairly and consistently enforced to the extent it is consistent with state statutes.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

The rule is clear, concise, and understandable.

8. Written criticisms of the rule recieved in the last five years

The agency has not received any written criticism of rule in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

The rule was adopted before July 29, 2010 and does not issue a permit.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

The agency completed its previous five-year review process on September 26, 2008. No action was required for this rule in that approved five-year review report.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

Once the proposed changes are implemented, the Board believes the rule will impose the least burden and costs on persons regulated by the rule.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

The agency has determined that there is no corresponding federal law.

14. Proposed course of action

The agency plans to submit a notice of final rulemaking to the Council by December 31, 2015.

**Analysis of R4-23-659**

1. Authorization of the rules by existing statute(s)

   The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and (2), 32-1904(B)(3) and (5), 32-1929, 32-1930, 32-1931, and 32-1934.

2. Objective

   The rule requires the development of policy and procedures for safe administration of drugs in the hospital, including criteria for use of drugs brought into the hospital by patients and drug samples.

3. Analysis of effectiveness in achieving the objective

   The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes and rules

   The rule is consistent with existing state statutes and rules. However, on January 24, 2013, the Board appointed a Task Force to review and recommend changes to the specific rules related to compounding, specifically sterile pharmaceutical compounding. The Task Force continues to meet, but has not presented recommendations to the Board. Those rule changes will require the Board staff to look at the hospital rules, which have not been amended as a whole since January 5, 2003. The Board intends to amend the hospital rules where necessary to conform with the changes to the compounding rules, specifically looking at the designation in hospital rules about "director of pharmacy," any references to sterile compounding, and issues related to urgent care centers. The Board will also look at the hospital rules as they relate to changes to the Long-term Care Pharmacy rules that will go into effect on 11/10/13.

5. Status of enforcement of the rule

   The rule is fairly and consistently enforced to the extent it is consistent with state statutes.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

   See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

   The rule is clear, concise, and understandable.

8. Written criticisms of the rule recieved in the last five years

   The agency has not received any written criticism of rule in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

   The rule was adopted before July 29, 2010 and does not issue a permit.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

    No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

    The agency completed its previous five-year review process on September 26, 2008. No action was required for this rule in that approved five-year review report.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

    Once the proposed changes are implemented, the Board believes the rule will impose the least burden and costs on persons regulated by the rule.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

    The agency has determined that there is no corresponding federal law.

14. Proposed course of action

The agency plans to submit a notice of final rulemaking to the Council by December 31, 2015.

**Analysis of R4-23-660**

1. Authorization of the rules by existing statute(s)

The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and (2), 32-1904(B)(3) and (5), 32-1929, 32-1930, 32-1931, and 32-1934.

2. Objective

The rule establishes the criteria for handling and distributing investigational drugs in a hospital.

3. Analysis of effectiveness in achieving the objective

The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes and rules

The rule is consistent with existing state statutes and rules. However, on January 24, 2013, the Board appointed a Task Force to review and recommend changes to the specific rules related to compounding, specifically sterile pharmaceutical compounding. The Task Force continues to meet, but has not presented recommendations to the Board. Those rule changes will require the Board staff to look at the hospital rules, which have not been amended as a whole since January 5, 2003. The Board intends to amend the hospital rules where necessary to conform with the changes to the compounding rules, specifically looking at the designation in hospital rules about "director of pharmacy," any references to sterile compounding, and issues related to urgent care centers. The Board will also look at the hospital rules as they relate to changes to the Long-term Care Pharmacy rules that will go into effect on 11/10/13.

5. Status of enforcement of the rule

The rule is fairly and consistently enforced to the extent it is consistent with state statutes.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

   See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

   The rule is clear, concise, and understandable.

8. Written criticisms of the rule recieved in the last five years

   The agency has not received any written criticism of rule in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

   The rule was adopted before July 29, 2010 and does not issue a permit.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

    No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

    The agency completed its previous five-year review process on September 26, 2008. No action was required for this rule in that approved five-year review report.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

    Once the proposed changes are implemented, the Board believes the rule will impose the least burden and costs on persons regulated by the rule.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

    The agency has determined that there is no corresponding federal law.

14. Proposed course of action

The agency plans to submit a notice of final rulemaking to the Council by December 31, 2015.

**Analysis of R4-23-670**

1. Authorization of the rules by existing statute(s)

The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and (2), 32-1904(B)(3) and (5), 32-1929, 32-1930, 32-1931, and 32-1934.

2. Objective

The rule regulates activities related to the preparation and distribution of sterile pharmaceutical products, including minimum space, equipment, environment, quality assurance, product recalls, process and product validation testing, and record keeping.

