

NOTICES OF PROPOSED RULEMAKING

Unless exempted by A.R.S. § 41-1005, each agency shall begin the rulemaking process by first submitting to the Secretary of State's Office a Notice of Rulemaking Docket Opening followed by a Notice of Proposed Rulemaking that contains the preamble and the full text of the rules. The Secretary of State's Office publishes each Notice in the next available issue of the *Register* according to the schedule of deadlines for *Register* publication. Under the Administrative Procedure Act (A.R.S. § 41-1001 et seq.), an agency must allow at least 30 days to elapse after the publication of the Notice of Proposed Rulemaking in the *Register* before beginning any proceedings for making, amending, or repealing any rule. (A.R.S. §§ 41-1013 and 41-1022)

NOTICE OF PROPOSED RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

[R08-121]

PREAMBLE

1. Sections Affected

R4-23-202
R4-23-203
R4-23-302
R4-23-407

Rulemaking Action

Amend
Amend
Amend
Amend

2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rule is implementing (specific):

Authorizing statutes: A.R.S. §§ 32-1904(A)(1) and (5) and 32-1904(B)(5), (7), and (10)

Implementing statutes: A.R.S. §§ 32-1922, 32-1923, 32-1924, 32-1964, and 32-1968

3. A list of all previous notices appearing in the *Register* addressing the proposed rule:

Notice of Rulemaking Docket Opening: 14 A.A.R. 717, February 29, 2008

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

Name: Dean Wright, Compliance Officer
Address: Board of Pharmacy
1700 W. Washington St., Suite 250
Phoenix, AZ 85007
Telephone: (602) 771-2727
Fax: (602) 771-2749
E-mail: dwright@azpharmacy.gov

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

During the Board's Five-year Rule Review approved by the Governor's Regulatory Review Council (G.R.R.C.) on July 10, 2007, the Board identified three rules to amend because of inconsistencies with other rules and one rule to amend by adding a more current incorporation by reference. In the first two rules, R4-23-202(B)(3)(b)(ii), R4-23-202(B)(4)(b)(ii), R4-23-203(B)(3)(b)(ii), and R4-23-203(B)(4)(b)(ii) reference an "examination fee specified in R4-23-205(C)." However, R4-23-205(C) lists only an application fee. R4-23-205(C) was changed from an examination fee to an application fee on May 1, 2004. The Board intends to correct the inconsistency by inserting the word "application" in place of the word "examination" in R4-23-202(B)(3)(b)(ii), R4-23-202(B)(4)(b)(ii), R4-23203(B)(3)(b)(ii), and R4-23-302(B)(4)(b)(ii). In the third rule, R4-23-302(D) cites R4-23-104. R4-23-104 was repealed and replaced by R4-23-111 on May 1, 2004. To be consistent, the Board intends to amend R4-23-302(D) by replacing "R4-23-104" with "R4-23-111." In the fourth rule, R4-23-407(D)(2) incorporates by reference "21 CFR 1306.25, published April 1, 2001." To bring the rule up to date, the Board intends to amend R4-23-407(D) by incorporating the April 1, 2008 edition of 21 CFR 1306.25. The rules will include format, style, and grammar necessary to comply with the current rules of the Secretary of State and the Governor's Regulatory Review Council.

The Board believes that amending these rules will benefit the public and the pharmacy community by clearly establishing standards for pharmacist licensure, intern training sites, and pharmacy intern preceptor privileges and practice standards for prescription dispensing in Arizona.

Notices of Proposed Rulemaking

6. A reference to any study relevant to the rule that the agency reviewed and proposes either to rely on or not to rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The agency did not review or rely on any study relevant to the rule.

7. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

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

The proposed rules will impact the Board, pharmacists, interns, and pharmacies. The proposed rules' impact on the Board will be the usual rulemaking-related costs, which are minimal.

The proposed rules will have no economic impact on pharmacists, interns, and pharmacies. The rules are necessary to correct inconsistencies discovered by the Board during its Five-year Rule Review approved by the Governor's Regulatory Review Council (G.R.R.C.) on July 10, 2007. The Board identified three rules to amend because of inconsistencies with other rules and one rule to amend by adding a more current incorporation by reference. In the first two rules, R4-23-202(B)(3)(b)(ii), R4-23-202(B)(4)(b)(ii), R4-23-203(B)(3)(b)(ii), and R4-23-203(B)(4)(b)(ii) reference an "examination fee specified in R4-23-205(C)." However, R4-23-205(C) lists only an application fee. R4-23-205(C) was changed from an examination fee to an application fee on May 1, 2004. The proposed rules make changes to correct the inconsistency by inserting the word "application" in place of the word "examination" in R4-23-202(B)(3)(b)(ii), R4-23-202(B)(4)(b)(ii), R4-23-203(B)(3)(b)(ii), and R4-23-302(B)(4)(b)(ii). In the third rule, R4-23-302(D) cites R4-23-104. R4-23-104 was repealed and replaced by R4-23-111 on May 1, 2004. To be consistent, the proposed rules amend R4-23-302(D) by replacing "R4-23-104" with "R4-23-111." In the fourth rule, R4-23-407(D)(2) incorporates by reference "21 CFR 1306.25, published April 1, 2001." To bring the rule up to date, the proposed rules amend R4-23-407(D) by incorporating the April 1, 2008 edition of 21 CFR 1306.25. The proposed rules have no economic impact on pharmacies, pharmacists, or interns, but simply correct inconsistencies with other rules and bring one rule up to date with a current incorporation by reference of a federal regulation. The proposed rules have no economic impact on the public.

The proposed rules will benefit the public and the pharmacy community by clearly establishing standards for pharmacist licensure, intern training sites, and pharmacy intern preceptor privileges and practice standards for prescription dispensing in Arizona.

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name: Dean Wright, Compliance Officer
Address: Board of Pharmacy
1700 W. Washington St., Suite 250
Phoenix, AZ 85007
Telephone: (602) 771-2727
Fax: (602) 771-2749
E-mail: dwright@azpharmacy.gov

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

Comments may be written or presented orally. Written comments must be received by 5:00 p.m., Monday, June 9, 2008. An oral proceeding is scheduled for:

Date: June 9, 2008
Time: 10:15 a.m.
Location: 1700 W. Washington St., 3rd Floor Board Room
Phoenix, AZ 85007

A person may request information about the oral proceeding by contacting the person listed above.

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

Not applicable

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

21 CFR 13056.25, published April 1, 2008, and no future amendments or editions, located at R4-23-407(D)(2)

13. The full text of the rule follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 2. PHARMACIST LICENSURE

Section

R4-23-202. Licensure by Examination

R4-23-203. Licensure by Reciprocity

ARTICLE 3. INTERN TRAINING AND PHARMACY INTERN PRECEPTOR

Section

R4-23-302. Training Site and Pharmacy Intern Preceptors

ARTICLE 4. PROFESSIONAL PRACTICES

Section

R4-23-407. Prescription Requirements

ARTICLE 2. PHARMACIST LICENSURE

R4-23-202. Licensure by Examination

A. No change

1. No change
2. No change
3. No change

B. No change

1. No change
 - a. No change
 - b. No change
 - c. No change
2. No change
3. An applicant for licensure by examination shall:
 - a. Make application on a form furnished by the Board, and
 - b. Submit with the application for licensure by examination form:
 - i. The documents specified in the application form, and
 - ii. The ~~examination~~ application fee specified in R4-23-205(C) made payable to the Arizona State Board of Pharmacy by money order or certified or personal check.
4. An applicant for licensure by examination shall:
 - a. Make NAPLEX and MPJE registration on forms furnished by the Board or NABP; and
 - b. Submit with the registration forms:
 - i. The documents specified in the registration forms, and
 - ii. The ~~examination~~ application fee specified by and made payable to NABP by money order, certified check, or bank draft.
5. No change