3. Analysis of effectiveness in achieving the objective

The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes and rules

The rule is consistent with existing state statutes and rules. However, on January 24, 2013, the Board appointed a Task Force to review and recommend changes to the specific rules related to compounding, specifically sterile pharmaceutical compounding. The Task Force continues to meet, but has not presented recommendations to the Board. Those rule changes will require the Board staff to look at the hospital rules, which have not been amended as a whole since January 5, 2003. The Board intends to amend the hospital rules where necessary to conform with the changes to the compounding rules, specifically looking at the designation in hospital rules about "director of pharmacy," any references to sterile compounding, and issues related to urgent care centers. The Board will also look at the hospital rules as they relate to changes to the Long-term Care Pharmacy rules that will go into effect on 11/10/13.

5. Status of enforcement of the rule

The rule is fairly and consistently enforced to the extent it is consistent with state statutes.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

   See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

   The rule is clear, concise, and understandable.

8. Written criticisms of the rule recieved in the last five years

   The agency has not received any written criticism of rule in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

   The rule was adopted before July 29, 2010 and does not issue a permit.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

    No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

    The agency completed its previous five-year review process on September 26, 2008. No action was required for this rule in that approved five-year review report.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

    Once the proposed changes are implemented, the Board believes the rule will impose the least burden and costs on persons regulated by the rule.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

The agency has determined that there is no corresponding federal law.

14. Proposed course of action

The agency plans to submit a notice of final rulemaking to the Council by December 31, 2014.

**Analysis of R4-23-671**

1. Authorization of the rules by existing statute(s)

The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and (2), 32-1904(B)(3), 32-1929, 32-1930, and 32-1931.

2. Objective

The rule establishes a class of pharmacy known as limited service pharmacy. Limited service pharmacies are niche pharmacies focused on meeting specific patient needs. The rule outlines operating standards that protect the public health.

3. Analysis of effectiveness in achieving the objective

The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes and rules

The rule is consistent with state statutes and rules.

5. Status of enforcement of the rule

The rule is fairly and consistently enforced to the extent it is consistent with state statutes.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

The rule is clear, concise, and understandable.

8. Written criticisms of the rule recieved in the last five years

The agency has not received any written criticism of rule in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

   The rule was adopted before July 29, 2010.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

    No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

    The agency completed its previous five-year review process on September 26, 2008. No action was required for this rule in that approved five-year review report.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

    The agency has determined that the rule imposes the least burden and costs on the regulated community necessary to achieve its regulatory objective.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

    The agency has determined that there is no corresponding federal law.

14. Proposed course of action

    The rule was last amended on October 1, 2006. No action is required on this rule.

**Analysis of R4-23-672**

1. Authorization of the rules by existing statute(s)

The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and (2), 32-1904(B)(3), 32-1929, 32-1930, and 32-1931.

2. Objective

Correctional facilities (prisons and jails) offer pharmacy services to residents (inmates). The rule establishes the minimum standards of pharmacy practice in correctional facilities.

3. Analysis of effectiveness in achieving the objective

The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes and rules

The rule is consistent with state statutes and rules.

5. Status of enforcement of the rule

The rule is fairly and consistently enforced to the extent it is consistent with state statutes.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

The rule is clear, concise, and understandable.

8. Written criticisms of the rule recieved in the last five years

The agency has not received any written criticism of rule in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

The rule was adopted before July 29, 2010.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

    The agency completed its previous five-year review process on September 26, 2008. No action was required for this rule in that approved five-year review report.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

    The agency has determined that the rule imposes the least burden and costs on the regulated community necessary to achieve its regulatory objective.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

    The agency has determined that there is no corresponding federal law.

14. Proposed course of action

    The rule was last amended on December 3, 2004. No action is required on this rule.

**Analysis of R4-23-673**

1. Authorization of the rules by existing statute(s)

   The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and (2), 32-1904(B)(3), 32-1929, 32-1930, and 32-1931.

2. Objective

   The rule establishes minimum standards for operating a limited-service mail-order pharmacy.

3. Analysis of effectiveness in achieving the objective

   The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes and rules

   The rule is consistent with state statutes and rules.

5. Status of enforcement of the rule

The rule is fairly and consistently enforced to the extent it is consistent with state statutes.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

   See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

   The rule is clear, concise, and understandable.

8. Written criticisms of the rule recieved in the last five years

   The agency has not received any written criticism of rule in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

   The rule was adopted before July 29, 2010.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

    No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

    The agency completed its previous five-year review process on September 26, 2008. No action was required for this rule in that approved five-year review report.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

    The agency has determined that the rule imposes the least burden and costs on the regulated community necessary to achieve its regulatory objective.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

The agency has determined that there is no corresponding federal law.

14. Proposed course of action

The rule was last amended on December 3, 2004. No action is required on this rule.

**Analysis of R4-23-674**

1. Authorization of the rules by existing statute(s)

The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and (2), 32-1904(B)(3), 32-1929, 32-1930, and 32-1931.

2. Objective

The rule establishes the minimum standards for operating a limited-service long-term care pharmacy.