C. No change

1. No change
2. No change
 - a. No change
 - b. No change
3. No change

D. No change

1. No change
2. No change

E. No change

1. No change
2. No change

F. No change

1. No change
 - a. No change

- b. No change
- c. No change
- 2. No change
 - a. No change
 - b. No change
 - c. No change
- 3. No change
- 4. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - f. No change
- 5. No change
 - a. No change
 - b. No change
 - c. No change

R4-23-203. Licensure by Reciprocity

- A. No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
 - 5. No change
- B. No change
 - 1. No change
 - a. No change
 - b. No change
 - 2. No change
 - 3. An applicant for licensure by reciprocity shall:
 - a. Make application on a form furnished by the Board, and
 - b. Submit with the application for licensure by reciprocity form:
 - i. The documents specified in the application form, and
 - ii. The reciprocity and ~~examination~~ application fee specified in R4-23-205(B) and (C) and made payable to the Arizona State Board of Pharmacy by money order or certified or personal check.
 - 4. An applicant for licensure by reciprocity shall:
 - a. Make MPJE registration on a form furnished by the Board or NABP; and
 - b. Submit with the registration form:
 - i. The documents specified in the registration form; and
 - ii. The ~~examination~~ application fee specified by and made payable to NABP by money order, certified check, or bank draft.
 - 5. No change
- C. No change
 - 1. No change
 - 2. No change
 - a. No change
 - b. No change
 - 3. No change
- D. No change
 - 1. No change
 - 2. No change
- E. No change

ARTICLE 3. INTERN TRAINING AND PHARMACY INTERN PRECEPTOR

R4-23-302. Training Site and Pharmacy Intern Preceptors

- A. No change
 - 1. No change

- 2. No change
- B.** No change
- C.** No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
 - 5. No change
- D.** Revocation of preceptorship privileges. The Board shall revoke a pharmacy intern preceptor's privilege to train pharmacy or graduate interns if the Board determines that a pharmacy intern preceptor fails to provide experiential training as specified in R4-23-301(E) or violates A.R.S. ~~Chapter 18~~ Title 32, Chapter 18 or ~~Chapter 27~~ A.R.S. Title 36, Chapter 27 or the federal act. ~~R4-23-104~~ R4-23-111 applies to revocation of preceptor privileges.
- E.** No change
- F.** No change

ARTICLE 4. PROFESSIONAL PRACTICES

R4-23-407. Prescription Requirements

- A.** No change
 - 1. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - f. No change
 - g. No change
 - h. No change
 - i. No change
 - j. No change
 - k. No change
 - l. No change
 - 2. No change
 - 3. No change
- B.** No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
- C.** No change
- D.** Transfer of prescription order information. For a transfer of prescription order information to be valid, a pharmacy permit-tee or pharmacist-in-charge shall ensure that:
 - 1. No change
 - 2. The original prescription order information for a Schedule III, IV, or V controlled substance is transferred only as specified in 21 CFR 1306.25, published ~~April 1, 2004~~ April 1, 2008, and no future amendments or editions, incorporated by reference and on file with the Board;
 - 3. No change
 - 4. No change
 - a. No change
 - i. No change
 - (1) No change
 - (2) No change
 - (3) No change
 - ii. No change
 - (1) No change
 - (2) No change
 - iii. No change
 - (1) No change
 - (2) No change

- (3) No change
- (4) No change
- (5) No change
- (6) No change
- (7) No change
- (8) No change
- b. No change
 - i. No change
 - ii. No change
 - (1) No change
 - (2) No change
 - iii. No change
 - (1) No change
 - (2) No change
 - (3) No change
 - (4) No change
 - (5) No change
 - (6) No change
 - (7) No change
 - (8) No change
- 5. No change
 - a. No change
 - b. No change
- 6. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - i. No change
 - (1) No change
 - (2) No change
 - (3) No change
 - (4) No change
 - ii. No change
 - (1) No change
 - (2) No change
 - (3) No change
 - (4) No change
 - (5) No change
 - (6) No change
 - (7) No change
 - (8) No change
 - e. No change
 - i. No change
 - (1) No change
 - (2) No change
 - (3) No change
 - (4) No change
 - (5) No change
 - ii. No change
 - f. No change
- E.** No change
 - 1. No change
 - a. No change
 - b. No change
 - i. No change
 - ii. No change
 - c. No change
 - i. No change

- ii. No change
- iii. No change
- 2. No change
- 3. No change
- 4. No change
- 5. No change
- F. No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
 - a. No change
 - b. No change
 - 5. No change
 - 6. No change

NOTICE OF PROPOSED RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

[R08-120]

PREAMBLE

- | | |
|------------------------------------|---------------------------------|
| <u>1. Sections Affected</u> | <u>Rulemaking Action</u> |
| R4-23-301 | Amend |
| R4-23-601 | Amend |
| R4-23-613 | Amend |
| R4-23-1003 | Amend |
- 2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rule is implementing (specific):**
Authorizing statutes: A.R.S. § 32-1904(A)(1)
Implementing statutes: A.R.S. §§ 32-1904(B)(3) and (7) and 36-2523
- 3. A list of all previous notices appearing in the Register addressing the proposed rule:**
Notice of Rulemaking Docket Opening: 14 A.A.R. 535, February 22, 2008
- 4. The name and address of agency personnel with whom persons may communicate regarding the rule:**
- | | |
|------------|---|
| Name: | Dean Wright, Compliance Officer |
| Address: | Board of Pharmacy
1700 W. Washington St., Suite 250
Phoenix, AZ 85007 |
| Telephone: | (602) 771-2727 |
| Fax: | (602) 771-2749 |
| E-mail: | dwright@azpharmacy.gov |
- 5. An explanation of the rule, including the agency's reasons for initiating the rule:**
A.R.S. § 32-1984 specifies that distributors and purchasers (including pharmacies) of prescription-only drugs must establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription-only drugs for at least three years. R4-23-601 (General Provisions), R4-23-613 (Procedure for Discontinuing a Pharmacy), and R4-23-1003 (Records and Order Forms) allow the above-mentioned records to be kept for only two years. To be consistent with the statute, the Board intends to amend R4-23-601, R4-23-613, and R4-23-1003 to replace the two-year record retention requirement with a three-year record retention requirement.
- The Board has determined that with the present National Association of Boards of Pharmacy (NABP) licensure process, it is not necessary to have an intern provide a recent photograph with the intern's application for licensure. The

Notices of Proposed Rulemaking

photograph requirement, specified in R4-23-301(H)(2)(e), will be deleted by this rulemaking. The Board also determined that it is too burdensome to have foreign graduate applicants provide the original Foreign Pharmacy Graduate Examination Committee (FPGEC) certification document required in R4-23-301(H)(2)(f). There have been instances where the original document was lost in the mail before arriving at the Board office. R4-23-301(H)(2)(f), which becomes subsection (e) after deleting the photograph requirement will be amended to by deleting the words "an original" and inserting the words "a notarized copy of the applicant's." The use of a notarized copy of the FPGEC certification document will provide the necessary proof that the applicant took and passed the required Foreign Pharmacy Graduate Examination without taking the chance of losing the original document in the mail. The rules will include format, style, and grammar necessary to comply with the current rules of the Secretary of State and the Governor's Regulatory Review Council.

The Board believes that amending these rules will benefit the public and the pharmacy community by clearly establishing practice standards for pharmacy interns and pharmacies and uniform standards for maintaining the records of receipt, disposal, and inventory of drugs and controlled substances in Arizona.

6. A reference to any study relevant to the rule that the agency reviewed and proposes either to rely on or not to rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The agency did not review or rely on any study relevant to the rule.

7. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

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

The proposed rules will impact the Board, pharmacists, interns, and pharmacies. The proposed rules' impact on the Board will be the usual rulemaking-related costs, which are minimal.