3. Analysis of effectiveness in achieving the objective

The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes and rules

In August 2005 rules R4-23-701, R4-23-701.01, R4-23-701.02, R4-23-701.03, and R4-23-703 underwent a Five-year Rule Review, and the Board recommended a task force be appointed. A task force was appointed by the Board in 2008 to review the rules and several meetings were held before the Governor's moratorium on rulemaking was implemented in March 2009. The rules were again due for a Five-Year Rule Review in August 2010, however the rulemaking moratorium was still in effect through September 2011. The Board appointed another task force in 2012 to review the rules. The changes recommended by the task force included changes to R4-23-674. A Notice of Rulemaking Docket Opening was published on December 14, 2012. A Notice of Proposed Rulemaking was published on February 22, 2013. A Notice of Final Rulemaking was

published on September 27, 2013. The rule will be amended by final rulemaking at 19 A.A.R. 2894, effective November 10, 2013.

5. Status of enforcement of the rule

   The rule is fairly and consistently enforced to the extent it is consistent with state statutes.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

   See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

   The rule is clear, concise, and understandable.

8. Written criticisms of the rule recieved in the last five years

   The agency has not received any written criticism of rule in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

   The rule complies with the exception in subsection (A)(2) of A.R.S. § 41-1037, because the rule issues an alternative permit specified in A.R.S. § 32-1930.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

    No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

    The agency completed its previous five-year review process on September 26, 2008. No action was required for this rule in that approved five-year review report.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

    The agency has determined that the rule imposes the least burden and costs on the regulated community necessary to achieve its regulatory objective.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

    The agency has determined that there is no corresponding federal law.

14. Proposed course of action

    The rule was last amended November 10, 2013. No further action is required on this rule.

**Analysis of R4-23-675**

1. Authorization of the rules by existing statute(s)

   The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and (2), 32-1904(B)(3), 32-1929, 32-1930, and 32-1931.

2. Objective

   The rule establishes the minimum standards for operating a limited-service sterile pharmaceutical products pharmacy.

3. Analysis of effectiveness in achieving the objective

   The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes and rules

   The rule is consistent with existing state statutes and rules. However, on January 24, 2013, the Board appointed a Task Force to review and recommend changes to the specific rules related to compounding, specifically sterile pharmaceutical compounding. The Task Force continues to meet, but has not presented recommendations to the Board. Those rule changes will require the Board staff to look at the hospital

rules, which have not been amended as a whole since January 5, 2003. The Board intends to amend the hospital rules where necessary to conform with the changes to the compounding rules, specifically looking at the designation in hospital rules about "director of pharmacy," any references to sterile compounding, and issues related to urgent care centers. The Board will also look at the hospital rules as they relate to changes to the Long-term Care Pharmacy rules that will go into effect on 11/10/13.

5. Status of enforcement of the rule

   The rule is fairly and consistently enforced to the extent it is consistent with state statutes.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

   See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

   The rule is clear, concise, and understandable.

8. Written criticisms of the rule recieved in the last five years

   The agency has not received any written criticism of rule in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

   The rule was adopted before July 29, 2010.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

    No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

The agency completed its previous five-year review process on September 26, 2008. No action was required for this rule in that approved five-year review report.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

Once the proposed changes are implemented, the Board believes the rule will impose the least burden and costs on persons regulated by the rule.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

The agency has determined that there is no corresponding federal law.

14. Proposed course of action

The agency plans to submit a notice of final rulemaking to the Council by December 31, 2014.

**Analysis of R4-23-681**

1. Authorization of the rules by existing statute(s)

The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and (2), 32-1904(B)(3), 32-1929, 32-1930, and 32-1931.

2. Objective

The rule establishes recognition of nuclear pharmacies as those have specially trained and qualified personnel that compound radioactive pharmaceuticals pursuant to physician orders. The rule also addresses compliance and regulatory provisions of this specialty pharmacy.

3. Analysis of effectiveness in achieving the objective

The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes and rules

The rule is consistent with existing state statutes and rules. However, on January 24, 2013, the Board appointed a Task Force to review and recommend changes to the specific rules related to compounding,

specifically sterile pharmaceutical compounding. The Task Force continues to meet, but has not presented recommendations to the Board. Those rule changes will require the Board staff to look at the hospital rules, which have not been amended as a whole since January 5, 2003. The Board intends to amend the hospital rules where necessary to conform with the changes to the compounding rules, specifically looking at the designation in hospital rules about "director of pharmacy," any references to sterile compounding, and issues related to urgent care centers. The Board will also look at the hospital rules as they relate to changes to the Long-term Care Pharmacy rules that will go into effect on 11/10/13.

5. Status of enforcement of the rule

   The rule is fairly and consistently enforced to the extent it is consistent with state statutes.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

   See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

   The rule is clear, concise, and understandable.

8. Written criticisms of the rule recieved in the last five years

   The agency has not received any written criticism of rule in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

   The rule was adopted before July 29, 2010 and does not issue a permit.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

    No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

The agency completed its previous five-year review process on September 26, 2008. No action was required for this rule in that approved five-year review report.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

Once the proposed changes are implemented, the Board believes the rule will impose the least burden and costs on persons regulated by the rule.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

The agency has determined that there is no corresponding federal law.

14. Proposed course of action

The agency plans to submit a notice of final rulemaking to the Council by December 31, 2015.