The proposed rules will have minimal economic impact on pharmacists and pharmacies. The rules are necessary to make the rules consistent with statute, specifically A.R.S. § 32-1984. The amendments to R4-23-601, R4-23-613, and R4-23-1003 will bring those rules back to the three-year record retention requirement that was in place until July 12, 2006. The three-year record retention is required by statute and will result in a minimal increase in recordkeeping costs for pharmacies. The proposed rules will provide a minimal cost savings for intern applicants by removing the cost of a photograph. The cost of a notarized copy of a Foreign Pharmacy Graduate Examination certification document is minimal compared to the cost of replacing the original document lost in the mail. The proposed rules have no economic impact on the public.

The proposed rules will benefit the public and the pharmacy community by clearly establishing practice standards for pharmacy interns and pharmacies and uniform standards for maintaining the records of receipt, disposal, and inventory of drugs and controlled substances in Arizona.

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name: Dean Wright, Compliance Officer
Address: Board of Pharmacy
1700 W. Washington St., Suite 250
Phoenix, AZ 85007
Telephone: (602) 771-2727
Fax: (602) 771-2749
E-mail: dwright@azpharmacy.gov

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

Comments may be written or presented orally. Written comments must be received by 5:00 p.m., Monday, June 9, 2008. An oral proceeding is scheduled for:

Date: June 9, 2008
Time: 10:30 a.m.
Location: 1700 W. Washington St., 3rd Floor Board Room
Phoenix, AZ 85007

A person may request information about the oral proceeding by contacting the person listed above.

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

Not applicable

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

None

13. The full text of the rule follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 3. INTERN TRAINING AND PHARMACY INTERN PRECEPTORS

Section

R4-23-301. Intern Licensure

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

Section

R4-23-601. General Provisions

R4-23-613. Procedure for Discontinuing a Pharmacy

ARTICLE 10. UNIFORM CONTROLLED SUBSTANCES AND DRUG OFFENSES

Section

R4-23-1003. Records and Order Forms

ARTICLE 3. INTERN TRAINING AND PHARMACY INTERN PRECEPTORS

R4-23-301. Intern Licensure

- A.** No change
- B.** No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
- C.** No change
- D.** No change
 - 1. No change
 - 2. No change
 - 3. No change
- E.** No change
- F.** No change
 - 1. No change
 - 2. No change
- G.** No change
- H.** Intern application. An applicant for licensure as a pharmacy intern or graduate intern shall:
 - 1. No change
 - 2. File an application on a form furnished by the Board, that includes:
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. ~~A recent photograph of the applicant that is no larger than 2 1/2" x 3" with the applicant's signature on the front;~~
 - f. If the applicant graduated from an unapproved college or school of pharmacy, an original a notarized copy of the applicant's Foreign Pharmacy Graduate Examination Committee (FPGEC) certification document;
 - ~~g.~~ f. No change
 - ~~h.~~ g. No change
- I.** No change
- J.** No change
- K.** No change
 - 1. No change

2. No change

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

R4-23-601. General Provisions

- A. No change
 1. No change
 2. No change
- B. No change
- C. No change
- D. Record of receipt and disposal of narcotics or other controlled substances, prescription-only drugs or devices, nonprescription drugs, precursor chemicals, or regulated chemicals.
 1. Every person manufacturing a narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical, including repackaging or relabeling, shall prepare and retain for not less than ~~two~~ three years the manufacturing, repackaging, or relabeling date for each narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical.
 2. Every person receiving, selling, delivering, or disposing of a narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical shall record and retain for not less than ~~two~~ three years the following information:
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 3. No change
 4. No change
- E. No change

R4-23-613. Procedure for Discontinuing a Pharmacy

- A. A pharmacy permittee or pharmacist-in-charge shall provide written notice to the Board and the Drug Enforcement Administration (D.E.A.) at least 14 days before discontinuing operation of the pharmacy. The notice shall contain the following information:
 1. No change
 2. No change
 3. Name and address of the location where the discontinuing pharmacy's records of purchase and disbursement of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical will be kept and the person responsible for the records. These records shall be kept for a minimum of ~~two~~ three years from the date the pharmacy is discontinued;
 4. No change
 5. No change
- B. No change
- C. No change
- D. The pharmacist-in-charge of the pharmacy discontinuing business shall ensure that:
 1. No change
 2. No change
 3. All controlled substances are transferred as follows:
 - a. No change
 - b. No change
 - c. Keep the original of the inventory with the discontinued pharmacy's records of narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical purchase and disbursement for a minimum of ~~two~~ three years from the date the pharmacy is discontinued;
 - d. No change
 - e. No change
- E. No change
- F. During the ~~two-year~~ three-year record retention period specified in subsection (A)(3), the person described in subsection (A)(3) shall provide to the Board upon its request a discontinued pharmacy's records of the purchase and disbursement of narcotics or other controlled substances, prescription-only drugs or devices, nonprescription drugs, precursor chemicals, or regulated chemicals.
- G. No change

ARTICLE 10. UNIFORM CONTROLLED SUBSTANCES AND DRUG OFFENSES

R4-23-1003. Records and Order Forms

A. Records

1. If the pharmacist-in-charge of a pharmacy is replaced by another pharmacist-in-charge, the new pharmacist-in-charge shall complete an inventory of all controlled substances in the pharmacy within 10 days of assuming the responsibility. This inventory and any other required controlled substance inventory shall:
 - a. Include an exact count of all Schedule II controlled substances;
 - b. Include an exact count of all Schedule III through Schedule V controlled substances or an estimated count if the stock container contains fewer than 1001 units;
 - c. Indicate the date the inventory is taken and whether the inventory is taken before opening of business or after close of business for the pharmacy;
 - d. Be signed by:
 - i. The pharmacist-in-charge; or
 - ii. For other required inventories, the pharmacist who does the inventory;
 - e. Be kept separately from all other records; and
 - f. Be available in the pharmacy for inspection by the Board or its designee for not less than ~~two~~ three years.
2. A loss of a controlled substance shall be reported:
 - a. Within 10 days of discovery;
 - b. On a DEA form 106;
 - c. By the pharmacist-in-charge of a pharmacy or a manufacturer;
 - d. By the permittee or ~~manager~~ designated representative of a full-service wholesaler; and
 - e. To the federal Drug Enforcement Administration (DEA), the Narcotic Division of the Department of Public Safety (DPS), and the Board of Pharmacy. A copy of the DEA form 106 shall be kept on file by the pharmacy permittee. The DEA form 106 shall state whether the police investigated the loss.
3. Every person manufacturing any controlled substance, including repackaging or relabeling, shall record and retain for not less than ~~two~~ three years the manufacturing, repackaging, or relabeling date for each controlled substance.
4. Every person receiving, selling, delivering, or disposing of any controlled substance shall record and retain for not less than ~~two~~ three years the following information:
 - a. The name, strength, dosage form, and quantity of each controlled substance received, sold, delivered, or disposed;
 - b. The name, address, and DEA registration number of the person from whom each controlled substance is received;
 - c. The name, address, and DEA registration number of the person to whom each controlled substance is sold or delivered or who disposes of each controlled substance; and
 - d. The date of each transaction.
5. A full-service drug wholesale permittee or the designated representative shall complete an inventory of all controlled substances in the manner prescribed in subsection (A)(1). The permittee or designated representative shall conduct this inventory:
 - a. On May 1 of each year or as directed by the Board; and
 - b. If there is a change of ownership, or discontinuance of business, or within 10 days of a change of a designated representative.
6. A drug manufacturer permittee or the pharmacist-in-charge shall complete an inventory of all controlled substances in the manner prescribed in subsection (A)(1). The permittee or pharmacist-in-charge shall conduct this inventory:
 - a. On May 1 of each year or as directed by the Board; and
 - b. If there is a change of ownership, or discontinuance of business, or within 10 days of a change of a pharmacist-in-charge.

- B. Order form. For purposes of A.R.S. § 36-2524, "Order Form" means DEA Form 222c.

NOTICE OF PROPOSED RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

[R08-118]

PREAMBLE

- 1. Sections Affected**

R4-23-422	<u>Rulemaking Action</u>
R4-23-423	Amend
	Repeal
- 2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):**

Authorizing statutes: A.R.S. § 32-1904(A)(1)
Implementing statutes: A.R.S. § 32-1970
- 3. A list of all previous notices appearing in the Register addressing the proposed rules:**

Notice of Rulemaking Docket Opening: 14 A.A.R. 34, January 4, 2008
- 4. The name and address of agency personnel with whom persons may communicate regarding the rules:**

Name:	Dean Wright, Compliance Officer
Address:	Board of Pharmacy 1700 W. Washington St., Suite 250 Phoenix, AZ 85007
Telephone:	(602) 771-2727
Fax:	(602) 771-2749
E-mail:	dwright@azpharmacy.gov
- 5. An explanation of the rules, including the agency's reasons for initiating the rules:**

Recruiting members to serve on volunteer committees is always difficult. Busy healthcare providers are even more challenging to identify, and the shortage of healthcare providers in Arizona just adds to the difficulty. Finding qualified individuals who can attend meetings regularly has been almost impossible. For this reason, the Board proposes that the Drug Therapy Management Advisory Committee be eliminated. The use of a drug therapy management advisory committee does not afford any additional layer of protection to the public, as the supervising physician has final authority and responsibility over the actions of a pharmacist under a drug therapy management agreement. A Board staff pharmacist has been serving on the committee and will continue to review the initial and renewal drug therapy management agreement applications for the Board's approval. Section R4-23-422 (Drug Therapy Management - Duties of the Board) will be amended to remove the requirements that the Board appoint a Drug Therapy Management Advisory Committee and consult with the appointed committee in subsections (A)(1) and (2). Section R4-23-422 will be further amended by adding language in a new subsection (C) that requires the Board staff to review initial and renewal drug therapy management agreement applications and advise the Board regarding the approval or denial of reviewed drug therapy management agreement applications. Section R4-23-423 (Drug Therapy Management Advisory Committee) will be repealed. The rules will include format, style, and grammar necessary to comply with the current rules of the Secretary of State and Governor's Regulatory Review Council.

The Board believes that approval of these rules will benefit the public health and safety by expanding the use of pharmacists' under-utilized knowledge of drugs and drug therapy to manage a specific patient under written protocol from the patient's physician. Because a pharmacist is more accessible than a physician, a patient whose drug therapy is managed by a pharmacist benefits by receiving drug therapy monitoring and adjustment that reduces health care costs, including the use of fewer or less costly drugs, more effective or better tolerated drugs, early recognition and treatment of adverse drug reactions, and fewer hospital admissions.
- 6. A reference to any study relevant to the rule that the agency reviewed and proposes either to rely on or not to rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:**

The agency did not review or rely on any study relevant to the rule.
- 7. A showing of good cause why the rules are necessary to promote a statewide interest if the rules will diminish a previous grant of authority of a political subdivision of this state:**

Not applicable

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

The proposed rules will impact the Board and pharmacists. The proposed rule's impact on the Board will be the usual rulemaking-related costs, which are minimal.

The Board estimates the proposed rules will have no economic impact on pharmacists. The rulemaking is eliminating the requirement that the Board appoint a Drug Therapy Management Advisory Committee. This committee is not required in statute and the Board feels that it is not necessary to the process of evaluating and approving drug therapy management agreements. The use of a drug therapy management advisory committee does not afford any additional layer of protection to the public, as the supervising physician has final authority and responsibility over the actions of a pharmacist under a drug therapy management agreement.

The proposed rules will have no economic impact on the public.

The Board believes that approval of these rules will benefit the public health and safety by expanding the use of pharmacists' under-utilized knowledge of drugs and drug therapy to manage a specific patient under written protocol from the patient's physician. Because a pharmacist is more accessible than a physician, a patient whose drug therapy is managed by a pharmacist benefits by receiving drug therapy monitoring and adjustment that reduces health care costs, including the use of fewer or less costly drugs, more effective or better tolerated drugs, early recognition and treatment of adverse drug reactions, and fewer hospital admissions.

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name: Dean Wright, Compliance Officer
Address: Board of Pharmacy
1700 W. Washington St., Suite 250
Phoenix, AZ 85007
Telephone: (602) 771-2727
Fax: (602) 771-2749
E-mail: dwright@azpharmacy.gov

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

Comments may be written or presented orally. Written comments must be received by 5:00 p.m., Monday, June 9, 2008. An oral proceeding is scheduled for:

Date: June 9, 2008
Time: 10:00 a.m.
Location: 1700 W. Washington St., 3rd Floor Board Room
Phoenix, AZ 85007

A person may request information about the oral proceeding by contacting the person listed above.

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

Not applicable

12. Incorporations by reference and their location in the rules:

None

13. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 4. PROFESSIONAL PRACTICES

Section

R4-23-422. Drug Therapy Management – Duties of the Board

R4-23-423. ~~Drug Therapy Management Advisory Committee~~ Repealed

ARTICLE 4. PROFESSIONAL PRACTICES

storage and counting device that has not left the pharmacy from being returned to the drug's original cell, cassette, or stock bottle. The Board is aware that there are pharmacies who through technology, such as bar coding, can ensure that a drug previously counted by a mechanical storage and counting device that has not left the pharmacy is safe to return to the drug's cell or cassette. In such pharmacies, the label that is affixed to the drug container now can include the drug's manufacturer, name, strength, and lot number. The pharmacy's system can then scan the container label and the cell or cassette label and correctly match the drug with the cell or cassette, thus allowing the drug to be returned to the proper cell or cassette. The proposed rule adds an exception to R4-23-615(B) to allow a previously counted drug that has not left the pharmacy to be returned to its cell or cassette if the Board or its designee approves the drug return method. The proposed rule adds a new subsection (G) to R4-23-615 specifying the requirements for Board approval of a drug return method. The rule includes format, style, and grammar necessary to comply with the current rules of the Secretary of State and the Governor's Regulatory Review Council.

The Board believes that amending this rule will benefit the public health and safety by establishing clear standards for the use of mechanical storage and counting devices, including the safe return of previously counted drug that has not left the pharmacy to the correct drug's cell or cassette within a mechanical storage and counting device.

6. A reference to any study relevant to the rule that the agency reviewed and proposes either to rely on or not to rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The agency did not review or rely on any study relevant to the rule.

7. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

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

The rule has little economic impact except the cost to the Board for the usual rulemaking-related costs, which are minimal. The Board will have to approve the return method used by a pharmacy, which includes the cost of a Board Compliance Officer's inspection of the drug return method, which is minimal. The rule does not require a pharmacy to return a drug to a cell or cassette, but a pharmacy that chooses to return drug to its cell or cassette must use an approved method. The Board estimates the rule will have minimal if any economic impact on pharmacies. A pharmacy might save some staff time by not manually counting drugs previously counted by a device. The Board cannot quantify the time savings that might occur. The rule does not impose any costs on small business or consumers.

The public, Board, pharmacists, and pharmacies benefit from rules that are clear, concise, and understandable. The rule benefits the public health and safety by establishing clear standards for the use of mechanical storage and counting devices, including the safe return of previously counted drug that has not left the pharmacy to the correct drug's cell or cassette within a mechanical storage and counting device.

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name: Dean Wright, Compliance Officer
Address: Board of Pharmacy
1700 W. Washington St., Suite 250
Phoenix, AZ 85007
Telephone: (602) 771-2727
Fax: (602) 771-2749
E-mail: dwright@azpharmacy.gov

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

Comments may be written or presented orally. Written comments must be received by 5:00 p.m., Monday, June 9, 2008. An oral proceeding is scheduled for:

Date: June 9, 2008
Time: 10:45 a.m.
Location: 1700 W. Washington St., 3rd Floor Board Room
Phoenix, AZ 85007

A person may request information about the oral proceeding by contacting the person listed above.