**Analysis of R4-23-682**

1. Authorization of the rules by existing statute(s)

The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and (2), 32-1904(B)(3), 32-1929, 32-1930, and 32-1931.

2. Objective

The rule establishes the specific standards for a limited-service nuclear pharmacy in conjunction with and to augment the general requirements established in R4-23-681.

3. Analysis of effectiveness in achieving the objective

The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes and rules

The rule is consistent with existing state statutes and rules. However, on January 24, 2013, the Board appointed a Task Force to review and

recommend changes to the specific rules related to compounding, specifically sterile pharmaceutical compounding. The Task Force continues to meet, but has not presented recommendations to the Board. Those rule changes will require the Board staff to look at the hospital rules, which have not been amended as a whole since January 5, 2003. The Board intends to amend the hospital rules where necessary to conform with the changes to the compounding rules, specifically looking at the designation in hospital rules about "director of pharmacy," any references to sterile compounding, and issues related to urgent care centers. The Board will also look at the hospital rules as they relate to changes to the Long-term Care Pharmacy rules that will go into effect on 11/10/13.

5. Status of enforcement of the rule

   The rule is fairly and consistently enforced to the extent it is consistent with state statutes.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

   See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

   The rule is clear, concise, and understandable.

8. Written criticisms of the rule recieved in the last five years

   The agency has not received any written criticism of rule in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

   The rule was adopted before July 29, 2010.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

    No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

The agency completed its previous five-year review process on September 26, 2008. No action was required for this rule in that approved five-year review report.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

Once the proposed changes are implemented, the Board believes the rule will impose the least burden and costs on persons regulated by the rule.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

The agency has determined that there is no corresponding federal law.

14. Proposed course of action

The agency plans to submit a notice of final rulemaking to the Council by December 31, 2015.

**Analysis of R4-23-692**

1. Authorization of the rules by existing statute(s)

The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and (2), 32-1901(9) through (12), 32-1904(B)(3), 32-1929, 32-1930 and 32-1931.

2. Objective

The rule establishes the standards for compressed medical gas distributors, including permit application, drug listing, drug manufacturing and distribution, and recordkeeping.

3. Analysis of effectiveness in achieving the objective

The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes and rules

The rule is consistent with state and federal statutes and rules.

5. Status of enforcement of the rule

The rule is fairly and consistently enforced to the extent it is consistent with state statutes.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

   See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

   The rule is clear, concise, and understandable.

8. Written criticisms of the rule recieved in the last five years

   The agency has not received any written criticism of rule in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

   The rule complies with the exception in subsection (A)(2) of A.R.S. § 41-1037, because the rule issues an alternative permit specified in A.R.S. § 32-1930.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

    No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

    The Board opened a docket to amend the rule to comply with the previous five-year rule review on 6/15/12. A Notice of Proposed Rulemaking was published on 7/20/12. The Notice of Final Rulemaking was published on 1/25/13. The amended rules became effective on 3/10/13. All planned action is completed.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

The agency has determined that the rule imposes the least burden and costs on the regulated community necessary to achieve its regulatory objective.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

The rule is not more stringent than federal law as it relates to current good manufacturing practice and record keeping. To ensure that the rule is not more stringent, the Board has chosen to incorporate the federal law by reference, specifically 21 CFR 210 through 211.

14. Proposed course of action

The rule was last amended by final rulemaking at 19 A.A.R. 97, effective March 10, 2013. No action is required on this rule.

**Analysis of R4-23-693**

1. Authorization of the rules by existing statute(s)

The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and (2), 32-1901(9) through (12), 32-1904(B)(3), 32-1929, 32-1930 and 32-1931.

2. Objective

The rule establishes the standards for compressed medical gas suppliers, including permit application, drug procurement and distribution, and recordkeeping.

3. Analysis of effectiveness in achieving the objective

The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes and rules

Senate Bill 1188 was passed during the 2013 Legislative Session. The bill added "durable medical equipment" to the Compressed Medical Gas Supplier permit required in A.R.S. §§ 32-1930 and 32-1931. The Board intends to amend the rule to add durable medical equipment into the compressed medical gas supplier rule. The title of the Section will become Durable Medical Equipment and Compressed Medical Gas Supplier.

"Durable medical equipment and" will be inserted immediately preceding all instances of "compressed medical gas supplier" in the rule.

5. Status of enforcement of the rule

   The rule is fairly and consistently enforced to the extent it is consistent with state statutes.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

   See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

   The rule is clear, concise, and understandable.

8. Written criticisms of the rule recieved in the last five years

   The agency has not received any written criticism of rule in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

   The rule was adopted before July 29, 2010.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

    No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

    The agency completed its previous five-year review process on September 26, 2008. No action was required for this rule in that approved five-year review report.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

Once the proposed changes are implemented, the Board believes the rule will impose the least burden and costs on persons regulated by the rule.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

The agency has determined that there is no corresponding federal law.

14. Proposed course of action

The agency plans to submit a notice of final rulemaking to the Council by December 31, 2014.

**Analysis of R4-23-801**

1. Authorization of the rules by existing statute(s)

The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1).

2. Objective

The rule establishes when a dietary supplement is considered a drug, and therefore subject to A.R.S. Title 32, Chapter 18 and 4 A.A.C. 23.

3. Analysis of effectiveness in achieving the objective

The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes and rules

The rule is consistent with state statutes and rules.

5. Status of enforcement of the rule

The rule is fairly and consistently enforced to the extent it is consistent with state statutes.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

The rule is clear, concise, and understandable.

8. Written criticisms of the rule recieved in the last five years

The agency has not received any written criticism of rule in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

The rule was adopted before July 29, 2010 and does not issue a permit.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

The agency completed its previous five-year review process on September 26, 2008. No action was required for this rule in that approved five-year review report.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

The agency has determined that the rule imposes the least burden and costs on the regulated community necessary to achieve its regulatory objective.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

The agency has determined that there is no corresponding federal law.

14. Proposed course of action

The rule was last amended on January 5, 2003. No action is required on this rule.

**Analysis of R4-23-802**

1. Authorization of the rules by existing statute(s)

The agency's general and specific rulemaking authority is found in A.R.S. §§ 32-1904(A)(1).

2. Objective

The rule establishes to whom a veterinary drug manufacturer or supplier may distribute a prescription-only veterinary drug and a nonprescription veterinary drug.

3. Analysis of effectiveness in achieving the objective

The rule effectively achieves its objective.

4. Analysis of consistency with state and federal statutes and rules

The rule is consistent with state statutes and rules.

5. Status of enforcement of the rule

The rule is fairly and consistently enforced to the extent it is consistent with state statutes.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

The rule is clear, concise, and understandable.

8. Written criticisms of the rule recieved in the last five years

The agency has not received any written criticism of rule in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

The rule was adopted before July 29, 2010 and does not issue a permit.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

    The agency completed its previous five-year review process on September 26, 2008. No action was required for this rule in that approved five-year review report.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

    The agency has determined that the rule imposes the least burden and costs on the regulated community necessary to achieve its regulatory objective.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

    The agency has determined that there is no corresponding federal law.

14. Proposed course of action

    The rule was last amended on January 5, 2003. No action is required on this rule.

Attachment A contains the statutes referened in the rule analysis and Attachment B contains the rules reviewed in this report.

# INTRODUCTION

The Arizona State Board of Pharmacy protects the health, safety and welfare of the citizens of Arizona by regulating the practice of pharmacy and the distribution, sale and storage of prescription medications and devices and non-prescription medications.

The Board accomplishes its mission by:

- Issuing licenses to pharmacists, pharmacy interns and pharmacy technicians,
- Issuing permits to pharmacies, manufacturers, wholesalers and distributors,
- Conducting compliance inspections of permitted facilities, and
- Investigating complaints & adjudicating violations of applicable state and federal laws and rules.
- Promulgating and reviewing state rules and regulations.

The rules in 4 A.A.C. 23, Article 12, establish a prescription medication donation program, including requirements for eligibility to particpate, donating medication, eligible prescriptiom medications, eligibility requirements to receive donated prescription medications, donor form, recipient form, recordkeeping, handling fee, policies and procedures, dispensing donated prescription medications, and responsibilities of the physician-in-charge or pharmacist-in-charge of a participating phuysician's office, pharmacy, or health care institution.

The rules have been in place for five years and were intended to allow long-term care facilities to donate unused patient medication to participating physicians or pharmacies to redispense the unused medications to eligible individuals who might otherwise be unable to afford medications. To date no physician or pharmacy has come to the Board seeking to particpate in the program. We are not sure why no one has chosen to particiate, but suspect it is the fact that there is not much profit to be made in the business.

# INFORMATION THAT IS IDENTICAL FOR ALL RULES

3. Analysis of effectiveness in achieving the objective

   The rules effectively achieves their objective.

4. Analysis of consistency with state and federal statutes and rules

   The rules are consistent with state statutes and rules, specifically the statutes in A.R.S. Title 32, Chapter 18 and the rules in 4 A.A.C. 23. The drug storage and distribution requirements of the rules are required by the state statutes and rules and are consistent with the federal Food, Drug, and Cosmetic Act, which applies to manufacturers and distributors.

5. Status of enforcement of the rule

   The rules are fairly and consistently enforced to the extent it is consistent with state statutes, specifically the statutes in A.R.S. Title 32, Chapter 18 and the rules in 4 A.A.C. 23.

6. The estimated economic, small business and consumer impact of the rule as compared to the economic, small business and consumer impact statement prepared on the last making of the rule.

   See the attached Economic Impact Statement Comparison.

7. Analysis of clarity, conciseness, and understandability of the rule

   With the exception of R4-23-1211, the rules are clear, concise, and understandable.

8. Written criticisms of the rule recieved in the last five years

   The agency has not received any written criticism of the rules in the past five years.

9. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license or agency authorization, whether the rule complies with section 41-1037.