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

Not applicable

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

None

13. The full text of the rule follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

Section

R4-23-615. Mechanical Storage and Counting Device for a Drug in Solid, Oral Dosage Form

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

R4-23-615. Mechanical Storage and Counting Device for a Drug in Solid, Oral Dosage Form

- A.** No change
1. No change
 2. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - f. No change
 3. No change
- B.** A pharmacy permittee or pharmacist-in-charge shall ensure that any drug previously counted by a mechanical storage and counting device for a drug in a solid, oral dosage form that has not left the pharmacy is not returned to the drug's original cell, cassette, or stock bottle, unless the drug return method is approved by the Board or its designee as specified in subsection (G). This subsection does not prevent a pharmacy permittee or pharmacist-in-charge from using a manual or mechanical counting device to count and dispense a previously counted drug that has not left the pharmacy if the previously counted drug is dispensed before its beyond-use-date.
- C.** No change
1. No change
 2. No change
 3. No change
- D.** No change
- E.** No change
1. No change
 2. No change
 3. No change
 4. No change
 5. No change
- F.** No change
- G.** Returning a drug previously counted by a mechanical storage and counting device for a drug in a solid, oral dosage form that has not left the pharmacy to the drug's original cell or cassette.
1. Before returning a drug previously counted by a mechanical storage and counting device that has not left the pharmacy to the drug's cell or cassette, a pharmacy permittee or pharmacist-in-charge shall:
 - a. Apply for approval from the Board or its designee for the drug return method to be used in returning the drug;
 - b. Develop a drug return method that uses technology, such as bar coding, to prevent drug return errors;
 - c. Provide documentation depicting the drug return method;
 - d. Demonstrate the drug return method for a Board Compliance Officer;
 - e. Receive approval from the Board or its designee for the drug return method to be used in returning the drug.
 2. Before approving a request to waive the drug return prohibition in subsection (B), the Board or its designee shall:
 - a. Receive a request in writing from the pharmacy permittee or pharmacist-in-charge;
 - b. Review the documentation of the drug return method; and
 - c. Receive a satisfactory inspection report from a Board Compliance Officer that the drug return method uses technology to prevent drug return errors.

NOTICE OF PROPOSED RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 45. BOARD OF RESPIRATORY CARE EXAMINERS

[R08-125]

PREAMBLE

- | | |
|------------------------------------|---------------------------------|
| 1. <u>Sections Affected</u> | <u>Rulemaking Action</u> |
| R4-45-214 | Amend |
| R4-45-218 | New Section |
- 2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):**
Authorizing statute: A.R.S. § 32-3504(A)(2)
Implementing statute: A.R.S. § 32-3554
- 3. List of all previous notices appearing in the Register addressing the proposed rules:**
Notice of Rulemaking Docket Opening: 14 A.A.R. 895, March 28, 2008
Notice of Rulemaking Docket Opening: 14 A.A.R. 1144, April 11, 2008
- 4. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:**
Name: Mary Hauf Martin
Address: Board of Respiratory Care Examiners
1400 W. Washington St., Suite 200
Phoenix, AZ 85007
Telephone: (602) 542-5995
Fax: (602) 542-5900
E-mail: Mary@rb.state.az.us
- 5. An explanation of the rules, including the agency's reasons for initiating the rulemaking:**
Under A.R.S. § 32-3554, the Board has authority to reinstate a revoked license or amend conditions of probation. In this rulemaking, the Board establishes procedures to exercise this authority. Additionally, the Board is clarifying that failure to obey an order issued by any regulatory board or court amounts to unprofessional conduct.
- 6. A reference to any study relevant to the rule that the agency reviewed and proposes either to rely on or not to rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:**
None
- 7. A showing of good cause why the rules are necessary to promote a statewide interest if the rules will diminish a previous grant of authority of a political subdivision of this state:**
Not applicable
- 8. The preliminary summary of the economic, small business, and consumer impact:**
The economic impact of the reinstatement rule will be minimal and will be assumed voluntarily by an individual who wishes to resume practice as a respiratory therapist or to practice without conditions of probation. The clarification regarding unprofessional conduct will have an economic impact only on individuals who disobey an order issued by a regulatory board or court.
- 9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:**
Name: Mary Hauf Martin
Address: Board of Respiratory Care Examiners
1400 W. Washington St., Suite 200
Phoenix, AZ 85007
Telephone: (602) 542-5995
Fax: (602) 542-5900

Notices of Proposed Rulemaking

E-mail: Mary@rb.state.az.us

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

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

Date: Tuesday, June 3, 2008

Time: 10:00 a.m.

Location: 1400 W. Washington St., Suite 200
Phoenix, AZ 85007

The rulemaking record will close at 5:00 p.m. on Friday, June 6, 2008.

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

None

12. Incorporations by reference and their location in the rules:

None

13. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 45. BOARD OF RESPIRATORY CARE EXAMINERS

ARTICLE 2. LICENSURE

Section

R4-45-214. Standards of Professional Conduct

R4-45-218. Reinstatement Following Revocation; Modification of Probation

ARTICLE 2. LICENSURE

R4-45-214. Standards of Professional Conduct

Conduct or practice that is contrary to recognized standards of ethics of the respiratory therapy profession, as used in A.R.S. § 32-3501(10)(i), includes the following:

1. No change
2. No change
3. Violating a formal order, condition of probation, or stipulation issued by the Board, another regulatory entity of any state, or a court of law;
4. No change
5. No change
6. No change
7. No change
8. No change
9. No change
10. No change
11. No change
12. No change
13. No change
14. No change
15. No change
16. No change
17. No change
18. No change
19. No change
20. No change
21. No change

R4-45-218. Reinstatement Following Revocation; Modification of Probation

A. Under A.R.S. § 32-3554, a former licensee whose license is revoked, may apply to the Board after one year to have the

license reinstated. A licensee who is placed on probation may apply to the Board after one year to have the conditions of probation modified.

- B.** If a former licensee wishes to have a revoked license reinstated after the time stated in subsection (A), the former licensee shall comply with R4-45-201. The Board shall not issue a temporary license to a former licensee who applies for reinstatement.
- C.** A licensee who is placed on probation shall comply with R4-45-207 while on probation. If the licensee wishes to have the conditions of probation modified after the time stated in subsection (A), the licensee shall submit to the Board:
 - 1. A letter that contains the following information:
 - a. Name and address of licensee.
 - b. License number.
 - c. Date on which probation was imposed.
 - d. Reason that probation was imposed.
 - e. Conditions of probation.
 - f. Modification of conditions of probation requested, and
 - g. Reason a modification of conditions is warranted, and
 - 2. Evidence that supports the request for modification of conditions.

NOTICE OF PROPOSED RULEMAKING

TITLE 19: ALCOHOL, HORSE AND DOG RACING, LOTTERY, AND GAMING

CHAPTER 3: ARIZONA STATE LOTTERY COMMISSION

[R08-123]

PREAMBLE

1. Sections Affected

R19-3-401
R19-3-402
R19-3-403
R19-3-404
R19-3-405
R19-3-406
R19-3-407
R19-3-408
R19-3-409
R19-3-410
R19-3-411
R19-3-412
R19-3-413

Rulemaking Action

Amend
New Section

2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statute: A.R.S. § 5-504(B)

Specific statutes: A.R.S. §§ 5-504(C),(D),(H) and (I)

3. A list of all previous notices appearing in the Register addressing the proposed rules:

Notice of Rulemaking Docket Opening: 13 A.A.R. 3286, September 28, 2007

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

Name: J. Art Macias Jr., Executive Director

Address: Arizona State Lottery
4740 E. University Drive
Phoenix, AZ 85034

Telephone: (480) 921-4505

Fax: (480) 921-4488

E-mail: amacias@azlottery.gov

Notices of Proposed Rulemaking

or

Name: Pam DiNunzio
Address: Arizona State Lottery
4740 E. University Drive
Phoenix, AZ 85034
Telephone: (480) 921-4489
Fax: (480) 921-4488
E-mail: pdinunzio@azlottery.gov

5. An explanation of the rules, including the agency's reason for initiating the rules:

Article 4, Design and Operation of On-Line Games, provides for the conduct of the Lottery's on-line games. The rules explain the common components of on-line games such as: game profiles, ticket purchases, drawings, ticket ownership and responsibilities, procedures to claim prizes, ticket validation requirements, and disputes concerning a ticket. These rules are being amended to accommodate new on-line game initiatives. The rules now distinguish between "drawing" and "non-drawing" on-line games and include various playstyles for non-drawing games. The rulemaking also amends outdated terminology and adds new language as necessary for greater clarity.

6. A reference to any study relevant to the rule that the agency reviewed and proposes either to rely on or not to rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

None

7. A showing of good cause why the rules are necessary to promote a statewide interest if the rules will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

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

The rules for Article 4, Design and Operation of On-Line Games, describe various provisions for the Lottery's on-line game products. The Lottery anticipates amendments to this Article will primarily impact the agency and Lottery retailers. The rulemaking also makes conforming and technical changes that are neutral with respect to economic impact.

A. Arizona State Lottery. Costs to the Lottery related to this rulemaking include expenses to administer the on-line game network, in addition to administrative costs associated with contract monitoring, game development, and providing customer service to retailers. These costs are included in the agency's appropriated budget and the Lottery does not anticipate any additional costs as a result of this rulemaking. In fact, the Lottery's new contract for on-line game services, which was effective in September 2006, actually saves the agency about \$4 million annually.

As part of this rulemaking, the Lottery proposes to add specific playstyles to accommodate future on-line game opportunities. This will provide flexibility for the Lottery to introduce new game initiatives or modify existing games in a timely manner, thereby providing the state and licensed retailers with the potential to increase revenue.

B. Businesses Directly Affected by this Rulemaking. The only businesses impacted by the rules are existing Lottery retailers and this rulemaking is expected to benefit retailers.

The rules now include provisions for both "drawing" games and "non-drawing" games. This allows the Lottery to introduce new types of on-line games, thus providing retailers with the potential to increase revenue. The Lottery currently has approximately 2600 total retailers. Retailers earn \$.065 for each \$1 on-line ticket transaction and are eligible for up to an additional one-half percent based on meeting performance criteria. As a result, an increase in on-line game sales also increases commissions earned. In FY07, retailers earned over \$31 million in total commissions.

Lottery retailers are also the only small businesses affected by these rules and the anticipated impact is the same. All retailers will benefit from the potential to increase sales, which results in a corresponding increase in retailer commissions.

C. Consumers and the Public. There are no costs to the general public associated with the adoption of these rules. These rules will provide players with additional or enhanced on-line games from which to choose.

D. State Revenues. Revenue generated from Lottery game sales are deposited into the Lottery Fund and Lottery Prize Fund. The amended rules allow the Lottery to respond more effectively to industry trends, thus providing the potential to increase state revenues. In FY07, total game sales were \$462.2 million and on-line game sales were approximately \$201.2 million. A percentage of Lottery game revenue is returned to the state to fund various beneficiary programs as specified in A.R.S. § 5-522. The Lottery returned almost \$140 million to state beneficiaries in FY07.

This rulemaking will not have any identifiable economic impact on political subdivisions of the state, or private and public employment.

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name: J. Art Macias Jr., Executive Director

Address: Arizona State Lottery
4740 E. University Drive
Phoenix, AZ 85034

Telephone: (480) 921-4505

Fax: (480) 921-4488

E-mail: amacias@azlottery.gov

or

Name: Pam DiNunzio

Address: Arizona State Lottery
4740 E. University Drive
Phoenix, AZ 85034

Telephone: (480) 921-4489

Fax: (480) 921-4488

E-mail: pdinunzio@azlottery.gov

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

Date: June 27, 2008

Time: 10:00 a.m.

Location: Arizona Lottery
4740 E. University Drive
Phoenix, AZ 85034

Nature: Oral Proceeding

The close of record is 5:00 p.m. on June 26, 2008 for written comments and at the end of the oral proceeding for verbal comments.

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

Not applicable

12. Incorporations by reference and their location in the rules:

None

13. The full text of the rules follows:

TITLE 19: ALCOHOL, HORSE AND DOG RACING, LOTTERY, AND GAMING

CHAPTER 3: ARIZONA STATE LOTTERY COMMISSION

ARTICLE 4. DESIGN AND OPERATION OF ON-LINE GAMES

Section

- R19-3-401. Definitions
- R19-3-402. Game Profile
- R19-3-403. Ticket Purchases, Characteristics, and Restrictions
- R19-3-404. Drawings
- R19-3-405. Determination of a Winning Game Play
- R19-3-406. Ticket Ownership and Responsibility; Prize Payment
- R19-3-407. Ticket Validation Requirements
- R19-3-408. Procedure for Claiming Prizes
- R19-3-409. Claim Period
- R19-3-410. Disputes Concerning a Ticket

- R19-3-411. Prize Fund
R19-3-412. Multi-State Lottery Association Games
R19-3-413. Game Playstyle

ARTICLE 4. DESIGN AND OPERATION OF ON-LINE GAMES

R19-3-401. Definitions

Definitions: In this Article, unless the context otherwise requires, these words and terms shall have the following meanings:

1. ~~“Cash Value” means payment of the Division 1 (jackpot) prize pool share amount paid in one lump sum as provided in the prize structure in the game profile.~~
2. ~~“Drawing” means the process used to randomly select the winning play symbols from the defined game matrix or playstyle.~~
3. ~~“On-line Lottery Game” means a game where tickets are purchased through a network of Arizona Lottery-issued computer terminals located in retail outlets. The terminals are linked to a central computer that records the wagers.~~
4. ~~“Fixed payout prize” means a set prize dollar amount for that specific prize in the prize structure.~~
5. ~~“Game board” or “board” means the area of the selection slip which contain containing a matrix that lists all the offered play symbols. More than one game board may appear on the selection slip.~~
6. ~~“Game option” means a game feature that is tied to a specific game which the player has a choice to play.~~
7. ~~“Game play” or “play” means the selected play symbols which appear on a ticket as a single wager. More than one game play may appear on a ticket.~~
8. ~~“Game profile” means the written document in which the Lottery Commission authorizes the Director to issue an order that contains all of the non-confidential game fundamentals required by these rules for an on-line game.~~
9. ~~“Game ticket” or “ticket” means a receipt produced by a Lottery-issued terminal equipment evidencing the purchase of a participation in a game or game option. The ticket contains a security code, ticket price, a retailer number, a serial number and the game symbols purchased for one or more specific drawings.~~
10. ~~“Matrix” means the number of selections a player may choose from a predetermined pool of play symbols from which the player may select a predetermined number of play symbols.~~
11. ~~“Multiple winners” means a situation in which more than one claimant redeems an individual share in one wager.~~
“On-line lottery game” means a game where tickets are purchased through a network of Lottery-issued equipment located in retail outlets. The equipment is linked to a central computer that records the wagers. On-line games may be categorized as “drawing” or “non-drawing.”
12. ~~“Pari-mutuel” means a system in which those holding winning tickets divide the total prize amount in proportion to their wagers.~~
13. ~~“Play style” means the description in the game profile of the matrix, play symbols, and the manner of selecting the winning play symbols.~~
14. ~~“Play symbols” means the numbers, letters, symbols, or pictures used in the matrix a game to determine if a player is entitled to a prize.~~
15. ~~“POWERBALL” means a multi-state game that is conducted pursuant to the rules of the Multi-State Lottery Association (MUSL) and approved by a game profile.~~
16. ~~“Prize category” means the value of a specific prize.~~
17. ~~“Prize structure” means the chart of the prize value, number of prizes or prize payout percentage, any fixed payments, any pari-mutuel payments, and the odds of winning the prizes.~~
“Prize symbols” means the printed image or images that indicates the prize or prizes available in that game.
18. ~~“Prohibited games” mean on line or electronic keno or internet games.~~
19. ~~“Quick pick” means the random selection by a terminal Lottery-issued equipment of one or more play symbols from the defined game matrix or playstyle.~~
“Quick Pick card” means a pre-printed game play card with a barcode that when scanned by the Lottery-issued equipment generates a quick pick ticket for a specific game and price point.
20. ~~“Selection slip” means a preprinted set of game boards provided by the Lottery upon which the player selects play symbols and game options. Each selection slip may have multiple game boards.~~
21. ~~“Share” means any single winning game play, which is equal to any other share in the same prize division.~~
22. ~~“Terminal” means a device authorized by the Lottery linked to a central computer for the purpose of issuing Lottery tickets and entering, receiving, and processing Lottery transactions.~~
“Validation number” means the unique multi-digit code on each ticket that is used to authenticate winning tickets.
23. ~~“Winning numbers or winning play symbols” means the numbers or play symbols from the defined game matrix randomly selected at each drawing which determine winning game plays contained on a ticket.~~