   The rules were adopted before July 29, 2010.

10. Any analysis submitted to the agency by another person that compares the rule's impact on this state's competitiveness to the impact on businesses in other states

No analysis was submitted.

11. If applicable, that the agency completed the previous five-year review process

This is the first five-year review since the rules were made.

12. A determination that the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

The agency has determined that the rules impose the least burden and costs on the regulated community necessary to achieve their regulatory objective.

13. A determination that the rule is not more stringent than a corresponding federal law unless there is statutory authority to exceed the requirements of that federal law

The agency has determined that the rules are not more stringent than federal law as it applies to drug storage and distribution. Other aspects of the rules do not have a corresponding federal law and comply with state law.

**Analysis of R4-23-1201**

1. Authorization of the rules by existing statute(s)

   The agency's general rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and 32-1904(B)(3). The agency's specific rulemaking authority is found in A.R.S. § 32-1909.

2. Objective

   The rule establishes the eligibility requirements for participation in the prescription medication donation program to ensure that the participatants in the program meet current licensure and regulatory requirements.

14. Proposed course of action

   The rule was made by final rulemaking at 14 A.A.R. 4320, effective January 3, 2009. No action is required on this rule.

**Analysis of R4-23-1202**

1. Authorization of the rules by existing statute(s)

   The agency's general rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and 32-1904(B)(3). The agency's specific rulemaking authority is found in A.R.S. § 32-1909.

2. Objective

   The rule establishes who may donate medications in the prescriptiom medication donation program to ensure that only eligible medications are donated to the program.

14. Proposed course of action

   The rule was made by final rulemaking at 14 A.A.R. 4320, effective January 3, 2009. No action is required on this rule.

**Analysis of R4-23-1203**

1. Authorization of the rules by existing statute(s)

   The agency's general rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and 32-1904(B)(3). The agency's specific rulemaking authority is found in A.R.S. § 32-1909.

2. Objective

The rule establishes which medications are eligible for donation in the prescription medication donation program.

14. Proposed course of action

The rule was made by final rulemaking at 14 A.A.R. 4320, effective January 3, 2009. No action is required on this rule.

**Analysis of R4-23-1204**

1. Authorization of the rules by existing statute(s)

The agency's general rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and 32-1904(B)(3). The agency's specific rulemaking authority is found in A.R.S. § 32-1909.

2. Objective

The rule establishes the requirements an individual must meet to be eligible to receive donated prescription medication.

14. Proposed course of action

The rule was made by final rulemaking at 14 A.A.R. 4320, effective January 3, 2009. No action is required on this rule.

**Analysis of R4-23-1205**

1. Authorization of the rules by existing statute(s)

The agency's general rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and 32-1904(B)(3). The agency's specific rulemaking authority is found in A.R.S. § 32-1909.

2. Objective

The rule establishes the requirements an individual, manufacturer, or health care institution must meet to be a donor of prescription medication to the prescription medication donation program to ensure the donor understands which medications may be donated.

14. Proposed course of action

The rule was made by final rulemaking at 14 A.A.R. 4320, effective January 3, 2009. No action is required on this rule.

**Analysis of R4-23-1206**

1. Authorization of the rules by existing statute(s)

The agency's general rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and 32-1904(B)(3). The agency's specific rulemaking authority is found in A.R.S. § 32-1909.

2. Objective

The rule establishes the "recipient form" that must be completed before an individual may receive donated prescription medication to ensure that the recipient of donated medications meets the eligibility requirements.

14. Proposed course of action

The rule was made by final rulemaking at 14 A.A.R. 4320, effective January 3, 2009. No action is required on this rule.

**Analysis of R4-23-1207**

1. Authorization of the rules by existing statute(s)

The agency's general rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and 32-1904(B)(3). The agency's specific rulemaking authority is found in A.R.S. § 32-1909.

2. Objective

The rule establishes the recordkeeping requirements of the prescription medication donation program to ensure an audit trail for all donated medications.

14. Proposed course of action

The rule was made by final rulemaking at 14 A.A.R. 4320, effective January 3, 2009. No action is required on this rule.

**Analysis of R4-23-1208**

1. Authorization of the rules by existing statute(s)

The agency's general rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and 32-1904(B)(3). The agency's specific rulemaking authority is found in A.R.S. § 32-1909.

2. Objective

The rule establishes the handling fee a participating physician's office, pharmacy, or health care institution may charge a recipient for dispensing a donated prescription medication. The established fee zero to $4.50 meets the requirements of a formula.

14. Proposed course of action

The rule was made by final rulemaking at 14 A.A.R. 4320, effective January 3, 2009. No action is required on this rule.

**Analysis of R4-23-1209**

1. Authorization of the rules by existing statute(s)

The agency's general rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and 32-1904(B)(3). The agency's specific rulemaking authority is found in A.R.S. § 32-1909.

2. Objective

The rule requires that a participating physician's office, pharmacy, and health care institution must develop, implement, and comply with policies and procedures for the receipt, storage, and distribution of donated prescription medications to ensure the safety of the medication.