R19-3-402. Game Profile

- A. Each game or game option shall have a Game Profile and at a minimum, the Profile shall contain the following information:

Notices of Proposed Rulemaking

1. Game name or game option name;
 2. Matrix/description of how to play and win;
 3. Game playstyle, if applicable;
 - ~~3-4~~ Retail sales price;
 - ~~4-5~~ Purchase conditions and characteristics;
 - ~~5-6~~ Play symbols and prize symbols, if any;
 - ~~6-7~~ Prize structure, including the approximate odds, the prize amounts available, the prize pool percentage, if alternate prize structures are to be used, any subsection (B) provisions, and any special Division 1 (jackpot) prize specifications;
 - ~~7-8~~ Special features, if any; and
 - ~~8-9~~ Prize draw eligibility requirements, including filing period for eligibility in a winners drawing, if applicable.
- B. Each on-line game or option may include specific variants that provide added or alternative methods of winning. Any variants shall be described in the Game Profile.
- C. The Commission shall approve the Game Profile prior to the game being sold to the public.

R19-3-403. Ticket Purchases, Characteristics, and Restrictions

- A. To ~~play purchase~~ an on-line game ~~ticket~~, a player shall select the ~~specified number of play symbols from the defined game matrix approved in the Game Profile for input into the terminal~~ specific game or games available through the Lottery-issued equipment. Selection methods include:
1. ~~Communicating the play symbols and game options to a retailer~~ Hand-marking a selection slip with the required number of play symbols, or
 2. ~~Marking the selection slip and submitting the selection slip to a~~ Verbally communicating the game, play symbols, and options to the retailer, or
 3. Requesting a ~~“Quick Pick,”~~ “quick pick,” or
 4. Marking a ~~“Quick Pick”~~ “quick pick” box on a selection slip; ~~slip, or~~
 5. Submitting a “Quick Pick card” for the selected game and price point.
- B. Game plays ~~must be~~ may be manually entered into the Lottery terminal ~~manually or by inserting a Lottery selection slip that is hand marked by the player~~ Lottery-issued equipment by the retailer. Alternatively, a player may enter game plays into the Lottery-issued player-activated equipment. Facsimiles, simulations, copies of selection slips, or other materials not printed or approved by the Lottery are prohibited from use.
- ~~C.~~ To claim a prize, a player must submit the original ticket for validation. Selection slips are not proof of purchase.
- ~~D.~~ The ticket holder is responsible for the accuracy of ticket data. The Lottery shall not be liable for ticket errors.
- ~~D.~~ To claim a prize, a player shall submit the original ticket for validation. Selection slips or Quick Pick cards are not proof of purchase.

R19-3-404. Drawings

- A. The drawings shall be held at the times and places established in the Game Profile.
- B. The ~~on-line~~ game drawing shall randomly select the winning play symbols from those defined in the Game Profile. Mechanical, electrical, or computerized drawing methods may be used to make the random selection.

R19-3-405. Determination of a Winning Game Play

- A. A player ~~of a drawing game~~ shall win the ~~prize(s)~~ prize or prizes indicated in the prize structure by matching the winning play symbols selected at the drawing to the ~~player’s~~ player’s play symbols ~~selected by the player.~~
- ~~B.~~ A player of a non-drawing game shall win the prize or prizes indicated in the prize structure as provided in the game profile.
- ~~B.C.~~ Players may win on each game play on a ticket.
- ~~C.D.~~ There may be multiple winning patterns on a single ticket that match winning patterns described in the Game Profile.
- ~~D.E.~~ The prize structure ~~ordered~~ defined in the Game Profile shall determine the pari-mutuel ~~and/or~~ or fixed prize amount to be paid on a single winning game play.

R19-3-406. Ticket Ownership and Responsibility; Prize Payment

- A. Until a ticket is signed, the ticket is owned by its physical possessor.
- B. The Director shall recognize as the owner of a winning on-line ticket the person whose signature appears upon the ticket in the area designated for that purpose.
1. If more than one signature appears on the ticket, the Director is authorized to require that one or more of those claimants be designated to receive the payment. A claim form shall be submitted by each claimant who is designated to receive a portion of the prize claimed from the winning ticket.
 2. Prior to payment of a prize, a claimant who has signed the ticket may designate another claimant to receive the prize by signing a relinquishment of claim statement.
 3. When the winning ticket was purchased by a group of players, the group shall designate one of the claimants to sign the ticket for the group. Each claimant shall complete an individual claim form to receive the claimant’s portion of the

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- prize.
4. In the event there is an inconsistency in the information submitted on a claim form and as shown on the winning on-line ticket, the Director shall authorize an investigation and withhold all winnings payable to the ticket owner or holder until such time as the Director is satisfied that the proper person is being paid.
- C. Prior to paying the claimant a prize of \$600 or more, the Lottery shall match the winner's name against the lists of persons owing a debt to a participating state agency, furnished to the Lottery under A.R.S. § 5-525.
1. If there is a match on any of the claims submitted with a ticket, the amount that is owed shall be deducted from the prize due the claimant.
 2. The claimant shall be notified in writing of the amount of the ~~set-off~~ setoff and the agency to which it shall be paid.
 3. If the claimant has two or more agencies which are owed a debt, the Lottery shall pay a pro-rata share to each of the agencies, except that a Department of Economic Security overdue child support ~~set-off~~ setoff shall be paid in full before any amount shall be paid to another agency.
 4. The claimant shall be notified in writing that a right to appeal the ~~set-off~~ setoff exists ~~and must be commenced within 30 days of the receipt of this notification~~. The notification shall include the name and address of the agency with which to file the appeal and that the appeal shall commence within 30 days of receipt of the notification.
 5. If, after deducting withholding taxes and the ~~set-off~~ setoff, a portion of the prize remains, then that portion shall be paid to the winner with the notification of ~~set-off~~ setoff.
 6. The ~~amount of set-off~~ setoff amount shall be forwarded to the agency, and that agency shall be responsible for any appeal and crediting of the payment against the amount owed or refunding any amount to the winner.
 7. Upon a determination that a ~~set-off~~ setoff is due, the winner loses the right under subsection (B)(2) to assign any portion of the claim.
- D. Prizes shall be paid by cash, check, or if requested by the player, by Lottery tickets.
1. If a ticket contains more than one winning game play, any prize amounts shall be combined and paid in accordance with the prize payment limits specified in Section R19-3-408.
 2. Each winning game play wins the prize amount specified in the Game Profile.
- E. The Lottery is not responsible for lost or stolen tickets.

R19-3-407. Ticket Validation Requirements

- A. Each on-line game ticket shall be validated prior to the payment of a prize.
- B. To be eligible for a prize, a ticket holder ~~must~~ shall present a ticket meeting all of the following requirements:
1. Issued by the Lottery through a retailer, from ~~a terminal~~ Lottery equipment, in an authorized manner;
 2. Intact and not mutilated or tampered with in any manner;
 3. Not defectively printed;
 4. Not a reprinted ticket stating "Not for Sale" on the ticket;
 5. Not counterfeit or stolen;
 6. Able to pass all other confidential validation tests determined by the Director; and
 7. Validated in accordance with the provisions of sections R19-3-406 and R19-3-408.
 8. The ticket data is:
 - a. Recorded in the designated central computer system prior to the drawing;
 - b. In agreement with the computer record;
 - c. In the Lottery's official file of winning tickets;
 9. Any winning game play on the ticket consists of a selected set of play symbols from the defined game matrix or play-style.
 10. Has not been previously paid.
- C. If the ticket fails to pass any of the requirements in Section R19-3-407(B), the ticket is void and ineligible for any prize payout.

R19-3-408. Procedure for Claiming Prizes

- A. To claim a prize of up to and including \$599, the claimant shall present the ticket to any participating ~~on-line~~ licensed retailer or to a Lottery office, or mail the ticket to a Lottery office for validation. The licensed retailer shall pay ~~a winner a prize~~ all winning prizes up to and including \$100 and may pay ~~a winner a prize~~ all winning prizes from \$101 up to and including \$599 provided that:
1. All of the ticket validation criteria in Section R19-3-407 has been satisfied; and
 2. A proper validation slip, which is an authorization to pay, has been ~~issued by the terminal~~ generated by the Lottery-issued equipment.
- B. To claim a prize that the retailer does not validate or is not authorized to pay, including all prizes of \$600 or more, the claimant shall submit a claim form, available from any retailer, and the ticket to the Lottery. If the claim is:
1. Verified and validated by the Lottery as a winning ticket, the Lottery shall make payment of the amount due to the claimant, less any authorized debt ~~set-off amounts and/or withheld taxes~~ setoff amounts, or withheld taxes, or both.

2. Denied by the Lottery, the claimant shall be notified within 15 days from the day the claim is received in the Lottery office.
- C. If a prize winner dies prior to receiving full payment, the Lottery shall pay all remaining prize money to the prize winner's beneficiary or to any person designated by an appropriate judicial order.
- D. The Lottery is discharged of all liability upon payment of the prize money.
- E. Payment of prize money shall not be accelerated ahead of its normal date of payment.

R19-3-409. Claim Period

- A. ~~In order for~~ For the claimant to receive payment, a winning ~~on-line~~ drawing game ticket shall be received by the Lottery or a retailer no later than 5:00 p.m. (Phoenix time) on the 180th calendar day following the game drawing date.
- B. For a claimant to receive payment, a winning non-drawing game ticket shall be received by the Lottery or a retailer no later than 5:00 p.m. (Phoenix time) on the 180th calendar day following the sale of the ticket.
- ~~B.C.~~ If a claimant presents a valid winning ticket to a retailer for payment on the 180th calendar day ~~following the game drawing date~~ and is not paid the prize, the Director is authorized to pay the prize if the claimant presents the valid winning ticket to the Lottery no later than 5:00 p.m. (Phoenix time) on the following business day.
- ~~C.D.~~ The end of an on-line game shall be designated by the Director and on file at the Lottery.

R19-3-410. Disputes Concerning a Ticket

- A. If a dispute between the Lottery and a claimant occurs concerning a ticket, the Director is authorized to replace the disputed ticket with a ticket or tickets of equivalent sales price for any subsequent drawing from the same game.
- B. If a defective ticket is purchased, the Lottery shall replace the defective ticket with a ticket or tickets of equivalent sales price from ~~the same~~ any current game.
- C. Replacement of the disputed ticket is the sole and exclusive remedy for a claimant.
- D. If a dispute between the Lottery and a claimant occurs concerning the eligibility of an entry into a ~~Grand Prize~~ grand prize, second chance or promotional drawing, the Director is authorized to place any person's eligible entry that was not entered in the ~~Grand Prize~~ that drawing into a any subsequent ~~Grand Prize~~ drawing or drawings.

R19-3-411. Prize Fund

- A. Not less than 50 percent of the total annual revenue accruing from the sale of on-line game tickets shall be deposited in the state lottery prize fund for payment of prizes to the holders of winning tickets.
- B. If an on-line game is ~~terminated~~ ended for any reason, any remaining prize monies shall be held by the Lottery for a ~~period of 180 days from the date of the last drawing~~ the 180-day claim period and then used for additional prizes in any other Lottery game.

R19-3-412. Multi-State Lottery Association Games

- A. The Arizona Lottery is a participating member of the Multi-State Lottery Association (MUSL) referred to as a "party lottery" in the MUSL game rules may participate in one or more multi-state lottery associations as a party lottery.
- B. A game profile approved by the Commission and conforming to the information required in R19-3-403 shall be on file at the ~~Arizona State~~ Lottery for all ~~MUSL~~ multi-state lottery games played in Arizona.

R19-3-413. Game Playstyle

- A. The playstyle for a non-drawing game shall be fully described in the Game Profile and shall be one of the following methods of play unless a different method is prescribed by another rule:
 1. Match Two. The player shall win the prize or prizes indicated by matching two identical play symbols in the play area.
 2. Match Three. The player shall win the prize or prizes indicated by matching three identical play symbols in the play area.
 3. Add-up. The player shall win the prize or prizes indicated by either of the following ways:
 - a. The player adds up the play symbols and the amount is greater than or equal to the designated key symbol on the ticket, or
 - b. The player adds up the play symbols designated for the player and the total is greater than or equal to the control key symbol or symbols.
 4. Tic-Tac-Toe. The player shall win the prize or prizes indicated by matching three identical play symbols, in any row, or any column, or any diagonal, on a multi-symbol grid on the play area.
 5. Key Symbol or Symbols Match. The player shall win the prize or prizes indicated by locating the play symbol or symbols identical to the designated key play symbol or symbols.
 6. Key Symbol or Symbols Beat. The player shall win the prize or prizes indicated by locating the play symbol or symbols designated for the player in the ticket play area which is greater than the control play symbol or symbols.
 7. Symbols in Sequence. The player shall win the prize or prizes indicated by locating the designated play symbols in the specified sequential order.
 8. Spell Outs. The player shall win the prize or prizes indicated by locating the play symbols to form the designated

- word or words.
9. In Between. The player shall win the prize or prizes indicated by locating the play symbol or symbols designated for the player with a value less than the highest control play symbol or symbols and greater than the lowest control play symbol or symbols.
 10. Bingo. The player shall win the prize or prizes indicated by locating the play symbols on the designated play area or areas that are identical to the play symbols in the control area to form the specified pattern or patterns.
 11. Pattern. The player shall win the prize or prizes indicated by locating the play symbol or symbols on a multi-symbol play area that follow a designated pattern.
 12. Legend. The player shall win the prize or prizes indicated by locating the designated number or type of play symbols that correspond to a legend.
 13. Coordinates. The player shall win the prize or prizes indicated by locating the play symbol or symbols that direct the player to a location on the play area to reveal the specified play symbol, or the number or pattern of play symbols.
 14. Find. The player shall win the prize or prizes indicated by locating the designated play or prize symbol.
 15. Maze. The player shall win the prize or prizes indicated by locating the directional symbols to make a path or paths leading to a designated prize symbol.
 16. Grid. The player shall win the prize or prizes indicated by locating the specified number or pattern of play symbols on a grid on the play area.
 17. Elimination. The player shall win the prize indicated by locating the corresponding prize or prize symbol on a prize table to eliminate all but one remaining prize amount or symbol.
 18. Raffle. The player shall win a prize by matching exactly the player's raffle number to any one of the numbers drawn by the Lottery.
 19. Sets. The player shall win the prize or prizes indicated by locating the designated group or groups of play symbols, without repetition or deletion of any play symbol, within a specified location of the play area.
- B.** More than one game and more than one playstyle may appear on a ticket.