14. Proposed course of action

The rule was made by final rulemaking at 14 A.A.R. 4320, effective January 3, 2009. No action is required on this rule.

**Analysis of R4-23-1210**

1. Authorization of the rules by existing statute(s)

The agency's general rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and 32-1904(B)(3). The agency's specific rulemaking authority is found in A.R.S. § 32-1909.

2. Objective

The rule establishes the standards for dispensing donated prescription medication received under the prescription medication donation program to ensure patient safety and proper records.

14. Proposed course of action

The rule was made by final rulemaking at 14 A.A.R. 4320, effective January 3, 2009. No action is required on this rule.

**Analysis of R4-23-1211**

1. Authorization of the rules by existing statute(s)

   The agency's general rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and 32-1904(B)(3). The agency's specific rulemaking authority is found in A.R.S. § 32-1909.

2. Objective

   The rule establishes the responsibilities of the physician or pharmacist-in-charge of a participating physician's office, pharmacy, or health care institution to ensure patient safety and proper records.

7. Analysis of clarity, conciseness, and understandability of the rule

   The rule is clear, concise, and understandable., except for subsection (9)(a) needs to have the word "and" replaced with the word "or." The use of "and" seems to require the use of federal, state, and local guidelines, but the intent was to allow the use of one or more of the guidelines not all three.

14. Proposed course of action

    The rule was made by final rulemaking at 14 A.A.R. 4320, effective January 3, 2009. The agency proposes to submit a rulemaking to the Council addressing the issues identified in this report by December 2016.

Attachment A contains the statutes referened in the rule analysis and Attachment B contains the rules reviewed in this report.

# ARIZONA BOARD OF PHARMACY

4 A.A.C. 23, Article 11

July 2014

# TABLE OF CONTENTS

# INTRODUCTION

The Arizona State Board of Pharmacy protects the health, safety and welfare of the citizens of Arizona by regulating the practice of pharmacy and the distribution, sale and storage of prescription medications and devices and non-prescription medications.

The Board accomplishes its mission by:

- Issuing licenses to pharmacists, pharmacy interns and pharmacy technicians,
- Issuing permits to pharmacies, manufacturers, wholesalers and distributors,
- Conducting compliance inspections of permitted facilities, and
- Investigating complaints & adjudicating violations of applicable state and federal laws and rules.
- Promulgating and reviewing state rules and regulations.

The rules in 4 A.A.C. 23, Article 11, establish the eligibility and qualifications requirements for pharmacy technician and pharmacy technician trainee licensure, the procedures for pharmacy technician and pharmacy technician trainee licensure, the permissible and prohibited activities of pharmacy technician trainees and pharmacy technicians, including a policy and procedure manual specific for each pharmacy, the requirement that each pharmacy develop and implement a pharmacy technician training program, a pharmacy technician drug compounding training program, and alternative pharmacy technician training, and the continuing education requirements for renewal of a pharmacy technician's license.

# INFORMATION THAT IS IDENTICAL FOR ALL RULES

1. **Effectiveness in Achieving Objectives**

The rules reviewed are effective in achieving their stated objectives.

1b. **Objective**

The general objective of the rules is to establish the licensure, training, practice, and continuing education requirements for pharmacy technician trainees and pharmacy technicians in Arizona.

2. **Written Criticisms of the Rules Received in the Past Five Years**

The agency has not received any written criticisms of the rules in the past five years.

3. **Authorization of the Rules by Existing Statutes**

The agency's general rulemaking authority is found in A.R.S. §§ 32-1904(A)(1) and 32-1904(B)(7); with specific authority found in A.R.S. §§ 32-1923.01, 32-1924, 32-1925, 32-1926, and 32-1927.01.

4. **Consistency with Statutes and Other Rules Made by the Agency**

The rules reviewed are consistent with the statutes for the agency, namely A.R.S. Title 32, Chapter 18. In addition, the rules are consistent both internally and with relation to the agency's other rules.

4a. **Enforcement**

The rules are enforced as written without incident.

6. **Economic, Small Business, and Consumer Impact Comparison**

The economic impact has not differed from that projected when the rules were amended effective March 10, 2013 (19 A.A.R. 102) and November 10, 2013 (19 A.A.R. 2911) and made effective April 30, 2005 (11 A.A.R. 1105). The main costs are born by the agency and include staff time to process new and renewal applications. As of August 31, 2014, the Board had licensed 11,578 pharmacy technicians and 8,249 pharmacy technician trainees compared to the 7,349 pharmacy technicians and 6,059 pharmacy technician trainees licensed on 6/30/08 as reported during the Board's last 5-year rule review of the technician rules in 2009. Obviously, pharmacy technician is becoming a career path for many people, as the numbers of technicians continues to grow. The Board will work with the pharmacies to amend the rules to ensure that technicians are trained as required by the rule and that the training is documented. The new time-frame implemented in 2013 is working very well. The increase in the time-frame was needed to ensure that the Board office was able to get all the required documentation for licensure of an increasingly large number of technician applicants.

7. **Analysis Submitted by Another Person Regarding the Rules' Impact on this State's Business Competitiveness as Compared to the Competitiveness of Businesses in Other States**

No analysis was submitted to the agency.

8. **Completion of the Previous Five-Year-Review Report Process**

The agency's previous five-year-review report was approved by the Council on May 5, 2009. In that report, the agency identified the following issues requiring amendment:

R4-23-1102 and R4-23-1105 When the rules were made in 2004, the Board felt that the majority of applicants would follow the normal progression of licensure as a pharmacy technician trainee, proceed through the training required in R4-23-1105(B), pass the pharmacy technician examination, and apply for licensure as a pharmacy technician. However, we found that many applicants had already passed the pharmacy technician examination either before the law changed or in another state. These applicants may not have completed a pharmacy's training course, but had a job in a pharmacy and needed a license to work. The Board's staff licensed the applicants without the required proof of completing a pharmacy technician training program as required in R4-23-1101(A)(1). The Board is inconsistently enforcing a rule, which should be amended to reflect the real world situation. The Board intended to amend the rule by deleting subsection (A)(1). Because the statute requires pharmacy technician training, the Board intended to amend R4-23-1105 to add an in-store training requirement for pharmacy technicians as part of their orientation.

R4-23-1104 To improve the clarity, conciseness, and understandability of the rule, the Board intended to add language to require technicians to "correctly" input prescription order data and to "correctly" package prescription drugs. The Board intended to add a new subsection (C) requiring a technician to "accurately perform the functions listed in subsection (A) and (B)."

The agency planned to submit a rulemaking to the Council for R4-23-1104 and R4-23-1105 by December 31, 2009 and for R4-23-1102 by June 30, 2010. However, these actions were not completed until a 2013 rulemaking. See, 19 A.A.R. 102.

9. **Probable Benefits Outweigh Probable Costs / Rules Impose Least Burden on Regulated Persons**

The changes made to the rules in 2013 have benefitted regulated persons by clarifying the training requirements for pharmacy technician trainees and pharmacy technicians and the required performance measure for technicians, thereby allowing consistent enforcement of the rules by the Board. The changes made to the rules in 2013 imposed minimal costs to the regulated persons, and those costs have remained minimal. The rules now impose the least burden and probable costs to regulated persons, which are outweighed by the probable benefits of the rules.

10. **Stringency Compared with Corresponding Federal Law**

There is no federal law that corresponds with the rules reviewed.

11. **For Rules Adopted After July 29, 2010 that Require Issuance of a Regulatory Permit, License, or Agency Authorization, Whether the Rule Complies with the General Permit Requirement in A.R.S. § 41-1037.**

Although the rules were last amended in 2013, the rules comply with the exception in subsection (A)(2) of A.R.S. § 41-1037, because the rules issue a specific license specified in A.R.S. § 32-1924.

12. **Proposed Course of Action**

The agency proposes to submit a final rulemaking to the Council addressing the issues identified in the specific analysis of R4-23-1105 by December 31, 2015.

## INDIVIDUAL ANALYSIS

**R4-23-1101**

**1b. Objective of the Rule**

The rule establishes the eligibility and qualification requirements for pharmacy technician and pharmacy technician trainee licensure.

**5. Clarity, Conciseness, and Understandability**

The rule is clear, concise, and understandable as written.

**R4-23-1102**

**1b. Objective of the Rule**

The rule establishes the procedures for pharmacy technician licensure.

**5. Clarity, Conciseness, and Understandability**

The rule is clear, concise, and understandable as written.

**R4-23-1103**

**1b. Objective of the Rule**

The rule establishes the procedures for pharmacy technician trainee licensure.

**5. Clarity, Conciseness, and Understandability**

The rule is clear, concise, and understandable as written.

**R4-23-1104**

**1b. Objective of the Rule**

The rule establishes the permissible and prohibited activities of pharmacy technician trainees and pharmacy technicians and requires a policy and procedure manual specific for each pharmacy.

### 5. Clarity, Conciseness, and Understandability

The rule is clear, concise, and understandable as written.

## R4-23-1105

### 1b. Objective of the Rule

The rule requires that each pharmacy develop and implement a pharmacy technician training program, a pharmacy technician drug compounding training program, and alternative pharmacy technician training.

### 5. Clarity, Conciseness, and Understandability

The Board has found that the changes made in 2013, did not take into account what happens to the training record of a technician who moves jobs to another company. The new company will not have a record of the training of that technician as required in subsections (B)(3)(b), (C)(3)(b), and (D)(3)(b). A Board Compliance Officer doing an inspection will not be able to view the training record of that technician as required in subsections (B)(3)(b), (C)(3)(b), and (D)(3)(b). The Board intends to amend the rule to provide a method for technicians to prove they have completed the necessary training.

## R4-23-1106

### 1b. Objective of the Rule

The rule establishes continuing education requirements for renewal of a pharmacy technician's license.

### 5. Clarity, Conciseness, and Understandability

The rule is clear, concise, and understandable as written.